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### Contents

#### I *Legislative acts*

#### DIRECTIVES

- ★ **Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast) <sup>(1)</sup>** ..... 1
- ★ **Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels <sup>(1)</sup>** ..... 45
- ★ **Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) <sup>(1)</sup>** ..... 79
- ★ **Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments <sup>(1)</sup>** ..... 107
- ★ **Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) <sup>(1)</sup>** ..... 149

Price: EUR 10

(Continued overleaf)

<sup>(1)</sup> Text with EEA relevance

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts <sup>(1)</sup> .....	251
★ Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) <sup>(1)</sup> .....	309
★ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits <sup>(1)</sup> .....	357



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<sup>(1)</sup> Text with EEA relevance

## I

*(Legislative acts)*

## DIRECTIVES

**DIRECTIVE 2014/28/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 26 February 2014****on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast)****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Council Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) It is necessary to clarify in this Directive that certain articles were identified following the United Nations

recommendations on the transport of dangerous goods as being pyrotechnic articles or ammunition, thus falling outside the scope of this Directive. Commission Directive 2004/57/EC of 23 April 2004 on the identification of pyrotechnic articles and certain ammunition for the purposes of Council Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses <sup>(5)</sup>, which currently contains a list of such articles, should therefore be repealed.

(3) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(6)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(4) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products <sup>(7)</sup>, lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 93/15/EEC should therefore be adapted to that Decision.

(5) Safety during storage is covered by Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances <sup>(8)</sup> which sets out safety requirements for establishments where explosives are present. Safety of

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 121, 15.5.1993, p. 20.

<sup>(4)</sup> See Annex V, Part A.

<sup>(5)</sup> OJ L 127, 29.4.2004, p. 73.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(7)</sup> OJ L 218, 13.8.2008, p. 82.

<sup>(8)</sup> OJ L 10, 14.1.1997, p. 13.

explosives during transport is regulated by international conventions and agreements, including the United Nations recommendations on the transport of dangerous goods. Those aspects should therefore not fall under the scope of this Directive.

- (6) Pyrotechnic articles require appropriate measures to ensure the protection of end-users and the safety of the public. Pyrotechnic articles are covered by Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles <sup>(1)</sup>. This Directive should therefore not apply to pyrotechnic articles.
- (7) The scope of this Directive should cover ammunition, but only as regards the rules governing controls on transfers and the associated arrangements. Since ammunition is transferred under conditions similar to those under which arms are transferred, transfers of ammunition should be governed by provisions similar to those applicable to arms, as set out in Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons <sup>(2)</sup>.
- (8) This Directive should apply to all forms of supply, including distance selling.
- (9) The definition of the explosives covered by this Directive should be based on the definition of such products as set out in the United Nations recommendations on the transport of dangerous goods.
- (10) In order to ensure the free movement of explosives it is necessary to harmonise the laws relating to making explosives available on the market.
- (11) Economic operators should be responsible for the compliance of explosives with this Directive in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons and public security and to guarantee fair competition on the Union market.
- (12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market explosives which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (13) In order to facilitate communication between economic operators, market surveillance authorities and end-users,

Member States should encourage economic operators to include a website address in addition to the postal address.

- (14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (15) It is necessary to ensure that explosives from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those explosives. Provision should therefore be made for importers to make sure that the explosives they place on the market comply with the requirements of this Directive and that they do not place on the market explosives which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of explosives and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (16) The distributor makes an explosive available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the explosive does not adversely affect the compliance of the explosive.
- (17) Any economic operator that either places an explosive on the market under his own name or trade mark or modifies an explosive in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the explosive concerned.
- (19) Unique identification of explosives is essential if accurate and complete records of explosives are to be kept at all stages of the supply chain. This should allow the identification and the traceability of an explosive from its production site and its placing on the market until its final user and its use with a view to preventing misuse and theft and to assisting law enforcement authorities in the tracing of the origin of lost or stolen explosives. An efficient traceability system also facilitates market surveillance authorities' task of tracing economic operators who made non-compliant explosives available

<sup>(1)</sup> OJ L 178, 28.6.2013, p. 27.

<sup>(2)</sup> OJ L 256, 13.9.1991, p. 51.

- on the market. When keeping the information required under this Directive for the identification of economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with an explosive or to whom they have supplied an explosive.
- (20) The provisions of this Directive relating to the making available on the market should be limited to the expression of the essential safety requirements for explosives in order to protect the health and safety of persons, property and the environment. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for explosives which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation<sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (21) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (22) In order to enable economic operators to demonstrate and the competent authorities to ensure that explosives made available on the market conform to the essential safety requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants conformity assessment procedures should be chosen from among those modules. Because of their specific characteristics and the hazards involved, explosives should always be submitted to third party conformity assessment.
- (23) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of an explosive with this Directive and of other relevant Union harmonisation legislation.
- (24) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (25) The CE marking, indicating the conformity of an explosive, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (26) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (27) Experience has shown that the criteria set out in Directive 93/15/EEC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (28) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (29) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (30) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (31) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

- (32) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the explosives to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of conformity assessment bodies to be notified and the monitoring of notified bodies cover also activities carried out by subcontractors and subsidiaries.
- (33) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (34) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (35) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (36) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to explosives. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (37) Member States should take all appropriate measures to ensure that explosives may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Explosives should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (38) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to explosives presenting a risk to the health or safety of persons, or to property or the environment. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such explosives.
- (39) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (40) In the event of a serious threat to, or attack on, public security as a result of illicit possession or use of explosives or ammunition Member States should be allowed to derogate, under certain conditions, from this Directive with regard to transfer of explosives and ammunition in order to prevent such illicit possession or use.
- (41) It is essential to establish administrative cooperation mechanisms between competent authorities of Member States. Therefore, the competent authorities should base their approach on Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs or agricultural matters <sup>(1)</sup>.
- (42) This Directive should not affect the power of Member States to take measures with a view to preventing illegal trade in explosives and ammunition.
- (43) In order to achieve the objectives of this Directive, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of Union measures concerning adapting this Directive to United Nations recommendations on the transport of dangerous goods. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (44) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules
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- <sup>(1)</sup> OJ L 82, 22.3.1997, p. 1.



and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.

- (45) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (46) The examination procedure should be used for the adoption of the implementing acts in order to set up the practical arrangements for the operation of the system for the unique identification and traceability of explosives, as well as for setting out the technical arrangements for the application of the provisions on the transfer of explosives, in particular the model document to be used.
- (47) The examination procedure should also be used for the adoption of implementing acts with respect to compliant explosives which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (48) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant explosives which present a risk to the health or safety of persons, or to property or the environment, imperative grounds of urgency so require.
- (49) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (50) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (51) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant explosives are justified or not.
- (52) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

- (53) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market without the need to comply with further product requirements of explosives that have already been placed on the market in accordance with Directive 93/15/EEC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply explosives that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (54) Since the objective of this Directive, namely to ensure that explosives on the market fulfil the requirements providing for a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (55) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directives. The obligation to transpose the provisions which are unchanged arises under the earlier Directives.
- (56) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Directive shall apply to explosives for civil uses.
2. This Directive shall not apply to:
  - (a) explosives, including ammunition, intended for use, in accordance with national law, by the armed forces or the police;

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.

(b) pyrotechnic articles falling within the scope of Directive 2013/29/EU;

(c) ammunition, save as provided for in Articles 12, 13 and 14.

Annex I contains a non-exhaustive list of pyrotechnic articles and ammunition referred to in point (b) of this paragraph and in point 2 of Article 2 respectively identified following the United Nations recommendations on the transport of dangerous goods.

3. This Directive shall not prevent Member States from designating certain substances not covered by this Directive as explosives under national laws or regulations.

## Article 2

### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'explosives' means the materials and articles considered to be explosives in the United Nations recommendations on the transport of dangerous goods and falling within Class 1 of those recommendations;
- (2) 'ammunition' means projectiles with or without propelling charges and blank ammunition used in portable firearms, other guns and artillery;
- (3) 'safety' means the prevention of accidents and, where prevention fails, the containment of their effects;
- (4) 'security' means the prevention of use contrary to law and order;
- (5) 'approval' means the decision taken to allow envisaged transfers of explosives within the Union;
- (6) 'transfer' means any physical movement of explosives within the Union except movements within one and the same site;
- (7) 'making available on the market' means any supply of an explosive for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (8) 'placing on the market' means the first making available of an explosive on the Union market;
- (9) 'manufacturer' means any natural or legal person who manufactures an explosive or has an explosive designed or manufactured, and markets that explosive under his name or trade mark or uses it for his own purposes;
- (10) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (11) 'importer' means any natural or legal person established within the Union who places an explosive from a third country on the Union market;
- (12) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an explosive available on the market;
- (13) 'economic operators' means the manufacturer, the authorised representative, the importer, the distributor and any natural or legal person who engages in the storage, use, transfer, import, export or trade of explosives;
- (14) 'dealer' means any natural or legal person whose occupation consists wholly or partly in the manufacture, trade, exchange, hiring out, repair or conversion of fire arms and ammunition;
- (15) 'technical specification' means a document that prescribes technical requirements to be fulfilled by an explosive;
- (16) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (17) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (18) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (19) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to an explosive have been fulfilled;
- (20) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (21) 'recall' means any measure aimed at achieving the return of an explosive that has already been made available to the end-user;



- (22) 'withdrawal' means any measure aimed at preventing an explosive in the supply chain from being made available on the market;
- (23) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (24) 'CE marking' means a marking by which the manufacturer indicates that the explosive is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

#### Article 3

##### Free movement

Member States shall not prohibit, restrict or hinder the making available on the market of explosives which satisfy the requirements of this Directive.

#### Article 4

##### Making available on the market

Member States shall take the necessary measures to ensure that explosives may be made available on the market only if they comply with the requirements of this Directive.

### CHAPTER 2

#### OBLIGATIONS OF ECONOMIC OPERATORS

#### Article 5

##### Obligations of manufacturers

1. When placing their explosives on the market or when using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III and have the relevant conformity assessment procedure referred to in Article 20 carried out.

Where compliance of an explosive with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the explosive has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in design or characteristics of the explosive and changes in the harmonised standards or in other technical specifications by reference to which conformity of an explosive is declared shall be adequately taken into account.

5. Manufacturers shall ensure that explosives which they have placed on the market bear a unique identification in accordance with the system for the identification and traceability of explosives set out in Article 15. For explosives excluded from that system, manufacturers shall:

(a) ensure that explosives which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the small size, shape or design of the explosive does not allow it, that the required information is provided on its packaging or in a document accompanying the explosive;

(b) indicate on the explosive their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the explosive. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

6. Manufacturers shall ensure that explosives which they have placed on the market are accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

7. Manufacturers who consider or have reason to believe that an explosive which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that explosive into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the explosive presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the explosive available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the explosive with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have placed on the market.

## Article 6

### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 5(1) and the obligation to draw up technical documentation referred to in Article 5(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:
  - (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the explosive has been placed on the market;
  - (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an explosive;
  - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by explosives covered by the authorised representative's mandate.

## Article 7

### Obligations of importers

1. Importers shall place only compliant explosives on the market.
2. Before placing an explosive on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 20 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the explosive bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 5(5).

Where an importer considers or has reason to believe that an explosive is not in conformity with the essential safety requirements set out in Annex II, he shall not place the explosive on the market until it has been brought into conformity. Furthermore, where the explosive presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate, on the explosive, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not

possible, on its packaging or in a document accompanying the explosive. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the explosive is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an explosive is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex II.

6. Importers who consider or have reason to believe that an explosive which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that explosive into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the explosive presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the explosive available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

7. Importers shall, for 10 years after the explosive has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an explosive in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have placed on the market.

## Article 8

### Obligations of distributors

1. When making an explosive available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making an explosive available on the market distributors shall verify that the explosive bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by end-users in the Member State in which the explosive is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 5(5) and Article 7(3) respectively.

Where a distributor considers or has reason to believe that an explosive is not in conformity with the essential safety requirements set out in Annex II, he shall not make the explosive available on the market until it has been brought into conformity. Furthermore, where the explosive presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while an explosive is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex II.

4. Distributors who consider or have reason to believe that an explosive which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that explosive into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the explosive presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the explosive available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an explosive. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by explosives which they have made available on the market.

#### Article 9

#### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 5, where he places an explosive on the market under his name or trade mark or modifies an explosive already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 10

#### **Identification of economic operators**

For explosives not covered by the system set out in Article 15, economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with an explosive;

(b) any economic operator to whom they have supplied an explosive.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the explosive and for 10 years after they have supplied the explosive.

#### CHAPTER 3

#### **SECURITY PROVISIONS**

#### Article 11

#### **Transfers of explosives**

1. Explosives may be transferred only in accordance with paragraphs 2 to 8.

2. Approval to transfer explosives shall be obtained by the consignee from the competent authority in the Member State of the consignee. The competent authority shall verify that the consignee is legally authorised to acquire explosives and that he is in possession of the necessary licences or authorisations. The economic operator responsible for the transfer shall notify the competent authorities of the transit Member State of any movement of explosives through the Member State concerned and shall obtain prior approval of the transit Member State concerned.

3. Where a Member State considers that there is a problem regarding the verification of the entitlement to acquire explosives referred to in paragraph 2, that Member State shall forward the available information on the subject to the Commission which shall inform the other Member States thereof.

4. Where the competent authority in the Member State of the consignee approves a transfer, it shall issue to the consignee a document which includes all the information referred to in paragraph 5. Such a document shall accompany the explosives until they arrive at their stated destination. It shall be produced at the request of the relevant competent authorities. A copy of that document shall be retained by the consignee who shall present it, upon request, for examination by the competent authority in the Member State of the consignee.

5. Where transfers of explosives must be specially supervised in order to comply with special security requirements in the territory or part of the territory of a Member State, prior to the transfer the following information shall be provided by the consignee to the competent authority in the Member State of the consignee:

(a) the names and addresses of the economic operators concerned;

(b) the number and quantity of the explosives being transferred;

- (c) a full description of the explosives in question and of the means of identification, including the United Nations identification number;
- (d) where the explosives are to be placed on the market, information on compliance with conditions for placing on the market;
- (e) the means of transfer and the itinerary;
- (f) the expected dates of departure and arrival;
- (g) where necessary, the precise points of entry to and exit from Member States.

The information referred to in point (a) of the first subparagraph shall be sufficiently detailed in order to enable competent authorities to contact the economic operators and to obtain confirmation that the economic operators concerned are entitled to receive the consignment.

The competent authority in the Member State of the consignee shall examine the conditions under which the transfer may take place, with particular regard to the special security requirements. If the special security requirements are satisfied, approval for the transfer shall be granted. In the case of transit through the territory of other Member States, those Member States shall likewise examine and approve the particulars concerning the transfer.

6. Where the competent authority of a Member State considers that special security requirements referred to in paragraphs 4 and 5 are unnecessary, explosives may be transferred on their territory or part thereof without prior provision of information within the meaning of paragraph 5. The competent authority in the Member State of the consignee shall then grant an approval for a fixed period, which is liable to suspension or withdrawal at any time on the basis of a reasoned justification. The document referred to in paragraph 4, which shall accompany the explosives until they arrive at their destination, shall refer solely to that approval.

7. Without prejudice to the normal checks which the Member State of departure is to carry out in its territory, at the request of the competent authorities concerned, the consignees and the economic operators concerned shall forward to the authorities of the Member State of departure and to those of the Member State of transit all relevant information they possess concerning the transfer of explosives.

8. No economic operator may transfer explosives unless the consignee has obtained the necessary authorisations for the transfer in accordance with paragraphs 2, 4, 5 and 6.

## Article 12

### Transfers of ammunition

1. Ammunition may be transferred from one Member State to another only in accordance with the procedure laid down in paragraphs 2 to 5. Those paragraphs shall also apply to transfers of ammunition under mail-order sales.

2. Where ammunition is to be transferred to another Member State the person concerned shall, before any dispatch, communicate to the Member State in which that ammunition is located:

- (a) the names and addresses of the person selling or transferring the ammunition, of the person purchasing or acquiring the ammunition and, where appropriate, of the owner;
- (b) the address to which the ammunition is to be consigned or transported;
- (c) the quantity of ammunition to be consigned or transported;
- (d) data making it possible to identify the ammunition and also an indication that the ammunition has undergone a check in accordance with the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms;
- (e) the means of transfer;
- (f) the date of departure and the estimated date of arrival.

The information referred to in points (e) and (f) of the first subparagraph need not be supplied in the case of a transfer between dealers. The Member State shall examine the conditions under which the transfer is to be carried out, in particular with regard to security. Where the Member State authorises such a transfer it shall issue a licence incorporating all the particulars referred to in the first subparagraph. That licence shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities of the Member States.

3. Each Member State may grant dealers the right to effect transfers of ammunition from its territory to a dealer established in another Member State without the prior authorisation referred to in paragraph 2. To that end it shall issue an authorisation valid for three years which may at any time be suspended or cancelled by reasoned decision. A document referring to that authorisation shall accompany the ammunition until it reaches its destination. It shall be produced whenever so required by the competent authorities of the Member States.

Before effecting the transfer, the dealer shall communicate to the authorities of the Member State from which the transfer is to be effected all the particulars listed in the first subparagraph of paragraph 2.

4. Each Member State shall supply the other Member States with a list of the ammunition the transfer of which to its territory may be authorised without its prior consent.

Such lists of ammunition shall be communicated to dealers who have obtained approval for transferring ammunition without prior authorisation in accordance with the procedure laid down in paragraph 3.

5. Each Member State shall communicate all useful information at its disposal concerning definitive transfers of ammunition to the Member State, to the territory of which such a transfer has been effected.

All information that Member States receive in accordance with paragraphs 2 and 3 shall be communicated, not later than the time of the relevant transfers, to the Member States of destination and, where appropriate, not later than the time of transfer to the Member States of transit.

#### Article 13

##### Security derogations

By way of derogation from Article 11(2), (4), (5) and (6) and from Article 12, a Member State, in the event of serious threats to, or attacks on, public security as a result of illicit possession or use of explosives or ammunition, may take all necessary measures concerning transfers of explosives or ammunition in order to prevent such illicit possession or use.

The measures referred to in the first paragraph shall respect the principle of proportionality. They shall constitute neither a means of arbitrary discrimination nor a veiled restriction in trade between Member States.

Each Member State which adopts such measures shall notify the Commission of them forthwith. The Commission shall inform the other Member States thereof.

#### Article 14

##### Information exchange

1. Member States shall set up information exchange networks for the implementation of Articles 11 and 12. They shall notify the other Member States and the Commission of the national authorities responsible for forwarding or receiving information and for applying the procedures referred to in those Articles.

Member States shall keep at the disposal of the other Member States and of the Commission updated information concerning economic operators possessing licences or authorisations referred to in Article 16.

2. For the purposes of implementing this Directive, Regulation (EC) No 515/97, in particular the requirements thereof relating to confidentiality, shall apply *mutatis mutandis*.

#### Article 15

##### Identification and traceability of explosives

1. Economic operators shall adhere to a uniform system for the unique identification and traceability of explosives, that takes into account their size, shape or design, except where it is not necessary to place a unique identification on the explosive due to its low level of hazard, based on its characteristics and factors such as its low detonative effects, its uses and the low security risk it presents due to the low potential effects of misuse.

The system shall not apply to explosives transported and delivered unpackaged or in pump trucks for their direct unloading into the blast-hole, or explosives manufactured at blasting sites, and that are loaded immediately after being produced (in situ production).

2. That system shall provide for the collection and storage of data, including where appropriate by electronic means, enabling the unique identification and traceability of the explosive as well as for the placement of a unique identification on the explosive and/or its packaging enabling access to that data. Those data shall relate to the unique identification of the explosive, including its location while in the possession of economic operators and the identity of those economic operators.

3. The data referred to in paragraph 2 shall be tested at regular intervals and protected against accidental or malicious damage or destruction. Those data shall be stored for 10 years after the transaction took place or, where the explosives have been used or disposed of, 10 years after their use or disposal, even if the economic operator has ceased trading. They shall be immediately available at the request of the competent authorities.

4. The Commission may adopt implementing acts:

(a) laying down the practical arrangements for the operation of the system of unique identification and traceability referred to in paragraph 1, taking into account the size, shape or design of the explosives, in particular the format and structure of the unique identification, as provided for in paragraph 2;



(b) identifying the cases referred to in paragraph 1 where it is not necessary, due to the low level of hazard of an explosive, for economic operators to adhere to the system for the unique identification and traceability within the meaning of that paragraph.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

#### Article 16

##### **Licence or authorisation**

Economic operators shall be in possession of a licence or authorisation which entitles them to engage in the manufacture, storage, use, import, export, transfer or trade of explosives.

The first paragraph shall not apply to employees of an economic operator possessing a licence or authorisation.

#### Article 17

##### **Licensing of manufacturing activities**

When a Member State issues a licence or authorisation referred to in Article 16 for manufacturing of explosives, it shall check in particular that the economic operators responsible are capable of complying with the technical commitments they assume.

#### Article 18

##### **Seizures**

Each Member State shall adopt the necessary measures to enable the competent authorities to seize any explosive if there is sufficient evidence that that explosive will be illicitly acquired, used or dealt in.

#### CHAPTER 4

##### **CONFORMITY OF THE EXPLOSIVE**

#### Article 19

##### **Presumption of conformity of explosives**

Explosives, which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements set out in Annex II covered by those standards or parts thereof.

#### Article 20

##### **Conformity assessment procedures**

For the assessment of the conformity of explosives the manufacturer shall follow one of the following procedures referred to in Annex III:

(a) EU-type examination (Module B) and, at the choice of the manufacturer, any of the following:

(i) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);

(ii) conformity to type based on quality assurance of the production process (Module D);

(iii) conformity to type based on product quality assurance (Module E);

(iv) conformity to type based on product verification (Module F);

(b) conformity based on unit verification (Module G).

#### Article 21

##### **EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex II has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV, shall contain the elements specified in the relevant modules set out in Annex III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the explosive is placed or made available on the market.

3. Where an explosive is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the explosive with the requirements laid down in this Directive.

#### Article 22

##### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.



*Article 23***Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the explosive. Where that is not possible or not warranted on account of the nature of the explosive, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the explosive is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

5. In cases of explosives manufactured for own use, explosives transported and delivered unpackaged or in Mobile Explosives Manufacturing Units (MEMUs) for their direct unloading into the blast-hole, and explosives manufactured at the blasting sites which are loaded immediately after being produced (in situ production), the CE marking shall be affixed to the accompanying documents.

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

## CHAPTER 5

**NOTIFICATION OF CONFORMITY ASSESSMENT BODIES***Article 24***Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

*Article 25***Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 30.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

*Article 26***Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

*Article 27***Information obligation on notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 28***Requirements relating to notified bodies**

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the explosive it assesses.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of explosives nor the representative of any of those parties. This shall not preclude the use of explosives that are necessary for the operations of the conformity assessment body or the use of explosives for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of explosives or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex III and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of explosives in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex II, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex III or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 29

##### **Presumption of conformity of conformity assessment bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 28 insofar as the applicable harmonised standards cover those requirements.

#### Article 30

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 28 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex III.

#### Article 31

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the explosive or explosives for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 28.

#### Article 32

##### **Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and explosive or explosives concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### Article 33

##### **Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 34

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

#### Article 35

##### Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 49(2).

#### Article 36

##### Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the explosive with this Directive.

3. Where a notified body finds that the essential safety requirements set out in Annex II or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an explosive no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### Article 37

##### Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

#### Article 38

##### Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;

- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same explosives with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 39

##### Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 40

##### Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

#### CHAPTER 6

##### UNION MARKET SURVEILLANCE, CONTROL OF EXPLOSIVES ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

#### Article 41

##### Union market surveillance and control of explosives entering the Union market

Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to explosives.

Member States shall take all appropriate measures to ensure that explosives may be placed on the market only if, when properly stored and used for their intended purpose, they do not endanger the health or safety of persons.

#### Article 42

##### Procedure for dealing with explosives presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that an explosive presents

a risk to the health or safety of persons, or to property or the environment, they shall carry out an evaluation in relation to the explosive concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the explosive does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the explosive into compliance with those requirements, to withdraw the explosive from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the explosives concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the explosive's being made available on their national market, to withdraw the explosive from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant explosive, the origin of the explosive, the nature of the non-compliance alleged and the risk involved, the nature and



duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the explosive to meet requirements relating to the health or safety of persons, or to the protection of property or the environment; or
- (b) shortcomings in the harmonised standards referred to in Article 19 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the explosive concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the explosive from the market are taken in respect of the explosive concerned without delay.

#### Article 43

##### Union safeguard procedure

1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant explosive is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the explosive is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 42(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 44

##### Compliant explosives which present a risk

1. Where, having carried out an evaluation under Article 42(1), a Member State finds that although an explosive is in compliance with this Directive, it presents a risk to the health or safety of persons, or to property or the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the explosive concerned, when placed on the market, no longer presents that risk, to withdraw the explosive from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the explosives concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the explosive concerned, the origin and the supply chain of the explosive, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 49(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or to the protection of property or the environment, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 49(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.



## Article 45

**Formal non-compliance**

1. Without prejudice to Article 42, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 23 of this Directive;
- (b) the CE marking has not been affixed;
- (c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 23 or has not been affixed;
- (d) the EU declaration of conformity has not been drawn up;
- (e) the EU declaration of conformity has not been drawn up correctly;
- (f) technical documentation is either not available or not complete;
- (g) the information referred to in Article 5(5) or Article 7(3) is absent, false or incomplete;
- (h) any other administrative requirement provided for in Article 5 or Article 7 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the explosive being made available on the market or ensure that it is recalled or withdrawn from the market.

## CHAPTER 7

**DELEGATED AND IMPLEMENTING POWERS AND COMMITTEE**

## Article 46

**Delegated power**

The Commission shall be empowered to adopt delegated acts in accordance with Article 47 updating Annex I in order to align it to the United Nations recommendations on the transport of dangerous goods.

## Article 47

**Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 46 shall be conferred on the Commission for five years from 18 April 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 46 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

## Article 48

**Implementing acts**

The Commission shall adopt implementing acts setting out the technical arrangements for the application of Article 11, in particular the model document to be used.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 49(3).

## Article 49

**Committee procedure**

1. The Commission shall be assisted by the Committee on Civil Explosives. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

## CHAPTER 8

### TRANSITIONAL AND FINAL PROVISIONS

#### Article 50

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 51

##### Transitional provisions

1. Member States shall not impede the making available on the market of explosives covered by Directive 93/15/EEC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

2. Certificates issued under Directive 93/15/EEC shall be valid under this Directive.

3. Until replaced by the measures adopted pursuant to Article 15 of this Directive, Commission Directive 2008/43/EC of 4 April 2008 setting up, pursuant to Council Directive 93/15/EEC, a system for the identification and traceability of explosives for civil uses <sup>(1)</sup> shall continue to apply.

<sup>(1)</sup> OJ L 94, 5.4.2008, p. 8.

#### Article 52

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 2, 7 to 13 and 15 to 24 of Article 2, Articles 3 to 10, Article 14(1), Articles 15 and 16, point (i) of point (a) of Article 20, Articles 21 to 27, Article 28(1) to (4), (6), (7), (10) and (11), Articles 29 to 45, 50 and 51 and Annexes III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 53

##### Repeal

Directive 93/15/EEC as amended by the Regulations listed in Annex V, Part A, and Directive 2004/57/EC are repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law and the dates of application of the Directives set out in Annex V, Part B.

References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

#### Article 54

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, points 1, 3 to 6 and 14 of Article 2, Articles 11, 12 and 13, Article 14(2), Articles 17 to 19, points (ii) to (iv) of point (a) and point (b) of Article 20, Article 28(5), (8) and (9), Articles 46, 47, 48 and 49 and Annexes I, II, V and VI shall apply from 20 April 2016.

*Article 55***Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
D. KOURKOULAS

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## ANNEX I

## ARTICLES CONSIDERED IN THE RELEVANT UNITED NATIONS RECOMMENDATIONS TO BE PYROTECHNIC OR AMMUNITION

UN No	NAME and DESCRIPTION	CLASS/DIVISION	GLOSSARY (to be used as a guide for information only)
Group G			
0009	Ammunition, Incendiary with or without burster, expelling charge or propelling charge	1.2 G	<p>Ammunition</p> <p>Generic term related mainly to articles of military application consisting of all kind of bombs, grenades, rockets, mines, projectiles and other similar devices.</p> <p>Ammunition, Incendiary</p> <p>Ammunition containing incendiary substance. Except when the composition is an explosive per se, it also contains one or more of the following: a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.</p>
0010	Ammunition, Incendiary with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0009
0015	Ammunition, Smoke with or without burster, expelling charge or propelling charge	1.2 G	<p>Ammunition, Smoke</p> <p>Ammunition containing smoke-producing substance. Except when the substance is an explosive per se, the ammunition also contains one or more of the following: a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.</p>
0016	Ammunition, Smoke with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0015
0018	Ammunition, Tear-producing with burster, expelling charge or propelling charge	1.2 G	<p>Ammunition, Tear-producing with burster, expelling charge or propelling charge</p> <p>Ammunition containing tear-producing substance. It also contains one or more of the following: a pyrotechnic substance; a propelling charge with primer and igniter charge; a fuze with burster or expelling charge.</p>
0019	Ammunition, Tear-producing with burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0018
0039	Bombs, photo-flash	1.2 G	<p>Bombs</p> <p>Explosive articles which are dropped from aircraft. They may contain a flammable liquid with bursting charge, a photo-flash composition or a bursting charge. The term includes: bombs, photo-flash.</p>
0049	Cartridges, Flash	1.1 G	<p>Cartridges, Flash</p> <p>Articles consisting of a casing, a primer and flash powder, all assembled in one piece ready for firing.</p>
0050	Cartridges, Flash	1.3 G	See Entry for UN No 0049
0054	Cartridges, Signal	1.3 G	<p>Cartridges, Signal</p> <p>Articles designed to fire coloured flares or other signals from signal pistols, etc.</p>

UN No	NAME and DESCRIPTION	CLASS/DIVISION	GLOSSARY (to be used as a guide for information only)
0066	Cord, Igniter	1.4 G	Cord, Igniter  Article consisting of textile yarns covered with black powder or another fast burning pyrotechnic composition and of a flexible protective covering; or it consists of a core of black powder surrounded by a flexible woven fabric: It burns progressively along its length with an external flame and is used to transmit ignition from a device to a charge.
0092	Flares, Surface	1.3 G	Flares Articles containing pyrotechnic substances which are designed for use to illuminate, identify, signal or warn.
0093	Flares, Aerial	1.3 G	See Entry for UN No 0092
0101	Fuse, non-detonating	1.3 G	Fuse/Fuze  Although these two words have a common origin (French fusée, fusil) and are sometimes considered to be different spellings, it is useful to maintain the convention that fuse refers to a cord-like igniting device whereas fuze refers to a device used in ammunition which incorporates mechanical, electrical, chemical or hydrostatic components to initiate a train by deflagration or detonation.  Fuse, instantaneous, non-detonating (quick-match)  Article consisting of cotton yarns impregnated with fine black powder (quickmatch). It burns with an external flame and is used in ignition trains for fireworks, etc.
0103	Fuse, Igniter, tubular, metal clad	1.4 G	Fuse, igniter, tubular, metal clad  Article consisting of a metal tube with a core of deflagrating explosive.
0171	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.2 G	Ammunition, illuminating with or without burster, expelling charge or propelling charge  Ammunition designed to produce a single source of intense light for lighting up an area. The term includes illuminating cartridges, grenades and projectiles; and illuminating and target identification bombs.
0191	Signal devices, hand	1.4 G	Articles designed to produce signals.
0192	Signals, railway track, explosive	1.1 G	See Entry for UN No 0191
0194	Signals, distress, ship	1.1 G	See Entry for UN No 0191
0195	Signals, distress, ship	1.3 G	See Entry for UN No 0191
0196	Signals, smoke	1.1 G	See Entry for UN No 0191
0197	Signals, smoke	1.4 G	See Entry for UN No 0191
0212	Tracers for ammunition	1.3 G	Tracers for ammunition  Sealed articles containing pyrotechnic substances, designed to reveal the trajectory of a projectile.
0254	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.3 G	See Entry for UN No 0171

UN No	NAME and DESCRIPTION	CLASS/DIVISION	GLOSSARY (to be used as a guide for information only)
0297	Ammunition, illuminating with or without burster, expelling charge or propelling charge	1.4 G	See Entry for UN No 0254
0299	Bombs, photo-flash	1.3 G	See Entry for UN No 0039
0300	Ammunition, incendiary with or without burster, expelling charge or propelling charge	1.4 G	See Entry for UN No 0009
0301	Ammunition, tear-producing with burster, expelling charge	1.4 G	See Entry for UN No 0018
0303	Ammunition, smoke with or without burster, expelling charge	1.4 G	See Entry for UN No 0015
0306	Tracers for ammunition	1.4 G	See Entry for UN No 0212
0312	Cartridges, signal	1.4 G	Cartridges, signal Articles designed to fire coloured flares or other signals from signal pistols.
0313	Signals, smoke	1.2 G	See Entry for UN No 0195
0318	Grenades, practice, hand or rifle	1.3 G	Grenades hand or rifle Articles which are designed to be thrown by hand or to be projected by a rifle. The term includes: Grenades practice, hand or rifle.
0319	Primers, tubular	1.3 G	Primers, tubular Articles consisting of a primer for ignition and an auxiliary charge of deflagrating explosive such as black powder used to ignite the propelling charge in a cartridge case, e.g. cannon.
0320	Primers, tubular	1.4 G	See Entry for UN No 0319
0333	Fireworks	1.1 G	Fireworks Pyrotechnic articles designed for entertainment.
0334	Fireworks	1.2 G	See Entry for UN No 0333
0335	Fireworks	1.3 G	See Entry for UN No 0333
0336	Fireworks	1.4 G	See Entry for UN No 0333
0362	Ammunition, practice	1.4 G	Ammunition, practice Ammunition without a main bursting charge, containing a burster or expelling charge. Normally it also contains a fuze and a propelling charge.
0363	Ammunition, proof	1.4 G	Ammunition, proof Ammunition containing pyrotechnic substances, used to test the performance or strength of new ammunition, weapon component or assemblies.
0372	Grenades, practice, hand or rifle	1.2 G	See Entry for UN No 0318



UN No	NAME and DESCRIPTION	CLASS/DIVISION	GLOSSARY (to be used as a guide for information only)
0373	Signal devices, hand	1.4 S	See Entry for UN No 0191
0403	Flares, aerial	1.4 G	See Entry for UN No 0092
0418	Flares, surface	1.2 G	See Entry for UN No 0092
0419	Flares, surface	1.1 G	See Entry for UN No 0092
0420	Flares, aerial	1.1 G	See Entry for UN No 0092
0421	Flares, aerial	1.2 G	See Entry for UN No 0092
0424	Projectiles, inert with tracer	1.3 G	<p>Projectiles</p> <p>Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge. The term includes: Projectiles, inert, with tracer; projectiles with burster or expelling charge; projectiles with bursting charge.</p>
0425	Projectiles, inert with tracer	1.4 G	See Entry for UN No 0424
0428	Articles, pyrotechnic for technical purposes	1.1 G	<p>Articles, pyrotechnic for technical purposes</p> <p>Articles which contain pyrotechnic substances and are used for technical purposes such as heat generation, gas generation, theatrical effects, etc. The term excludes the following articles which are listed separately: all ammunition; cartridges, signal; cutters, cable, explosive; fireworks; flares, aerial; flares, surface; release devices, explosive; rivets, explosive; signal devices, hand; signals, distress; signals, railway track, explosive; signals, smoke.</p>
0429	Articles, pyrotechnic for technical purposes	1.2 G	See Entry for UN No 0428
0430	Articles, pyrotechnic for technical purposes	1.3 G	See Entry for UN No 0428
0431	Articles, pyrotechnic for technical purposes	1.4 G	See Entry for UN No 0428
0434	Projectiles with burster or expelling charge	1.2 G	<p>Projectiles</p> <p>Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge. The term includes: projectiles, inert, with tracer; projectiles with burster or expelling charge; projectiles with bursting charge.</p>
0435	Projectiles with burster or expelling charge	1.4 G	See Entry for UN No 0434
0452	Grenades, practice, hand or rifle	1.4 G	See Entry for UN No 0372
0487	Signal, smoke	1.3 G	See Entry for UN No 0194
0488	Ammunition, practice	1.3 G	<p>Ammunition, practice</p> <p>Ammunition without a main bursting charge, containing a burster or expelling charge. Normally it also contains a fuze and a propelling charge. The term excludes the following articles which are listed separately: Grenades, practice.</p>

UN No	NAME and DESCRIPTION	CLASS/DIVISION	GLOSSARY (to be used as a guide for information only)
0492	Signals, railway track, explosive	1.3 G	See Entry for UN No 0194
0493	Signals, railway track, explosive	1.4 G	See Entry for UN No 0194
0503	Air bag inflators, or Airbag modules, or seat belt pre-tensioners,	1.4 G	
Group S			
0110	Grenades, practice, hand or rifle	1.4 S	See Entry for UN No 0318
0193	Signals, railway track, explosive	1.4 S	See Entry for UN No 0194
0337	Fireworks	1.4 S	See Entry for UN No 0334
0345	Projectiles, inert with tracer	1.4 S	Projectiles Articles such as a shell or bullet which are projected from a cannon or other artillery gun, rifle or other small arm. They may be inert, with or without tracer, or may contain a burster or expelling charge or a bursting charge.
0376	Primers, tubular	1.4 S	See Entry for UN No 0319
0404	Flares, aerial	1.4 S	See Entry for UN No 0092
0405	Cartridges, signal	1.4 S	Cartridges, Signal Articles designed to fire coloured flares or other signals from signal pistols, etc.
0432	Articles, pyrotechnic or technical purpose	1.4 S	

## ANNEX II

## ESSENTIAL SAFETY REQUIREMENTS

**I. General requirements**

1. Each explosive must be designed, manufactured and supplied in such a way as to present a minimal risk to the safety of human life and health, and to prevent damage to property and the environment under normal, foreseeable conditions, in particular as regards the safety rules and standard practices until it is used.
2. Each explosive must attain the performance characteristics specified by the manufacturer in order to ensure maximum safety and reliability.
3. Each explosive must be designed and manufactured in such a way that when appropriate techniques are employed it can be disposed of in a manner which minimises effects on the environment.

**II. Special requirements**

1. As a minimum, the following information and properties, where appropriate, must be considered or tested:
  - (a) design and characteristic properties, including chemical composition, degree of homogeneity and, where appropriate, dimensions and grain size distribution;
  - (b) the physical and chemical stability of the explosive in all environmental conditions to which it may be exposed;
  - (c) sensitiveness to impact and friction;
  - (d) compatibility of all components as regards their physical and chemical stability;
  - (e) the chemical purity of the explosive;
  - (f) resistance of the explosive against influence of water where it is intended to be used in humid or wet conditions and where its safety or reliability may be adversely affected by water;
  - (g) resistance to low and high temperatures, where the explosive is intended to be kept or used at such temperatures and its safety or reliability may be adversely affected by cooling or heating of a component or of the explosive as a whole;
  - (h) the suitability of the explosive for use in hazardous environments (e.g. firedamp atmospheres, hot masses) if it is intended to be used under such conditions;
  - (i) safety features intended to prevent untimely or inadvertent initiation or ignition;
  - (j) the correct loading and functioning of the explosive when used for its intended purpose;
  - (k) suitable instructions and, where necessary, markings in respect of safe handling, storage, use and disposal;
  - (l) the ability of the explosive, its wrapping or other components to withstand deterioration during storage until the 'use by' date specified by the manufacturer;
  - (m) specification of all devices and accessories needed for reliable and safe functioning of the explosive.
2. Each explosive shall be tested under realistic conditions. If this is not possible in a laboratory, the tests shall be carried out in the conditions in which the explosive is to be used.
3. Requirements for the groups of explosives
  - 3.1. Blasting explosives shall also comply with the following requirements:
    - (a) the proposed method of initiation must ensure safe, reliable and complete detonation or deflagration as appropriate, of the blasting explosive. In the particular case of black powder, it is the capacity as regards deflagration which shall be checked;

- (b) blasting explosives in cartridge form must transmit the detonation safely and reliably from one end of the train of cartridges to the other;
- (c) the fumes produced by blasting explosives intended for underground use may contain carbon monoxide, nitrous gases, other gases, vapours or airborne solid residues only in quantities which do not impair health under normal operating conditions.

3.2. Detonating cords, safety fuses, other fuses and shock tubes shall also comply with the following requirements:

- (a) the covering of detonating cords, safety fuses, other fuses and shock tubes must be of adequate mechanical strength and adequately protect the explosive filling when exposed to normal mechanical stress;
- (b) the parameters for the burning times of safety fuses must be indicated and must be reliably met;
- (c) detonating cords must be capable of being reliably initiated, be of sufficient initiation capability and comply with requirements as regards storage even in particular climatic conditions.

3.3. Detonators (including delay detonators) and relays shall also comply with the following requirements:

- (a) detonators must reliably initiate the detonation of the blasting explosives which are intended to be used with them under all foreseeable conditions of use;
- (b) delay connectors for detonating cords must be reliably initiated;
- (c) the initiation capability must not be adversely affected by humidity;
- (d) the delay times of delay detonators must be sufficiently uniform to ensure that the probability of overlapping of the delay times of adjacent time steps is insignificant;
- (e) the electrical characteristics of electric detonators must be indicated on the packaging (e.g. no-fire current, resistance);
- (f) the wires of electric detonators must be of sufficient insulation and mechanical strength including the solidity of the link to the detonator, taking account of their intended use.

3.4. Propellants and rocket propellants shall also comply with the following requirements:

- (a) these materials must not detonate when used for their intended purpose;
  - (b) propellants where necessary (e.g. those based on nitrocellulose) must be stabilised against decomposition;
  - (c) solid rocket propellants, when in compressed or cast form, must not contain any unintentional fissures or gas bubbles which dangerously affect their functioning.
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## ANNEX III

## CONFORMITY ASSESSMENT PROCEDURES

## MODULE B

**EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an explosive and verifies and attests that the technical design of the explosive meets the requirements of this Directive that apply to it.
2. EU-type examination shall be carried out as an assessment of the adequacy of the technical design of the explosive through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete product (combination of production type and design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) the technical documentation. The technical documentation shall make it possible to assess the explosive's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive. The technical documentation shall contain wherever applicable, at least the following elements:
    - (i) a general description of the explosive;
    - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
    - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the explosive;
    - (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
    - (v) results of design calculations made, examinations carried out, etc.;
    - (vi) test reports;
  - (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
  - (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall:

For the explosive:

- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the explosive.

For the specimen(s):

- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive that apply to the explosive concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured explosives with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the explosive with the essential safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.



9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the explosive has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

#### MODULE C 2

##### **Conformity to type based on internal production control plus supervised product checks at random intervals**

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. *Product checks*

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by that body, in order to verify the quality of the internal checks on the explosive, taking into account, inter alia, the technological complexity of the explosives and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the explosive with the type described in the EU-type examination certificate and with the relevant requirements of this Directive. Where a sample does not conform to the acceptable quality level, the notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the explosive performs within acceptable limits, with a view to ensuring conformity of the explosive.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. *CE marking and EU declaration of conformity*

- 4.1. The manufacturer shall affix the CE marking to each individual explosive that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for each explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. *Authorised representative*

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### MODULE D

##### **Conformity to type based on quality assurance of the production process**

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

## 2. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the explosives concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

## 3. *Quality system*

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the explosives concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the explosive category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 3.2. The quality system shall ensure that the explosives are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point (e) of point 3.1 to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### 4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### 5. *CE marking and EU declaration of conformity*

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual explosive that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the explosive has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1;
  - (b) the information relating to the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. *Authorised representative*

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE E

**Conformity to type based on product quality assurance**

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the explosives concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. *Manufacturing*

The manufacturer shall operate an approved quality system for final product inspection and testing of the explosives concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. *Quality system*

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the explosives concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the explosive category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 3.2. The quality system shall ensure compliance of the explosives with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (d) the means of monitoring the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point (e) of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### 4. *Surveillance under the responsibility of the notified body*

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### 5. *CE marking and EU declaration of conformity*

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual explosive that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending 10 years after the explosive has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1;
  - (b) the information relating to the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. *Authorised representative*

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## MODULE F

### Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the explosives concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the explosives with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the explosives with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 4 or by examination and testing of the explosives on a statistical basis as specified in point 5.

4. *Verification of conformity by examination and testing of every product*

- 4.1. All explosives shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.
- 4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved explosive or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the explosive has been placed on the market.

5. *Statistical verification of conformity*

- 5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his explosives for verification in the form of homogeneous lots.
- 5.2. A random sample shall be taken from each lot. All explosives in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.



- 5.3. If a lot is accepted, all explosives of the lot shall be considered approved, except for those explosives from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved explosive or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the explosive has been placed on the market.

- 5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. *CE marking and EU declaration of conformity*

- 6.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual explosive that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 6.2. The manufacturer shall draw up a written EU declaration of conformity for each explosive type and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive type for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the explosives.

If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the explosives during the manufacturing process.

7. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

MODULE G

**Conformity based on unit verification**

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the explosive concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

2. *Technical documentation*

- 2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the explosive's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive. The technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the explosive;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the explosive;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the case of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc., and

(f) test reports.

2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the explosive has been placed on the market.

### 3. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosive with the applicable requirements of this Directive.

### 4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the explosive with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved explosive, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the explosive has been placed on the market.

### 5. *CE marking and EU declaration of conformity*

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each explosive that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the explosive has been placed on the market. The EU declaration of conformity shall identify the explosive for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

### 6. *Authorised representative*

The manufacturer's obligations set out in points 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. No ... (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of product allowing traceability):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. The notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

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<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX V

## PART A

**Repealed Directives with list of the successive amendments thereto  
(referred to in Article 53)**

Council Directive 93/15/EEC  
(OJ L 121, 15.5.1993, p. 20).

Regulation (EC) No 1882/2003 of the  
European Parliament and of the Council  
(OJ L 284, 31.10.2003, p. 1).

Only point (13) of Annex II

Regulation (EC) No 219/2009 of the  
European Parliament and of the Council  
(OJ L 87, 31.3.2009, p. 109).

Only point 2.2 of the Annex

Regulation (EU) No 1025/2012 of the  
European Parliament and of the Council  
(OJ L 316, 14.11.2012, p. 12).

Only point (b) of Article 26(1)

Commission Directive 2004/57/EC  
(OJ L 127, 29.4.2004, p. 73).

## PART B

**Time-limits for transposition into national law and dates of application  
(referred to in Article 53)**

Directive	Time-limit for transposition	Date of application
93/15/EEC (Articles 9, 10, 11, 12, 13 and 14)	30 September 1993	30 September 1993
93/15/EEC (all other articles)	30 June 1994	1 January 1995
2004/57/EC	31 December 2004	31 January 2005

## ANNEX VI

## CORRELATION TABLE

Directive 93/15/EEC	Directive 2004/57/EC	This Directive
Article 1(1)		Article 1(1)
Article 1(2)		Article 2(1)
Article 1(3)		Article 1(2)
Article 1(4)		Article 2(3) to (6), (8), (13) and (14)
—		Article 2(2), (7), (9) to (12) and (15) to (24)
Article 1(5)		Article 1(3)
Article 2(1)		Article 3
Article 2(2)		Article 4
Article 2(3)		Article 22
Article 3		Article 4 and Article 5(1)
—		Article 5(2) to (8)
—		Article 6
—		Article 7
—		Article 8
—		Article 9
		Article 10
Article 4(1)		Article 19
Article 4(2)		—
Article 5		Article 43(3)
Article 6(1)		Article 20
—		Article 21
—		Articles 24 to 27
Article 6(2)		Articles 28 to 40
Article 7(1)		Articles 22 and 23
Article 7(2)		Article 22
Article 7(3)		Article 22
—		Article 41
Article 8(1)		Articles 42 and 44
Article 8(2)		Article 43
Article 8(3)		Article 45
Article 9(1)		Article 11(1)
Article 9(2)		—
Article 9(3)		Article 11(2)
Article 9(4)		Article 11(3)

Directive 93/15/EEC	Directive 2004/57/EC	This Directive
Article 9(5)		Article 11(4)
Article 9(6)		Article 11(6)
Article 9(7)		Article 11(5)
Article 9(8)		Article 11(7)
Article 9(9)		Article 11(8)
Article 10(1)		Article 12(1)
Article 10(2)		Article 12(2)
Article 10(3)		Article 12(3)
Article 10(4)		Article 12(4)
Article 10(5)		Article 12(5)
Article 11		Article 13
Article 12(1)		Article 14(1)
Article 12(2)		Article 14(2)
Article 13(1)		Article 49(1)
Article 13(2)		—
Article 13(3)		Articles 46 and 47
—		Article 48
Article 13(4)		Article 49(2) to (5)
Article 13(5)		Articles 46 and 47
Article 14, first paragraph		Article 16
Article 14, second paragraph		Article 15(1) and (4)
Article 14, third paragraph		Article 15(2) and (4)
Article 14, fourth paragraph		Article 15(3)
Article 15		—
Article 16		Article 17
Article 17		Article 50
Article 18		Article 18
Article 19		Articles 51 and 52
—		Article 53
—		Article 54
Article 20		Article 55
	Article 1	—
	Article 2	—
	Article 3	—
	Article 4	—
	Article 5	—
	Annex I	Annex I
	Annex II	—



Directive 93/15/EEC	Directive 2004/57/EC	This Directive
Annex I		Annex II
Annex II		Annex III
Annex III		Article 28
Annex IV		Article 22
—		Annex IV
—		Annex V
—		Annex VI

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/29/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 26 February 2014**  
**on the harmonisation of the laws of the Member States relating to the making available on the**  
**market of simple pressure vessels**

(recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common

framework for the marketing of products <sup>(6)</sup> lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2009/105/EC should be adapted to that Decision.

(4) This Directive covers simple pressure vessels which are new to the Union market when they are placed on the market; that is to say they are either new simple pressure vessels made by a manufacturer established in the Union or simple pressure vessels, whether new or second-hand, imported from a third country.

(5) This Directive should apply to all forms of supply, including distance selling.

(6) Member States should ensure on their territory the protection of the health and safety of persons, and the protection of domestic animals and property with regard to the hazards resulting from the leakage or bursting of simple pressure vessels.

(7) Economic operators should be responsible for the compliance of simple pressure vessels with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons, and protection of domestic animals and property, and to guarantee fair competition on the Union market.

(8) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market simple pressure vessels which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(9) In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address.

<sup>(1)</sup> OJ C 27, 3.2.2009, p. 41.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 264, 8.10.2009, p. 12. Directive 2009/105/EC is the codification of Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels (OJ L 220, 8.8.1987, p. 48).

<sup>(4)</sup> See Annex V, Part A.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 82.

- (10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure for simple pressure vessels. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (11) It is necessary to ensure that simple pressure vessels from third countries entering the Union market comply with this Directive, and in particular that the appropriate conformity assessment procedures have been carried out by manufacturers with regard to those simple pressure vessels. Provision should therefore be made for importers to make sure that the simple pressure vessels they place on the market comply with the requirements of this Directive and that they do not place on the market simple pressure vessels which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (12) When placing a simple pressure vessel on the market, every importer should indicate on the simple pressure vessel his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the nature of the simple pressure vessel does not allow it.
- (13) The distributor makes a simple pressure vessel available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the simple pressure vessel does not adversely affect the compliance of the simple pressure vessel.
- (14) Any economic operator that either places a simple pressure vessel on the market under its own name or trade mark or modifies a simple pressure vessel in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (15) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the simple pressure vessel concerned.
- (16) Ensuring traceability of a simple pressure vessel throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant simple pressure vessels available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a simple pressure vessel or to whom they have supplied a simple pressure vessel.
- (17) This Directive should be limited to the expression of the essential safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for simple pressure vessels which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation<sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (18) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (19) In order to enable economic operators to demonstrate and the competent authorities to ensure that simple pressure vessels made available on the market comply with the essential safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (20) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a simple pressure vessel with this Directive and other relevant Union harmonisation legislation.
- (21) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (22) The CE marking, indicating the conformity of a simple pressure vessel, is the visible consequence of a whole process comprising conformity assessment in a broad
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- <sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.

- (23) A check on compliance with the relevant essential safety requirements is necessary in order to provide effective protection for end-users and third parties.
- (24) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (25) Experience has shown that the criteria set out in Directive 2009/105/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (26) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (27) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for the notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (28) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (29) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the

compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- (30) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the simple pressure vessels to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (31) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (32) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (33) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (34) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to simple pressure vessels. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (35) Member States should take all appropriate measures to ensure that simple pressure vessels may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Simple pressure vessels should be considered as non-compliant with the essential safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

- (36) Directive 2009/105/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against simple pressure vessels it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the aim of making it more efficient and of drawing on the expertise available in the Member States.
- (37) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to simple pressure vessels presenting a risk to the health or safety of persons, or to domestic animals or property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such simple pressure vessels.
- (38) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (39) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>(1)</sup>.
- (40) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (41) The examination procedure should be used for the adoption of implementing acts with respect to compliant simple pressure vessels which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (42) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant simple pressure vessels which present a risk to the health or safety of persons, to domestic animals or to property, imperative grounds of urgency so require.
- (43) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (44) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (45) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant simple pressure vessels are justified or not.
- (46) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (47) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into service, without the need to comply with further product requirements, of simple pressure vessels that have already been placed on the market in accordance with Directive 2009/105/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply simple pressure vessels that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (48) Since the objective of this Directive, namely to ensure that simple pressure vessels on the market fulfil the requirements providing for a high level of protection of health and safety of persons, as well as protection of domestic animals and property while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (49) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.



- (50) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Directive shall apply to simple pressure vessels ('vessels') manufactured in series with the following characteristics:

- (a) the vessels are welded, intended to be subjected to an internal gauge pressure greater than 0,5 bar and to contain air or nitrogen, and are not intended to be fired;
- (b) the parts and assemblies contributing to the strength of the vessel under pressure are made either of non-alloy quality steel or of non-alloy aluminium or non-age hardening aluminium alloys;
- (c) the vessel is made of either of the following elements:
  - (i) a cylindrical part of circular cross-section closed by outwardly dished and/or flat ends which revolve around the same axis as the cylindrical part;
  - (ii) two dished ends revolving around the same axis;
- (d) the maximum working pressure of the vessel does not exceed 30 bar and the product of that pressure and the capacity of the vessel ( $PS \times V$ ) does not exceed 10 000 bar.L;
- (e) the minimum working temperature is no lower than  $-50\text{ }^{\circ}\text{C}$  and the maximum working temperature is not higher than  $300\text{ }^{\circ}\text{C}$  for steel and  $100\text{ }^{\circ}\text{C}$  for aluminium or aluminium alloy vessels.

2. This Directive shall not apply to:

- (a) vessels specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
- (b) vessels specifically intended for installation in or the propulsion of ships and aircraft;

- (c) fire extinguishers.

#### Article 2

##### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'making available on the market' means any supply of a vessel for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (2) 'placing on the market' means the first making available of a vessel on the Union market;
- (3) 'manufacturer' means any natural or legal person who manufactures a vessel or has a vessel designed or manufactured, and markets that vessel under his name or trade mark;
- (4) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (5) 'importer' means any natural or legal person established within the Union who places a vessel from a third country on the Union market;
- (6) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a vessel available on the market;
- (7) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (8) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a vessel;
- (9) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (10) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (11) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

- (12) 'conformity assessment' means the process demonstrating whether the essential safety requirements of this Directive relating to a vessel have been fulfilled;
- (13) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (14) 'recall' means any measure aimed at achieving the return of a vessel that has already been made available to the end-user;
- (15) 'withdrawal' means any measure aimed at preventing a vessel in the supply chain from being made available on the market;
- (16) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (17) 'CE marking' means a marking by which the manufacturer indicates that the vessel is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

#### Article 3

##### **Making available on the market and putting into service**

1. Member States shall take all necessary steps to ensure that the vessels may be made available on the market and put into service only if they satisfy the requirements of this Directive when properly installed and maintained and used for the purposes for which they are intended.
2. The provisions of this Directive shall not affect the right of Member States to specify the requirements they deem necessary in order to ensure that workers are protected when using vessels, provided it does not mean that those vessels are modified in a way unspecified in this Directive.

#### Article 4

##### **Essential requirements**

1. Vessels of which the product of  $PS \times V$  exceeds 50 bar.L shall satisfy the essential safety requirements set out in Annex I.
2. Vessels of which the product of  $PS \times V$  is 50 bar.L or less shall be designed and manufactured in accordance with the sound engineering practice in one of the Member States.

#### Article 5

##### **Free movement**

Member States shall not impede the making available on the market and the putting into service on their territory of vessels which satisfy the requirements of this Directive.

#### CHAPTER 2

##### **OBLIGATIONS OF ECONOMIC OPERATORS**

#### Article 6

##### **Obligations of manufacturers**

1. When placing on the market their vessels of which the product of  $PS \times V$  exceeds 50 bar.L, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Annex I.

When placing on the market their vessels of which the product of  $PS \times V$  is 50 bar.L or less, manufacturers shall ensure that they have been designed and manufactured in accordance with the sound engineering practice in one of the Member States.

2. For vessels of which the product of  $PS \times V$  exceeds 50 bar.L, manufacturers shall draw up the technical documentation referred to in Annex II and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of a vessel of which the product of  $PS \times V$  exceeds 50 bar.L with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the inscriptions provided for in point 1 of Annex III.

Manufacturers shall ensure that vessels of which the product of  $PS \times V$  is 50 bar.L or less, bear the inscriptions laid down in point 1 of Annex III.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the vessel has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in vessels design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a vessel is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a vessel, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of vessels made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming vessels and vessel recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that vessels which they have placed on the market bear a type and serial or batch identification allowing their identification.

6. Manufacturers shall indicate on the vessel their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Annex III, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a vessel which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the vessel presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the vessel available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the vessel with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by vessels which they have placed on the market.

#### Article 7

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market

surveillance authorities for 10 years after the vessel has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a vessel;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by vessels covered by the authorised representative's mandate.

#### Article 8

##### Obligations of importers

1. Importers shall place only compliant vessels on the market.

2. Before placing on the market a vessel of which the product of  $PS \times V$  exceeds 50 bar.L, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the vessel bears the CE marking and the inscriptions provided for in point 1 of Annex III and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that a vessel of which the product of  $PS \times V$  exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Annex I, he shall not place the vessel on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market a vessel of which the product of  $PS \times V$  is 50 bar.L or less, importers shall ensure that it has been designed and manufactured in accordance with the sound engineering practice in one of the Member States, bears the inscriptions provided for in point 1.2 of Annex III and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3. Importers shall indicate on the vessel their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the vessel. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the vessel is accompanied by the instructions and safety information referred to in point 2 of Annex III, in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a vessel in respect of which the product of  $PS \times V$  exceeds 50 bar.L is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by a vessel, importers shall, to protect the health and safety of end-users, carry out sample testing of vessels made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming vessels and vessel recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a vessel which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the vessel presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the vessel available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. For vessels of which the product of  $PS \times V$  exceeds 50 bar.L, importers shall, for 10 years after the vessel has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a vessel in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by vessels which they have placed on the market.

#### Article 9

##### **Obligations of distributors**

1. When making a vessel available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making available on the market a vessel of which the product of  $PS \times V$  exceeds 50 bar.L, distributors shall verify that the vessel bears the CE marking and the inscriptions provided for in point 1 of Annex III, that it is accompanied by the required documents and by instructions and safety information referred to in point 2 of Annex III in a language which can be easily understood by end-users in the Member State in which the vessel is to be made available on the market,

and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that a vessel of which the product of  $PS \times V$  exceeds 50 bar.L is not in conformity with the essential safety requirements set out in Annex I, he shall not make the vessel available on the market until it has been brought into conformity. Furthermore, where the vessel presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making available on the market a vessel of which the product of  $PS \times V$  is 50 bar.L or less, distributors shall verify that the vessel bears the inscriptions provided for in point 1.2 of Annex III and is accompanied by the instructions and safety information referred to in point 2 of Annex III in a language which can be easily understood by end-users in the Member State in which the vessel is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

3. Distributors shall ensure that, while a vessel of which the product of  $PS \times V$  exceeds 50 bar.L is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a vessel which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that vessel into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the vessel presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the vessel available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a vessel. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by vessels which they have made available on the market.

#### Article 10

##### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places a vessel on the market under his name or trade mark or modifies a vessel already placed on the market in such a way that compliance with this Directive may be affected.

## Article 11

**Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a vessel;
- (b) any economic operator to whom they have supplied a vessel.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the vessel and for 10 years after they have supplied the vessel.

## CHAPTER 3

**CONFORMITY OF VESSELS OF WHICH THE PRODUCT OF  $PS \times V$  EXCEEDS 50 bar.L**

## Article 12

**Presumption of conformity of vessels of which the product of  $PS \times V$  exceeds 50 bar.L**

Vessels of which the product of  $PS \times V$  exceeds 50 bar.L and which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential safety requirements set out in Annex I covered by those standards or parts thereof.

## Article 13

**Conformity assessment procedures**

1. Prior to their manufacture, vessels of which the product of  $PS \times V$  exceeds 50 bar.L shall be subject to the EU-type examination (Module B) set out in point 1 of Annex II, as follows:

- (a) for vessels manufactured in accordance with the harmonised standards referred to in Article 12, at the choice of the manufacturer, in either of the following two manners:
  - (i) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence without examination of a specimen (Module B – design type);
  - (ii) assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence, plus examination of a prototype, representative of the production envisaged, of the complete vessel (Module B – production type).

- (b) for vessels not manufactured, or manufactured only partly, in accordance with the harmonised standards referred to in Article 12, the manufacturer shall submit for examination a prototype, representative of the production envisaged, of the complete vessel and the technical documentation and supporting evidence for examination and assessment of the adequacy of the technical design of the vessel (Module B – production type).

2. Prior to their placing on the market, vessels shall be subject to the following procedures:

- (a) where the product of  $PS \times V$  exceeds 3 000 bar.L, to conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Annex II;
- (b) where the product of  $PS \times V$  does not exceed 3 000 bar.L but exceeds 200 bar.L, at the choice of the manufacturer, to either of the following:
  - (i) conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Annex II;
  - (ii) conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2) set out in point 3 Annex II;
- (c) where the product of  $PS \times V$  does not exceed 200 bar.L but exceeds 50 bar.L, at the choice of the manufacturer, to either of the following:

- (i) conformity to type based on internal production control plus supervised vessel testing (Module C1) set out in point 2 of Annex II;
- (ii) conformity to type based on internal production control (Module C) set out in point 4 of Annex II.

3. The records and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 and 2 shall be drawn up in an official language of the Member State in which the notified body is established or in a language accepted by that body.

## Article 14

**EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential safety requirements set out in Annex I has been demonstrated.



2. The EU declaration of conformity shall have the model structure set out in Annex IV, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the vessel is placed or made available on the market.

3. Where a vessel is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the vessel with the requirements laid down in this Directive.

#### *Article 15*

### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### *Article 16*

### **Rules and conditions for affixing the CE marking and inscriptions**

1. The CE marking and the inscriptions referred to in point 1 of Annex III shall be affixed visibly, legibly and indelibly to the vessel or to its data plate.

2. The CE marking shall be affixed before the vessel is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

## **CHAPTER 4**

### **NOTIFICATION OF CONFORMITY ASSESSMENT BODIES**

#### *Article 17*

### **Notification**

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

#### *Article 18*

### **Notifying authorities**

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 23.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 19. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### *Article 19*

### **Requirements relating to notifying authorities**

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### Article 20

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

#### Article 21

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the vessel it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of vessels which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the vessels which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed vessels that are necessary for the operations of the conformity assessment body or the use of such vessels for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those vessels, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity

in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by point 3.2 of Annex I and by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind of vessel in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.



7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under point 3.2 of Annex I and under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

## Article 22

### Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 21 insofar as the applicable harmonised standards cover those requirements.

## Article 23

### Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 21 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under point 3.2 of Annex I and under Annex II.

## Article 24

### Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the vessel or vessels for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 21.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 21.

*Article 25***Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 21.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and vessel or vessels concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 24(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 21.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

*Article 26***Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

*Article 27***Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 28***Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

*Article 29***Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the vessel technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the vessel with this Directive.

3. Where a notified body finds that the essential safety requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a vessel no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### Article 30

##### **Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

#### Article 31

##### **Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same vessels with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 32

##### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 33

##### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

#### CHAPTER 5

##### **UNION MARKET SURVEILLANCE, CONTROL OF VESSELS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE**

#### Article 34

##### **Union market surveillance and control of vessels entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to vessels covered by Article 1 of this Directive.

#### Article 35

##### **Procedure for dealing with vessels presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a vessel covered by this Directive presents a risk to the health or safety of persons, or to domestic animals or property, they shall carry out an evaluation in relation to the vessel concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the vessel does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the vessel into compliance with those requirements, to withdraw the vessel from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the vessels concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the vessel's being made available on their national market, to withdraw the vessel from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant vessel, the origin of the vessel, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the vessel to meet requirements relating to the health or safety of persons, to the protection of domestic animals or property; or
- (b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the vessel concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the

Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the vessel from the market, are taken in respect of the vessel concerned without delay.

#### Article 36

##### Union safeguard procedure

1. Where, on completion of the procedure set out in Article 35(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant vessel is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the vessel is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 37

##### Compliant vessels which present a risk

1. Where, having carried out an evaluation under Article 35(1), a Member State finds that although a vessel is in compliance with this Directive, it presents a risk to the health or safety of persons, to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the vessel concerned, when placed on the market, no longer presents that risk, to withdraw the vessel from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the vessels concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the vessel concerned, the origin and the supply chain of the vessel, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 39(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or of domestic animals or of property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 39(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 38

##### Formal non-compliance

1. Without prejudice to Article 35, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Directive;
- (b) the CE marking has not been affixed;
- (c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 16 or has not been affixed;
- (d) the inscriptions referred to in point 1 of Annex III have not been affixed or have been affixed in violation of Article 16 or point 1 of Annex III;
- (e) the EU declaration of conformity has not been drawn up;
- (f) the EU declaration of conformity has not been drawn up correctly;

(g) the technical documentation is either not available or not complete.

(h) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;

(i) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the vessel being made available on the market or ensure that it is recalled or withdrawn from the market.

#### CHAPTER 6

##### COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

#### Article 39

##### Committee procedure

1. The Commission shall be assisted by the Committee on Simple Pressure Vessels. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 40

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.



The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 41

##### Transitional provisions

Member States shall not impede the making available on the market and/or the putting into service of vessels covered by Directive 2009/105/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued by approved inspection bodies under Directive 2009/105/EC shall be valid under this Directive.

#### Article 42

##### Transposition

1. Member States shall adopt and publish by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with Article 2, Articles 6 to 41, Annex II and Annex IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 43

##### Repeal

Directive 2009/105/EC, as amended by the Regulation listed in Annex V, Part A, is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

#### Article 44

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 1, 3, 4 and 5 and Annexes I and III shall apply from 20 April 2016.

#### Article 45

##### Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament  
The President  
M. SCHULZ

For the Council  
The President  
D. KOURKOULAS

## ANNEX I

## ESSENTIAL SAFETY REQUIREMENTS

1. **Materials**

Materials shall be selected according to the intended use of the vessels and in accordance with points 1.1 to 1.4.

1.1. *Pressurised parts*

The materials used for manufacturing the pressurised parts of the vessels shall be:

- (a) capable of being welded;
- (b) ductile and tough, so that a rupture at minimum working temperature does not give rise to either fragmentation or brittle-type fracture;
- (c) not adversely affected by ageing.

For steel vessels, the materials shall in addition meet the requirements set out in point 1.1.1 and, for aluminium or aluminium alloy vessels, those set out in point 1.1.2.

They shall be accompanied by an inspection slip as defined in point (i) of point 3.1 of Annex III, drawn up by the producer of the materials.

1.1.1. *Steel vessels*

Non-alloy quality steels shall meet the following requirements:

- (a) they shall be non-effervescent and supplied after normalisation treatment, or in an equivalent state;
- (b) the content per product of carbon shall be less than 0,25 % and that of sulphur and phosphorus shall each be less than 0,05 %;
- (c) they shall have the following mechanical properties per product:

(i) the maximum tensile strength  $R_{m,max}$  shall be less than 580 N/mm<sup>2</sup>;

(ii) the elongation after fracture shall be:

if test pieces are taken parallel to the direction of rolling:

thickness $\geq$ 3 mm:	A	$\geq$ 22 %,
thickness $<$ 3 mm:	A <sub>80 mm</sub>	$\geq$ 17 %,

if test pieces are taken perpendicular to the direction of rolling:

thickness $\geq$ 3 mm:	A	$\geq$ 20 %,
thickness $<$ 3 mm:	A <sub>80 mm</sub>	$\geq$ 15 %,

- (iii) the average bending rupture energy KCV for three longitudinal test pieces at minimum working temperature shall not be less than 35 J/cm<sup>2</sup>. Not more than one of the three figures may be less than 35 J/cm<sup>2</sup>, with a minimum of 25 J/cm<sup>2</sup>. In the case of steels intended to be used in the manufacture of vessels the minimum working temperature of which is lower than  $-10^{\circ}\text{C}$  and the wall thickness of which exceeds 5 mm, this property shall be checked.

1.1.2. *Aluminium vessels*

Non-alloy aluminium shall have an aluminium content of at least 99,5 % and the alloys referred to in point (b) of Article 1(1) shall display adequate resistance to intercrystalline corrosion at maximum working temperature.



Moreover, these materials shall satisfy the following requirements:

- (a) they shall be supplied in an annealed state;
- (b) they shall have the following mechanical characteristics per product:
  - the maximum tensile strength  $R_{m,max}$  shall be no more than 350 N/mm<sup>2</sup>,
  - the elongation after fracture shall be:
    - $A \geq 16\%$  if the test piece is taken parallel to the direction of rolling,
    - $A \geq 14\%$  if the test piece is taken perpendicular to the direction of rolling.

#### 1.2. *Welding materials*

The welding materials used to manufacture the welds on or of the vessel shall be appropriate to and compatible with the materials to be welded.

#### 1.3. *Accessories contributing to the strength of the vessel*

These accessories (for example bolts and nuts) shall be made of a material specified in point 1.1 or of other kinds of steel, aluminium or an appropriate aluminium alloy compatible with materials used for the manufacture of pressurised parts.

The latter materials shall at minimum working temperature have an appropriate elongation after fracture and bending rupture energy.

#### 1.4. *Non-pressurised parts*

All unpressurised parts of welded vessels shall be of materials which are compatible with that of the components to which they are welded.

### 2. **Vessel design**

(a) The manufacturer shall, when designing the vessel, define the use to which it will be put, and select:

- (i) the minimum working temperature  $T_{min}$ ;
- (ii) the maximum working temperature  $T_{max}$ ;
- (iii) the maximum working pressure PS.

However, should a minimum working temperature exceeding  $-10\text{ }^{\circ}\text{C}$  be selected, the qualities required of the materials shall be satisfied at  $-10\text{ }^{\circ}\text{C}$ .

(b) The manufacturer shall also take account of the following provisions:

- (i) it shall be possible to inspect the inside of vessels;
- (ii) it shall be possible to drain the vessels;
- (iii) the mechanical qualities shall be maintained throughout the period of use of the vessel for the intended purpose;
- (iv) the vessels shall, bearing in mind their prescribed use, be adequately protected against corrosion.

(c) The manufacturer shall take account of the fact that under the conditions of use envisaged:

- (i) the vessels shall not be subjected to stresses likely to impair their safety in use;
- (ii) internal pressure shall not permanently exceed the maximum working pressure PS. However, it may momentarily do so by up to 10 %.

- (d) Circumferential and longitudinal seams shall be made using full penetration welds or welds of equivalent effectiveness. Convex ends other than hemispherical ones shall have a cylindrical edge.

#### 2.1. *Wall thickness*

If the product of  $PS \times V$  is not more than 3 000 bar.L, the manufacturer shall select one of the methods described in points 2.1.1 and 2.1.2 for determining vessel wall thickness; if the product of  $PS \times V$  is more than 3 000 bar.L, or if the maximum working temperature exceeds 100 °C, such thickness shall be determined by the method described in point 2.1.1.

The actual wall thickness of the cylindrical section and ends shall, however, be not less than 2 mm in the case of steel vessels and not less than 3 mm in the case of aluminium or aluminium alloy vessels.

##### 2.1.1. *Calculation method*

The minimum thickness of pressurised parts shall be calculated having regard to the intensity of the stresses and to the following provisions:

- (a) the calculation pressure to be taken into account shall not be less than the maximum working pressure  $PS$  selected;
- (b) the permissible general membrane stress shall not exceed the lower of the values  $0,6 R_{eT}$  or  $0,3 R_m$ . The manufacturer shall use the  $R_{eT}$  and  $R_m$  minimum values guaranteed by the producer of the material in order to determine the permissible stress.

However, where the cylindrical portion of the vessel has one or more longitudinal welds made using a non-automatic welding process, the thickness calculated as referred to in the first paragraph shall be multiplied by the coefficient 1,15.

##### 2.1.2. *Experimental method*

Wall thickness shall be so determined as to enable the vessels to resist at ambient temperature a pressure equal to at least five times the maximum working pressure, with a permanent circumferential deformation factor of no more than 1 %.

### 3. **Manufacturing processes**

Vessels shall be constructed and subjected to production checks in accordance with points 2, 3 or 4 of Annex II.

#### 3.1. *Preparation of the component parts*

Preparation of the component parts (for example forming and chamfering) shall not give rise to surface defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the vessels.

#### 3.2. *Welds on pressurised parts*

The characteristics of welds and adjacent zones shall be similar to those of the welded materials and shall be free of any surface or internal defects detrimental to the safety of the vessels.

Welds shall be performed by qualified welders or operators possessing the appropriate level of competence, in accordance with approved welding processes. Such approval and qualification tests shall be carried out by notified bodies.

The manufacturer shall also, during manufacture, ensure consistent weld quality by conducting appropriate tests using adequate procedures. These tests shall be the subject of a report.

### 4. **Putting into service of the vessels**

Vessels shall be accompanied by the instructions drawn up by the manufacturer, as referred to in point 2 of Annex III.

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## ANNEX II

## CONFORMITY ASSESSMENT PROCEDURES

1. **EU-Type examination (Module B)**

- 1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the requirements of this Directive that apply to it.
- 1.2. EU-type examination shall be carried out in either of the following manners in accordance with Article 13:
  - assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a prototype, representative of the production envisaged, of the complete vessel (production type),
  - assessment of the adequacy of the technical design of the vessel through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a prototype vessel (design type).
- 1.3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the vessel's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the vessel. The technical documentation shall contain, wherever applicable, at least the following elements:

- (i) a general description of the vessel;
- (ii) conceptual design and manufacturing drawings and schemes of components, etc.;
- (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the vessel;
- (iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (v) results of design calculations made, examinations carried out, etc.;
- (vi) test reports;
- (vii) the instructions and safety information referred to in point 2 of Annex III;
- (viii) a document describing:
  - the materials selected,
  - the welding processes selected,

- the checks selected,
  - any pertinent details as to the vessel design;
- (d) where applicable, the prototype vessels representative of the production envisaged. The notified body may request further prototype vessels if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

When a prototype vessel is examined, the technical documentation shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed or a description of the proposed checks.

1.4. The notified body shall:

For the vessel:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the vessel.

For the prototype vessel(s):

- 1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;
- 1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.
- 1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
- 1.6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

- 1.8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

- 1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the vessel has been placed on the market.
- 1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

## **2. Conformity to type based on internal production control plus supervised vessel testing (Module C1)**

- 2.1. Conformity to type based on internal production control plus supervised vessel testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

### **2.2. Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

(a) the technical documentation, which shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed;

(b) the inspection document, describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(c) the EU-type examination certificate.

#### 2.3. *Vessel checks*

2.3.1. For each individual vessel manufactured, the notified body shall carry out the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive in accordance with the following points:

(a) The manufacturer shall present his vessels in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

(b) When a batch is examined, the notified body shall ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and shall perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure  $P_h$  equal to 1,5 times the vessel's design pressure in order to check its strength. The pneumatic test shall be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

(c) Moreover, the notified body shall carry out tests on test-pieces taken from a representative production test-piece or from a vessel, as the manufacturer chooses, in order to examine the weld quality. The tests shall be carried out on longitudinal welds. However, where differing weld techniques are used for longitudinal and circumferential welds, the tests shall be repeated on the circumferential welds.

(d) For the vessels subject to the experimental method referred to in point 2.1.2 of Annex I, these tests on test-pieces shall be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in point 2.1.2 of Annex I.

(e) In the case of accepted batches, the notified body shall affix its identification number, or cause that number to be affixed, to each vessel and shall draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.

(f) If a batch is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

(g) The manufacturer shall be able to supply on request by the relevant authorities the notified body's certificates of conformity referred to in point (e).

2.3.2. The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

2.3.3. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

#### 2.4. *CE marking and EU declaration of conformity*

2.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

2.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

2.4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

#### 2.5. *Authorised representative*

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. **Conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2)**

3.1. Conformity to type based on internal production control plus supervised vessel checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.3 and 3.4, and ensures and declares on his sole responsibility that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

3.2. *Manufacturing*

3.2.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3.2.2. Before commencing manufacture, the manufacturer shall provide a notified body of his choice with all necessary information, and in particular:

(a) the technical documentation, which shall also include:

- the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators,
- the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel,
- a report on the examinations and tests performed;

(b) the EU-type examination certificate;

(c) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

3.2.3. The document referred to in point (c) of point 3.2.2 shall include:

(a) a description of the means of manufacture and checking appropriate to the construction of the vessels;

(b) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(c) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;

(d) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

3.3. *Vessel checks*

The notified body shall carry out vessel checks or have them carried out on random samples at random intervals determined by the body, in order to verify the quality of the internal checks on the vessel, taking into account, inter alia, the technological complexity of the vessels and the quantity of production. An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

The notified body shall also ensure that the manufacturer actually checks series-produced vessels in accordance with point (c) of point 3.2.3.



Where a sample does not conform to the acceptable quality level, the notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the vessel performs within acceptable limits, with a view to ensuring conformity of the vessel.

The notified body shall supply the Member State which notified it and, on request, the other notified bodies, the other Member States and the Commission, with a copy of the inspection report issued by it.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

3.4. *CE marking and EU declaration of conformity*

3.4.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.4.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.

3.4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

3.5. *Authorised representative*

The manufacturer's obligations set out in point 3.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. **Conformity to type based on internal production control (Module C)**

4.1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.3, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

Before commencing manufacture, the manufacturer shall provide the notified body which issued the EU-type examination certificate with all necessary information, and in particular:

- (a) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;
- (b) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;
- (c) a report on the examinations and tests performed;
- (d) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate.

That document shall include:

- (i) a description of the means of manufacture and checking appropriate to the construction of the vessels;
- (ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

- (iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the Member State, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure; those examinations and tests shall be carried out under the responsibility of qualified staff who are independent from production personnel, and shall be the subject of a report;
- (iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

The notified body shall, before the date on which any manufacture begins, examine those documents in order to certify their conformity with the EU-type examination certificate.

#### 4.3. *CE marking and EU declaration of conformity*

- 4.3.1. The manufacturer shall affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 4.3.2. The manufacturer shall draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the national authorities for 10 years after the vessel has been placed on the market. The EU declaration of conformity shall identify the vessel model for which it has been drawn up.
- 4.3.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

#### 4.4. *Authorised representative*

The manufacturer's obligations set out in point 4.3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX III

## INSCRIPTIONS, INSTRUCTIONS, DEFINITIONS AND SYMBOLS

**1. CE marking and inscriptions**

1.1. Vessels of which the product of  $PS \times V$  exceeds 50 bar.L must bear the CE marking provided for in Annex II of Regulation (EC) No 765/2008 and the last two digits of the year in which the CE marking was affixed.

1.2. Vessels or their data plates shall bear at least the following information:

- (a) the maximum working pressure (PS in bar);
- (b) the maximum working temperature ( $T_{\max}$  in °C);
- (c) the minimum working temperature ( $T_{\min}$  in °C);
- (d) the capacity of the vessel (V in L);
- (e) the name, registered trade name or registered trade mark and the address of the manufacturer;
- (f) the type and serial or batch identification of the vessel.

1.3. Where the data plate is used, it shall be so designed that it cannot be reused and shall include a vacant space to enable other information to be provided.

**2. Instructions and safety information**

The instructions shall contain the following information:

- (a) the particulars given in point 1.2 except for the vessel's serial or batch identification;
- (b) the intended use of the vessel;
- (c) the maintenance and installation requirements for vessel safety.

**3. Definitions and symbols****3.1. Definitions**

- (a) The design pressure 'P' is the gauge pressure chosen by the manufacturer and used to determine the thickness of the vessel's pressurised parts.
- (b) The maximum working pressure 'PS' is the maximum gauge pressure which may be exerted under normal conditions of use of the vessel.
- (c) The minimum working temperature  $T_{\min}$  is the lowest stabilised temperature which the wall of the vessel may attain under normal conditions of use.
- (d) The maximum working temperature  $T_{\max}$  is the highest stabilised temperature which the wall of the vessel may attain under normal conditions of use.
- (e) The yield strength ' $R_{eT}$ ' is the value at the maximum working temperature  $T_{\max}$  of any of the following:
  - (i) the upper yield point  $R_{eH}$ , for a material with both a lower and an upper yield point;
  - (ii) the 0,2 % proof strength  $R_{p0,2}$ ;
  - (iii) the 1,0 % proof strength  $R_{p1,0}$  in the case of non-alloy aluminium.

## (f) Families of vessels:

Vessels form part of the same family if they differ from the prototype only in diameter, provided that the permissible requirements referred to in points 2.1.1 and 2.1.2 of Annex I are complied with, and/or in the length of their cylindrical portion within the following limits:

- (i) where a prototype has one or more shell rings in addition to the ends, variants shall have at least one shell ring;
- (ii) where a prototype has just two dished ends, variants shall have no shell rings.

Variations in length causing the apertures and/or penetrations to be modified shall be shown in the drawing for each variant.

## (g) A batch of vessels consists at the most of 3 000 vessels of the model of the same type.

## (h) There is series manufacture within the meaning of this Directive if more than one vessel of the same type is manufactured during a given period by a continuous manufacturing process, in accordance with a common design and using the same manufacturing processes.

## (i) Inspection slip: document by which the producer of the materials certifies that the products delivered meet the requirements of the order and in which he sets out the results of the routine in-plant inspection test, in particular chemical composition and mechanical characteristics, performed on products made by the same production process as the supply, but not necessarily on the products delivered.

## 3.2. Symbols

A	elongation after fracture ( $L_o = 5,65\sqrt{S_o}$ )	%
A <sub>80 mm</sub>	elongation after fracture ( $L_o = 80 \text{ mm}$ )	%
KCV	bending rupture energy	J/cm <sup>2</sup>
P	design pressure	Bar
PS	maximum working pressure	Bar
P <sub>h</sub>	hydrostatic or pneumatic test pressure	Bar
R <sub>p0,2</sub>	0,2 % proof strength	N/mm <sup>2</sup>
R <sub>eT</sub>	yield strength at maximum working temperature	N/mm <sup>2</sup>
R <sub>eH</sub>	upper yield point	N/mm <sup>2</sup>
R <sub>m</sub>	tensile strength	N/mm <sup>2</sup>
R <sub>m, max</sub>	maximum tensile strength	N/mm <sup>2</sup>
R <sub>p1,0</sub>	1,0 % proof strength	N/mm <sup>2</sup>
T <sub>max</sub>	maximum working temperature	°C
T <sub>min</sub>	minimum working temperature	°C
V	capacity of the vessel	L

## ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. Vessel/vessel model (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the vessel allowing traceability; it may, where necessary for the identification of the vessel, include an image):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. The notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

\_\_\_\_\_

<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX V

## PART A

**Repealed Directive with the amendment thereto  
(referred to in Article 43)**

Directive 2009/105/EC of the European Parliament and of the Council (OJ L 264, 8.10.2009, p. 12).	
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Only point (j) of Article 26(1)

## PART B

**Time-limits for transposition into national law and dates of application of the Directives set out in Part B of  
Annex IV to Directive 2009/105/EC  
(referred to in Article 43)**

Directive	Time-limits for transposition	Date of application
87/404/EEC	31 December 1989	1 July 1990 <sup>(1)</sup>
90/488/EEC	1 July 1991	—
93/68/EEC	30 June 1994	1 January 1995 <sup>(2)</sup>

<sup>(1)</sup> In accordance with the third subparagraph of Article 18(2) of Directive 87/404/EEC, Member States shall, for the period up to 1 July 1992, permit the placing on the market and/or in service of vessels conforming to the rules in force in their territories before 1 July 1990.

<sup>(2)</sup> In accordance with Article 14(2) of Directive 93/68/EEC, until 1 January 1997 Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995.

## ANNEX VI

## CORRELATION TABLE

Directive 2009/105/EC	This Directive
Article 1(1)	Article 1(1), introductory wording
Article 1(2)	Article 1(2)
Article 1(3)(a)	Article 1(1), points (a) to (e)
Article 1(3)(b)	—
Article 2	Article 3
—	Article 2
Article 3	Article 4
Article 4	Article 5
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
Article 5	—
Article 6	—
Article 7	—
Article 8	—
—	Article 13
Article 9	—
Article 10	—
Article 11(1) and (2)	—
Article 11(3)	Annex II, point 2.3
Article 12	—
Article 13(1)	Annex II, point 3.2.1
Article 13(2)	Annex II, point 3.2.2
Article 13(3)	—
Article 14	—
—	Article 14
—	Article 15
—	Article 16
—	Article 17
—	Article 18
—	Article 19
—	Article 20



Directive 2009/105/EC	This Directive
—	Article 21
—	Article 22
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28
—	Article 29
—	Article 30
—	Article 31
—	Article 32
—	Article 33
Article 15	—
Article 16	—
Article 17	—
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40
—	Article 41
Article 18	Article 42(2)
—	Article 42(1)
Article 19	Article 43
Article 20	Article 44
Article 21	Article 45
Annex I	Annex I
—	Annex II
Annex II, points 1, 2 and 4	Annex III
Annex II, point 3	Annex II, points 1.3(c), 2.2, 3.2.2 and 4.2(a)(b)(c)
Annex III	—
—	Annex IV
Annex IV	Annex V
Annex V	Annex VI

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 26 February 2014**  
**on the harmonisation of the laws of the Member States relating to electromagnetic compatibility**  
**(recast)**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) A number of amendments are to be made to Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC <sup>(3)</sup>. In the interests of clarity, that Directive should be recast.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(4)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products <sup>(5)</sup>, lays down common principles and reference provisions intended to

apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2004/108/EC should be adapted to that Decision.

(4) Member States should be responsible for ensuring that radiocommunications, including radio broadcast reception and the amateur radio service operating in accordance with International Telecommunication Union (ITU) radio regulations, electrical supply networks and telecommunications networks, as well as equipment connected thereto, are protected against electromagnetic disturbance.

(5) Provisions of national law ensuring protection against electromagnetic disturbance need to be harmonised in order to guarantee the free movement of electrical and electronic apparatus without lowering justified levels of protection in the Member States.

(6) This Directive covers products which are new to the Union market when they are placed on the market; that is to say they are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.

(7) This Directive should apply to all forms of supply, including distance selling.

(8) The equipment covered by this Directive should include both apparatus and fixed installations. However, separate provision should be made for each. This is so because, whereas apparatus as such may move freely within the Union, fixed installations on the other hand are installed for permanent use at a predefined location, as assemblies of various types of apparatus and, where appropriate, other devices. The composition and function of such installations correspond in most cases to the particular needs of their operators.

(9) Where this Directive regulates apparatus, it should apply to finished apparatus placed on the market. Certain components or sub-assemblies should, under certain conditions, be considered to be apparatus if they are made available to the end-user.

(10) Radio equipment and telecommunications terminal equipment should not be covered by this Directive

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 390, 31.12.2004, p. 24.

<sup>(4)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 82.

since they are already regulated by Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity <sup>(1)</sup>. The electromagnetic compatibility requirements in both Directives achieve the same level of protection.

- (11) Aircraft or equipment intended to be fitted into aircraft should not be covered by this Directive, since they are already subject to special Union or international rules governing electromagnetic compatibility.
- (12) This Directive should not regulate equipment which is inherently benign in terms of electromagnetic compatibility.
- (13) This Directive should not deal with the safety of equipment, since that is dealt with by separate Union or national legislation.
- (14) Manufacturers of equipment intended to be connected to networks should construct such equipment in a way that prevents networks from suffering unacceptable degradation of service when used under normal operating conditions. Network operators should construct their networks in such a way that manufacturers of equipment liable to be connected to networks do not suffer a disproportionate burden in order to prevent networks from suffering an unacceptable degradation of service. The European standardisation organisations should take due account of that objective (including the cumulative effects of the relevant types of electromagnetic phenomena) when developing harmonised standards.
- (15) Protection against electromagnetic disturbance requires obligations to be imposed on the various economic operators. Those obligations should be applied in a fair and effective way in order to achieve such protection.
- (16) Economic operators should be responsible for the compliance of apparatus with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests covered by this Directive, and to guarantee fair competition on the Union market.
- (17) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market apparatus which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (18) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (19) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (20) It is necessary to ensure that products from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those apparatus. Provision should therefore be made for importers to make sure that the apparatus they place on the market comply with the requirements of this Directive and that they do not place on the market apparatus which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of apparatus and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (21) When placing apparatus on the market, every importer should indicate on the apparatus his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the apparatus does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the apparatus.
- (22) The distributor makes apparatus available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the apparatus does not adversely affect the compliance of the apparatus.
- (23) Any economic operator that either places apparatus on the market under his own name or trade mark or modifies apparatus in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (24) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the apparatus concerned.

<sup>(1)</sup> OJ L 91, 7.4.1999, p. 10.

- (25) Ensuring traceability of apparatus throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant apparatus available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with apparatus or to whom they have supplied apparatus.
- (26) Fixed installations, including large machines and networks, may generate electromagnetic disturbance, or be affected by it. There may be an interface between fixed installations and apparatus, and the electromagnetic disturbances produced by fixed installations may affect apparatus, and vice versa. In terms of electromagnetic compatibility, it is irrelevant whether the electromagnetic disturbance is produced by apparatus or by a fixed installation. Accordingly, fixed installations and apparatus should be subject to a coherent and comprehensive regime of essential requirements.
- (27) This Directive should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation<sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements. Harmonised standards reflect the generally acknowledged state of the art as regards electromagnetic compatibility in the Union.
- (28) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (29) In order to enable economic operators to demonstrate and the competent authorities to ensure that apparatus made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (30) The conformity assessment obligation should require the manufacturer to perform an electromagnetic compatibility assessment of apparatus, based on relevant phenomena, in order to determine whether or not it meets the essential requirements of this Directive.
- (31) Where apparatus is capable of taking different configurations, the electromagnetic compatibility assessment should confirm whether the apparatus meets the essential requirements in the configurations foreseeable by the manufacturer as representative of normal use in the intended applications. In such cases it should be sufficient to perform an assessment on the basis of the configuration most likely to cause maximum disturbance and the configuration most susceptible to disturbance.
- (32) It is not appropriate to carry out the conformity assessment of apparatus placed on the market for incorporation into a given fixed installation, and otherwise not made available on the market, in isolation from the fixed installation into which it is to be incorporated. Such apparatus should therefore be exempted from the conformity assessment procedures normally applicable to apparatus. However, such apparatus should not be permitted to compromise the conformity of the fixed installation into which it is incorporated. Should apparatus be incorporated into more than one identical fixed installation, identifying the electromagnetic compatibility characteristics of these installations should be sufficient to ensure exemption from the conformity assessment procedure.
- (33) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of an apparatus with this Directive and with other relevant Union harmonisation legislation.
- (34) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (35) The CE marking, indicating the conformity of apparatus, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (36) Due to their specific characteristics, fixed installations need not be subject to the affixing of the CE marking or to the EU declaration of conformity.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

- (37) One of the conformity assessment procedures set out in this Directive requires the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (38) Experience has shown that the criteria set out in Directive 2004/108/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (39) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (40) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (41) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (42) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (43) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the apparatus to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (44) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (45) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (46) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (47) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to apparatus covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (48) Directive 2004/108/EC already provides for a safeguard procedure. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (49) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to apparatus presenting a risk to aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such apparatus.
- (50) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.



- (51) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (52) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (53) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure
- (54) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (55) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant apparatus are justified or not.
- (56) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (57) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into service, without the need to comply with further product requirements, of apparatus that has already been placed on the market in accordance with Directive 2004/108/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply apparatus that has been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (58) Since the objective of this Directive, namely to ensure the functioning of the internal market by requiring

equipment to comply with an adequate level of electromagnetic compatibility, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

- (59) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (60) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directive set out in Annex V,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

#### Subject matter

This Directive regulates the electromagnetic compatibility of equipment. It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility.

#### Article 2

#### Scope

1. This Directive shall apply to equipment as defined in Article 3.
2. This Directive shall not apply to:
  - (a) equipment covered by Directive 1999/5/EC;
  - (b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC <sup>(2)</sup>;

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.

<sup>(2)</sup> OJ L 79, 19.3.2008, p. 1.



- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union <sup>(1)</sup>, unless the equipment is made available on the market;
- (d) equipment the inherent nature of the physical characteristics of which is such that:
  - (i) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and
  - (ii) it operates without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
- (e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

For the purposes of point (c) of the first subparagraph, kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs are not regarded as equipment made available on the market.

3. Where, for the equipment referred to in paragraph 1, the essential requirements set out in Annex I are wholly or partly laid down more specifically by other Union legislation, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of that Union legislation.

4. This Directive shall not affect the application of Union or national legislation regulating the safety of equipment.

### Article 3

#### Definitions

1. For the purposes of this Directive, the following definitions shall apply:

- (1) 'equipment' means any apparatus or fixed installation;
- (2) 'apparatus' means any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

<sup>(1)</sup> Constitution and Convention of the International Telecommunication Union adopted by the Additional Plenipotentiary Conference (Geneva, 1992) as amended by the Plenipotentiary Conference (Kyoto, 1994).

- (3) 'fixed installation' means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location;
- (4) 'electromagnetic compatibility' means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;
- (5) 'electromagnetic disturbance' means any electromagnetic phenomenon which may degrade the performance of equipment; an electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself;
- (6) 'immunity' means the ability of equipment to perform as intended without degradation in the presence of an electromagnetic disturbance;
- (7) 'safety purposes' means the purposes of safeguarding human life or property;
- (8) 'electromagnetic environment' means all electromagnetic phenomena observable in a given location;
- (9) 'making available on the market' means any supply of apparatus for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (10) 'placing on the market' means the first making available of apparatus on the Union market;
- (11) 'manufacturer' means any natural or legal person who manufactures apparatus or has apparatus designed or manufactured, and markets that apparatus under his name or trade mark;
- (12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (13) 'importer' means any natural or legal person established within the Union who places apparatus from a third country on the Union market;
- (14) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market;

- (15) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (16) 'technical specification' means a document that prescribes technical requirements to be fulfilled by the equipment;
- (17) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (18) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (19) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (20) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to an apparatus have been fulfilled;
- (21) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (22) 'recall' means any measure aimed at achieving the return of apparatus that has already been made available to the end-user;
- (23) 'withdrawal' means any measure aimed at preventing apparatus in the supply chain from being made available on the market;
- (24) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (25) 'CE marking' means a marking by which the manufacturer indicates that the apparatus is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

2. For the purposes of this Directive, the following shall be considered as apparatus:

- (1) 'components' or 'sub-assemblies' intended for incorporation into an apparatus by the end-user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

- (2) 'mobile installations' defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations.

#### Article 4

#### **Making available on the market and/or putting into service**

Member States shall take all appropriate measures to ensure that equipment is made available on the market and/or put into service only if it complies with this Directive when properly installed, maintained and used for its intended purpose.

#### Article 5

#### **Free movement of equipment**

1. Member States shall not impede, for reasons relating to electromagnetic compatibility, the making available on the market and/or the putting into service in their territory of equipment which complies with this Directive.

2. The requirements of this Directive shall not prevent the application in any Member State of the following special measures concerning the putting into service or use of equipment:

- (a) measures to overcome an existing or predicted electromagnetic compatibility problem at a specific site;
- (b) measures taken for safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

Without prejudice to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations<sup>(1)</sup>, Member States shall notify those special measures to the Commission and to the other Member States.

The special measures which have been accepted shall be published by the Commission in the *Official Journal of the European Union*.

3. Member States shall not create any obstacles to the display and/or demonstration at trade fairs, exhibitions or similar events of equipment which does not comply with this Directive, provided that a visible sign clearly indicates that such equipment may not be made available on the market and/or put into service until it has been brought into conformity with this Directive. Demonstration may only take place provided that adequate measures have been taken to avoid electromagnetic disturbances.

<sup>(1)</sup> OJ L 204, 21.7.1998, p. 37.

*Article 6***Essential requirements**

The equipment shall meet the essential requirements set out in Annex I.

## CHAPTER 2

**OBLIGATIONS OF ECONOMIC OPERATORS***Article 7***Obligations of manufacturers**

1. When placing their apparatus on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2. Manufacturers shall draw up the technical documentation referred to in Annex II or Annex III and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in apparatus design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.

5. Manufacturers shall ensure that apparatus which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is provided on the packaging or in a document accompanying the apparatus.

6. Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18 in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the apparatus with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

*Article 8***Authorised representatives**

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 7(1) and the obligation to draw up technical documentation referred to in Article 7(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the apparatus has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the apparatus;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the apparatus covered by the authorised representative's mandate.

*Article 9***Obligations of importers**

1. Importers shall place only compliant apparatus on the market.

2. Before placing apparatus on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

Where an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not place the apparatus on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the apparatus is accompanied by instructions and the information referred to in Article 18 in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6. Importers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

7. Importers shall, for 10 years after the apparatus has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

8. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of apparatus in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

*Article 10***Obligations of distributors**

1. When making apparatus available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making apparatus available on the market distributors shall verify that the apparatus bears the CE marking, that it is accompanied by the required documents and by instructions and the information referred to in Article 18 in a language which can be easily understood by consumers and other end-users in the Member State in which the apparatus is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Annex I, he shall not make the apparatus available on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4. Distributors who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the apparatus presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the apparatus available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market.

#### Article 11

##### **Cases in which obligations of manufacturers apply to importers and distributors**

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 7, where he places apparatus on the market under his name or trade mark or modifies apparatus already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 12

##### **Identification of economic operators**

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with apparatus;
- (b) any economic operator to whom they have supplied apparatus.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the apparatus and for 10 years after they have supplied the apparatus.

#### CHAPTER 3

##### **CONFORMITY OF EQUIPMENT**

#### Article 13

##### **Presumption of conformity of equipment**

Equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those standards or parts thereof.

#### Article 14

##### **Conformity assessment procedures for apparatus**

Compliance of apparatus with the essential requirements set out in Annex I shall be demonstrated by means of either of the following conformity assessment procedures:

- (a) internal production control set out in Annex II;
- (b) EU type examination that is followed by Conformity to type based on internal production control set out in Annex III.

The manufacturer may choose to restrict the application of the procedure referred to in point (b) of the first paragraph to some

aspects of the essential requirements, provided that for the other aspects of the essential requirements the procedure referred to in point (a) of the first paragraph is applied.

#### Article 15

##### **EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV, shall contain the elements specified in the relevant modules set out in Annexes II and III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the apparatus is placed or made available on the market.

3. Where apparatus is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the apparatus with the requirements laid down in this Directive.

#### Article 16

##### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### Article 17

##### **Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the apparatus is placed on the market.

3. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.



#### Article 18

##### Information concerning the use of apparatus

1. Apparatus shall be accompanied by information on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the essential requirements set out in point 1 of Annex I.

2. Apparatus for which compliance with the essential requirements set out in point 1 of Annex I is not ensured in residential areas shall be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging.

3. The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be included in the instructions accompanying the apparatus.

#### Article 19

##### Fixed installations

1. Apparatus which has been made available on the market and which may be incorporated into a fixed installation shall be subject to all relevant provisions for apparatus set out in this Directive.

However, the requirements of Articles 6 to 12 and Articles 14 to 18 shall not be compulsory in the case of apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market.

In such cases, the accompanying documentation shall identify the fixed installation and its electromagnetic compatibility characteristics and shall indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation. It shall also include the information referred to in Article 7(5) and (6) and Article 9(3).

The good engineering practices referred to in point 2 of Annex I shall be documented and the documentation shall be held by the person or persons responsible at the disposal of the relevant national authorities for inspection for as long as the fixed installation is in operation.

2. Where there are indications of non-compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, the competent authorities of the Member State concerned may request evidence of compliance of the fixed installation, and, when appropriate, initiate an evaluation.

Where non-compliance is established, the competent authorities shall impose appropriate measures to bring the fixed installation into compliance with the essential requirements set out in Annex I.

3. Member States shall set out the necessary provisions for identifying the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements.

#### CHAPTER 4

##### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### Article 20

##### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

#### Article 21

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### Article 22

##### Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### Article 23

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

#### Article 24

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the apparatus it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the apparatus which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those apparatus, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex III and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of apparatus in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.



A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex III or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union

harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 25

##### **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

#### Article 26

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex III.

#### Article 27

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the apparatus for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

*Article 28***Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.
  2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.
  3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and apparatus concerned and the relevant attestation of competence.
  4. Where a notification is not based on an accreditation certificate as referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.
  5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.
- Only such a body shall be considered a notified body for the purposes of this Directive.
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

*Article 29***Identification numbers and lists of notified bodies**

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

*Article 30***Changes to notifications**

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

*Article 31***Challenge of the competence of notified bodies**

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

*Article 32***Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the apparatus with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an apparatus no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### Article 33

##### **Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

#### Article 34

##### **Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment

activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 35

##### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 36

##### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

#### CHAPTER 5

##### **UNION MARKET SURVEILLANCE AND CONTROL OF APPARATUS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE**

#### Article 37

##### **Union market surveillance and control of apparatus entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to apparatus.

#### Article 38

##### **Procedure for dealing with apparatus presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that an apparatus covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the apparatus concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the apparatus does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the apparatus into compliance with those requirements, to withdraw the apparatus from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation, and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the apparatus concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the apparatus's being made available on their national market, to withdraw the apparatus from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant apparatus, the origin of the apparatus, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the apparatus to meet the requirements relating to aspects of public interest protection covered by this Directive; or
- (b) shortcomings in the harmonised standards referred to in Article 13 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the apparatus concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no

objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the apparatus from the market, are taken in respect of the apparatus concerned without delay.

#### Article 39

##### Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant apparatus is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the apparatus is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 40

##### Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Directive;
- (b) the CE marking has not been affixed;
- (c) the EU declaration of conformity has not been drawn up;

- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) technical documentation is either not available or not complete;
- (f) the information referred to in Article 7(6) or Article 9(3) is absent, false or incomplete;
- (g) any other administrative requirement provided for in Article 7 or Article 9 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the apparatus being made available on the market or ensure that it is recalled or withdrawn from the market.

#### CHAPTER 6

#### COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

##### Article 41

##### Committee procedure

1. The Commission shall be assisted by the Committee on Electromagnetic Compatibility. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.
3. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

##### Article 42

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

##### Article 43

##### Transitional provisions

Member States shall not impede the making available on the market and/or the putting into service of equipment covered by Directive 2004/108/EC which is in conformity with that Directive and which was placed on the market before 20 April 2016.

##### Article 44

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with Article 2(2), points (9) to (25) of Article 3(1), Article 4, Article 5(1), Articles 7 to 12, Articles 15, 16 and 17, the first subparagraph of Article 19(1), Articles 20 to 43, and Annexes II, III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

##### Article 45

##### Repeal

Directive 2004/108/EC is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time-limit for transposition into national law and the dates of application of the Directive set out in Annex V.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

##### Article 46

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, Article 2, points (1) to (8) of Article 3(1), Article 3(2), Article 5(2) and (3), Article 6, Article 13, Article 19(3) and Annex I shall apply from 20 April 2016.

*Article 47*

**Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

D. KOURKOULAS

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## ANNEX I

## ESSENTIAL REQUIREMENTS

**1. General requirements**

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
- (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

**2. Specific requirements for fixed installations**

Installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the essential requirements set out in point 1.

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## ANNEX II

## MODULE A: INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5 of this Annex, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of this Directive that apply to it.

2. **Electromagnetic compatibility assessment**

The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Annex I.

The electromagnetic compatibility assessment shall take into account all normal intended operating conditions. Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the essential requirements set out in point 1 of Annex I in all the possible configurations identified by the manufacturer as representative of its intended use.

3. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

4. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured apparatus with the technical documentation referred to in point 3 of this Annex and with the essential requirements set out in point 1 of Annex I.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking to each individual apparatus that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for an apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

**6. Authorised representative**

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX III

## PART A

**Module B: EU-type examination**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in point 1 of Annex I.
2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified by the manufacturer or his authorised representative.
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall specify the aspects of the essential requirements for which examination is requested and shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall contain, wherever applicable, at least the following elements:
  - (i) a general description of the apparatus;
  - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
  - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
  - (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
  - (v) results of design calculations made, examinations carried out, etc.;
  - (vi) test reports.
4. The notified body shall examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

## PART B

### Module C: conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the apparatus concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **CE marking and EU declaration of conformity**

- 3.1. The manufacturer shall affix the CE marking to each individual apparatus that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 3.2. The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. **Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX IV

**EU declaration of conformity (No Xxxx) <sup>(1)</sup>**

1. Apparatus model/Product (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:  
  
Signed for and on behalf of:  
  
(place and date of issue):  
  
(name, function) (signature):

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<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX V

**Time-limit for transposition into national law and date of application**  
**(referred to in Article 45)**

Directive	Time-limit for transposition	Date of application
2004/108/EC	20 January 2007	20 July 2007

## ANNEX VI

**Correlation table**

Directive 2004/108/EC	This Directive
Article 1(1)	Article 1 and Article 2(1)
Article 1(2)	Article 2(2)(a) to (c)
Article 1(3)	Article 2(2)(d)
Article 1(4)	Article 2(3)
Article 1(5)	Article 2(4)
Article 2(1)(a)	Article 3(1)(1)
Article 2(1)(b)	Article 3(1)(2)
Article 2(1)(c)	Article 3(1)(3)
Article 2(1)(d)	Article 3(1)(4)
Article 2(1)(e)	Article 3(1)(5)
Article 2(1)(f)	Article 3(1)(6)
Article 2(1)(g)	Article 3(1)(7)
Article 2(1)(h)	Article 3(1)(8)
Article 2(2)	Article 3(2)
Article 3	Article 4
Article 4	Article 5
Article 5	Article 6
Article 6	Article 13
Article 7	Article 14
Article 8	Articles 16 and 17
Article 9(1)	Article 7(5)
Article 9(2)	Article 7(6)
Article 9(3)	Article 18(1)
Article 9(4)	Article 18(2)
Article 9(5)	Article 18(3)
Articles 10 and 11	Articles 37, 38 and 39
Article 12	Chapter 4
Article 13	Article 19
Article 14	Article 45
Article 15	Article 43
Article 16	Article 44
Article 17	Article 46
Article 18	Article 47
Annex I	Annex I



Directive 2004/108/EC	This Directive
Annex II and point 1 of Annex IV	Annex II
Annex III	Annex III
Point 2 of Annex IV	Annex IV
Annex V	Articles 16 and 17
Annex VI	Article 24
Annex VII	Annex VI

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/31/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 26 February 2014****on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments****(recast)****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common

framework for the marketing of products <sup>(6)</sup> lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2009/23/EC should therefore be adapted to that Decision.

(4) This Directive covers non-automatic weighing instruments which are new to the Union market when they are placed on the market; that is to say they are either new non-automatic weighing instruments made by a manufacturer established in the Union or non-automatic weighing instruments, whether new or second-hand, imported from a third country.

(5) Member States should have the responsibility of protecting the public against incorrect results of weighing operations by means of non-automatic weighing instruments when used for certain categories of applications.

(6) This Directive should apply to all forms of supply, including distance selling.

(7) Economic operators should be responsible for the compliance of non-automatic weighing instruments with this Directive in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests covered by this Directive, and to guarantee fair competition on the Union market.

(8) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market non-automatic weighing instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(9) In order to facilitate communication between economic operators, market surveillance authorities and end-users, Member States should encourage economic operators to include a website address in addition to the postal address.

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 122, 16.5.2009, p. 6. Directive 2009/23/EC is the codification of Council Directive 90/384/EEC of 20 June 1990 on the harmonization of the laws of the Member States relating to non-automatic weighing instruments (OJ L 189, 20.7.1990, p. 1).

<sup>(4)</sup> See Annex V, Part A.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 82.

- (10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (11) It is necessary to ensure that non-automatic weighing instruments from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those non-automatic weighing instruments. Provision should therefore be made for importers to make sure that the non-automatic weighing instruments they place on the market comply with the requirements of this Directive and that they do not place on the market non-automatic weighing instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of non-automatic weighing instruments and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (12) When placing a non-automatic weighing instrument on the market, every importer should indicate on the non-automatic weighing instrument his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided, including for cases where the importer should have to open the packaging only for the purpose of putting his name and address on the instrument.
- (13) The distributor makes a non-automatic weighing instrument available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the non-automatic weighing instrument does not adversely affect the compliance of that instrument.
- (14) Any economic operator that either places a non-automatic weighing instrument on the market under his own name or trade mark or modifies a non-automatic weighing instrument in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (15) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the non-automatic weighing instrument concerned.
- (16) Ensuring traceability of a non-automatic weighing instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant non-automatic weighing instruments available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a non-automatic weighing instrument or to whom they have supplied a non-automatic weighing instrument.
- (17) This Directive should be limited to the expression of the essential requirements as regards metrology and performance in relation to non-automatic weighing instruments. In order to facilitate conformity assessment with those essential requirements as regards metrology and performance, it is necessary to provide for a presumption of conformity for non-automatic weighing instruments which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation <sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements, in particular as to the metrological, design and construction characteristics.
- (18) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (19) Assessment of conformity with the relevant metrological and technical provisions is necessary to provide effective protection for users and third parties.
- (20) In order to enable economic operators to demonstrate and the competent authorities to ensure that non-automatic weighing instruments made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (21) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a non-automatic weighing instrument with the requirements of this Directive and of other relevant Union harmonisation legislation.
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- <sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

- (22) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (23) The CE marking and the supplementary metrology marking, indicating the conformity of a non-automatic weighing instrument, are the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking and the supplementary metrology marking should be laid down in this Directive.
- (24) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (25) Experience has shown that the criteria set out in Directive 2009/23/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (26) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (27) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (28) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (29) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies.
- However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (30) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the non-automatic weighing instruments to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (31) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (32) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (33) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (34) Member States should take all appropriate measures to ensure that non-automatic weighing instruments may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Non-automatic weighing instruments should be considered as non-compliant with the essential requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

- (35) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to non-automatic weighing instruments covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (36) Directive 2009/23/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against non-automatic weighing instruments it considers being non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on expertise available in Member States.
- (37) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to non-automatic weighing instruments presenting a risk to aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such non-automatic weighing instruments.
- (38) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (39) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (40) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (41) The examination procedure should be used for the adoption of implementing acts with respect to compliant non-automatic weighing instruments which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (42) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (43) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (44) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant non-automatic weighing instruments are justified or not.
- (45) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (46) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and/or putting into service, without the need to comply with further product requirements, of non-automatic weighing instruments that have already been placed on the market in accordance with Directive 2009/23/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply non-automatic weighing instruments that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (47) Since the objective of this Directive, namely to ensure that non-automatic weighing instruments on the market fulfil the requirements providing for a high level of protection of public interests covered by this Directive while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.



(48) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(49) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Directive shall apply to all non-automatic weighing instruments.

2. For the purposes of this Directive, the following categories of use of non-automatic weighing instruments shall be distinguished:

- (a) determination of mass for commercial transactions;
- (b) determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;
- (c) determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings;
- (d) determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
- (e) determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;
- (f) determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackages;
- (g) all applications other than those listed in points (a) to (f).

#### Article 2

### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'weighing instrument' means a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics;
- (2) 'non-automatic weighing instrument' or 'instrument' means a weighing instrument requiring the intervention of an operator during weighing;
- (3) 'making available on the market' means any supply of an instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (4) 'placing on the market' means the first making available of an instrument on the Union market;
- (5) 'manufacturer' means any natural or legal person who manufactures an instrument or has an instrument designed or manufactured, and markets that instrument under his name or trade mark;
- (6) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (7) 'importer' means any natural or legal person established within the Union who places an instrument from a third country on the Union market;
- (8) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an instrument available on the market;
- (9) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (10) 'technical specification' means a document that prescribes technical requirements to be fulfilled by an instrument;
- (11) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;



(12) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(13) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(14) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to an instrument have been fulfilled;

(15) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(16) 'recall' means any measure aimed at achieving the return of an instrument that has already been made available to the end-user;

(17) 'withdrawal' means any measure aimed at preventing an instrument in the supply chain from being made available on the market;

(18) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(19) 'CE marking' means a marking by which the manufacturer indicates that the instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

#### *Article 3*

##### **Making available on the market and putting into service**

1. Member States shall take all steps to ensure that only instruments that meet the applicable requirements of this Directive may be made available on the market.

2. Member States shall take all steps to ensure that instruments may not be put into service for the uses referred to in points (a) to (f) of Article 1(2) unless they meet the requirements of this Directive.

3. Member States shall take all steps to ensure that instruments put into service for the uses referred to in points (a) to (f) of Article 1(2) continue to conform to the applicable requirements of this Directive.

#### *Article 4*

##### **Essential requirements**

Instruments used or intended to be used for the applications listed in points (a) to (f) of Article 1(2) shall satisfy the essential requirements set out in Annex I.

Where the instrument includes, or is connected to, devices which are not used or intended to be used for the applications listed in points (a) to (f) of Article 1(2), such devices shall not be subject to those essential requirements.

#### *Article 5*

##### **Free movement of instruments**

1. Member States shall not impede the making available on the market of instruments which meet the requirements of this Directive.

2. Member States shall not impede the putting into service, for the uses referred to in points (a) to (f) of Article 1(2), of instruments which meet the requirements of this Directive.

#### CHAPTER 2

##### **OBLIGATIONS OF ECONOMIC OPERATORS**

#### *Article 6*

##### **Obligations of manufacturers**

1. When placing on the market their instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2. For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall draw up the technical documentation referred to in Annex II and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary metrology marking.

3. For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the instrument has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in instrument design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of an instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, as set out in Annex III.

For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 1 of Annex III.

For the instruments not intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix the inscriptions provided for in point 2 of Annex III.

Where an instrument which is intended to be used for any of the applications listed in points (a) to (f) of Article 1(2) includes, or is connected to, devices which are not used or intended to be used for the applications listed in points (a) to (f) of Article 1(2), manufacturers shall affix to each of those devices the restrictive use symbol as provided for in Article 18 and in point 3 of Annex III.

6. Manufacturers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, manufacturers shall immediately inform the competent national

authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the instrument with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

#### Article 7

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the instrument has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an instrument;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by instruments covered by the authorised representative's mandate.

#### Article 8

##### Obligations of importers

1. Importers shall place only compliant instruments on the market.

2. Before placing on the market an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall ensure that the appropriate

conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the instrument bears the CE marking and the supplementary metrology marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not place the instrument on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

Before placing on the market an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) importers shall ensure that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

3. Importers shall indicate on the instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted. Where this would require the packaging to be opened, those indications may be given on the packaging and in a document accompanying the instrument. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is accompanied by instructions and information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall carry out sample testing of instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming instruments and instrument recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that an instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the instrument presents a risk, importers

shall immediately inform the competent national authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. For the instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), importers shall, for 10 years after the instrument has been placed on the market keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have placed on the market.

#### Article 9

##### Obligations of distributors

1. When making an instrument available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the instrument bears the CE marking, and the supplementary metrology marking, that it is accompanied by the required documents and by instructions and information in a language which can be easily understood by end-users in the Member State in which the instrument is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is not in conformity with the essential requirements set out in Annex I, he shall not make the instrument available on the market until it has been brought into conformity. Furthermore, where the instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

Before making an instrument not intended to be used for the applications listed in points (a) to (f) of Article 1(2) available on the market, distributors shall verify that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

3. Distributors shall ensure that, while an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

4. Distributors who consider or have reason to believe that an instrument which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of an instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by instruments which they have made available on the market.

#### Article 10

##### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places an instrument on the market under his name or trade mark or modifies an instrument already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 11

##### Identification of economic operators

For instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2), economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with an instrument;
- (b) any economic operator to whom they have supplied an instrument.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the instrument and for 10 years after they have supplied the instrument.

#### CHAPTER 3

##### CONFORMITY OF INSTRUMENTS

#### Article 12

##### Presumption of conformity of instruments

Instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those standards or parts thereof.

#### Article 13

##### Conformity assessment procedures

1. The conformity of instruments to the essential requirements set out in Annex I may be established by either of the following conformity assessment procedures as selected by the manufacturer:

- (a) Module B as set out in point 1 of Annex II, followed either by Module D as set out in point 2 of Annex II, or by Module F as set out in point 4 of Annex II.

However, Module B shall not be compulsory for instruments which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load. For those instruments not submitted to Module B, Module D1 as set out in point 3 of Annex II or Module F1 as set out in point 5 of Annex II shall apply;

- (b) Module G as set out in point 6 of Annex II.

2. The documents and correspondence relating to the conformity assessment procedures referred to in paragraph 1 shall be drawn up in one of the official languages of the Member State where those procedures are carried out, or in a language accepted by the body notified in accordance with Article 19.

#### Article 14

##### EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the instrument is placed or made available on the market.

3. Where an instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the instrument with the requirements laid down in this Directive.

#### Article 15

##### Conformity marking

The conformity of an instrument intended to be used for the applications listed in points (a) to (f) of Article 1(2) with this Directive shall be indicated by the presence, on the instrument, of the CE marking and the supplementary metrology marking as specified in Article 16.

#### Article 16

##### General principles of the CE marking and of the supplementary metrology marking

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

2. The supplementary metrology marking shall consist of the capital letter 'M' and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.

3. The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, *mutatis mutandis*, to the supplementary metrology marking.

#### Article 17

##### Rules and conditions for affixing the CE marking, the supplementary metrology marking and other markings

1. The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the instrument or to its data plate.

2. The CE marking and the supplementary metrology marking shall be affixed before the instrument is placed on the market.

3. The supplementary metrology marking shall immediately follow the CE marking.

4. The CE marking and the supplementary metrology marking shall be followed by the identification number(s) of the notified body or bodies involved in the production control phase as set out in Annex II.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

5. The CE marking, the supplementary metrology marking and the identification number(s) of the notified body or bodies may be followed by any other mark indicating a special risk or use.

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

#### Article 18

##### Restrictive use symbol

The symbol referred to in the fourth subparagraph of Article 6(5) and specified in point 3 of Annex III shall be affixed to the devices in a clearly visible and indelible form.

#### CHAPTER 4

##### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### Article 19

##### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

#### Article 20

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 25.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 21. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.



#### Article 21

##### Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.
5. A notifying authority shall safeguard the confidentiality of the information it obtains.
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### Article 22

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

#### Article 23

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.
2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.
3. A conformity assessment body shall be a third-party body independent of the organisation or the instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design,

manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 24

##### **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 23 in so far as the applicable harmonised standards cover those requirements.

#### Article 25

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 23 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

#### Article 26

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.



2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the instrument or instruments for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 23.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 23.

#### Article 27

##### Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and instrument or instruments concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 26(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 23.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### Article 28

##### Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 29

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 23, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

#### Article 30

##### Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 41(2).

#### Article 31

##### Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the instrument with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### Article 32

##### Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

#### Article 33

##### Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 34

##### Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 35

##### Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or those groups, directly or by means of designated representatives.

## CHAPTER 5

**UNION MARKET SURVEILLANCE, CONTROL OF INSTRUMENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE***Article 36***Union market surveillance and control of instruments entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to instruments covered by Article 1 of this Directive.

*Article 37***Procedure for dealing with instruments presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that an instrument covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the instrument concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the instrument into compliance with those requirements, to withdraw the instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the instruments concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the

second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the instrument's being made available on their national market, to withdraw the instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant instrument, the origin of the instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the instrument to meet requirements relating to the aspects of public interest protection laid down in this Directive; or
- (b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the instrument from the market, are taken in respect of the instrument concerned without delay.

*Article 38***Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 37(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the

Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant instrument is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 39

##### **Compliant instruments which present a risk**

1. Where, having carried out an evaluation under Article 37(1), a Member State finds that although an instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the instrument concerned, when placed on the market, no longer presents that risk, to withdraw the instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the instruments concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the instrument concerned, the origin and the supply chain of the instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic

operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 41(3).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 40

##### **Formal non-compliance**

1. Without prejudice to Article 37, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Directive;
- (b) the CE marking or the supplementary metrology marking has not been affixed;
- (c) the inscriptions provided for in Article 6(5) have not been affixed or have been affixed in violation of Article 6(5);
- (d) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 17 or has not been affixed;
- (e) the EU declaration of conformity has not been drawn up;
- (f) the EU declaration of conformity has not been drawn up correctly;
- (g) technical documentation is either not available or not complete;
- (h) the information referred to in Article 6(6) or 8(3) is absent, false or incomplete;
- (i) any other administrative requirement provided for in Article 6 or 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

## CHAPTER 6

### COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

#### Article 41

##### Committee procedure

1. The Commission shall be assisted by the Committee on non-automatic weighing instruments. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 42

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 43

##### Transitional provisions

Member States shall not impede the making available on the market and/or the putting into service of instruments covered

by Directive 2009/23/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued under Directive 2009/23/EC shall be valid under this Directive.

#### Article 44

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016 the laws, regulations and administrative provisions necessary to comply with points (3) to (19) of Article 2, Articles 6 to 17, Articles 19 to 43 and Annex II, III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 45

##### Repeal

Directive 2009/23/EC, as amended by the Regulation listed in Annex V, Part A, is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex V, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

#### Article 46

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, points (1) and (2) of Article 2, Articles 3, 4, 5 and 18 and Annexes I, V and VI shall apply from 20 April 2016.

*Article 47*

**Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

*For the European Parliament*  
*The President*  
M. SCHULZ

*For the Council*  
*The President*  
D. KOURKOULAS

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## ANNEX I

## ESSENTIAL REQUIREMENTS

The terminology used is that of the International Organisation of Legal Metrology.

**Preliminary observation**

Where an instrument includes, or is connected to, more than one indicating or printing device used for the applications listed in points (a) to (f) of Article 1(2), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfil the essential requirements.

**Metrological requirements**1. *Units of mass*

The units of mass used shall be the legal units within the meaning of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement <sup>(1)</sup>.

Subject to compliance with this condition, the following units are permitted:

- (a) SI units: kilogram, microgram, milligram, gram, tonne;
- (b) imperial unit: troy ounce, if weighing precious metals;
- (c) other non-SI unit: metric carat, if weighing precious stones.

For instruments that make use of the imperial unit of mass referred to above, the relevant essential requirements specified below shall be converted to that unit, using simple interpolation.

2. *Accuracy classes*

## 2.1. The following accuracy classes have been defined:

- (a) I special
- (b) II high
- (c) III medium
- (d) IIII ordinary

The specifications of these classes are given in Table 1.

Table 1

Accuracy classes				
Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals $n = ((\text{Max})/(\text{e}))$	
		minimum value	minimum value	maximum value
I	$0,001 \text{ g} \leq e$	$100 \text{ e}$	50 000	—
II	$0,001 \text{ g} \leq e \leq 0,05 \text{ g}$	$20 \text{ e}$	100	100 000
	$0,1 \text{ g} \leq e$	$50 \text{ e}$	5 000	100 000
III	$0,1 \text{ g} \leq e \leq 2 \text{ g}$	$20 \text{ e}$	100	10 000
	$5 \text{ g} \leq e$	$20 \text{ e}$	500	10 000
IIII	$5 \text{ g} \leq e$	$10 \text{ e}$	100	1 000

<sup>(1)</sup> OJ L 39, 15.2.1980, p. 40.



The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff.

## 2.2. Scale intervals

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

$$1 \times 10^k, 2 \times 10^k, \text{ or } 5 \times 10^k \text{ mass units,}$$

k being any integer or zero.

2.2.2. For all instruments other than those with auxiliary indicating devices:

$$d = e.$$

2.2.3. For instruments with auxiliary indicating devices the following conditions apply:

$$e = 1 \times 10^k \text{ g;}$$

$$d < e \leq 10 d.$$

Those conditions do not apply for instruments of class I with  $d < 10^{-4}$  g, for which  $e = 10^{-3}$  g.

## 3. Classification

### 3.1. Instruments with one weighing range

Instruments equipped with an auxiliary indicating device shall belong to class I or class II. For these instruments the minimum capacity lower limits for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If  $d < 10^{-4}$  g, the maximum capacity of class I may be less than 50 000 e.

### 3.2. Instruments with multiple weighing ranges

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to point 3.1. If the weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

### 3.3. Multi-interval instruments

3.3.1. Instruments with one weighing range may have several partial weighing ranges (multi-interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range i of multi-interval instruments is defined by:

— its verification scale interval $e_i$	with $e_{(i+1)} > e_i$
— its maximum capacity $\text{Max}_i$	with $\text{Max}_r = \text{Max}$
— its minimum capacity $\text{Min}_i$	with $\text{Min}_i = \text{Max}_{(i-1)}$ and $\text{Min}_1 = \text{Min}$

where:

$$i = 1, 2, \dots, r,$$

i = partial weighing range number,

r = the total number of partial weighing ranges.

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, that class being the instrument's accuracy class.

Table 2

Multi-interval instruments				
$i = 1, 2, \dots, r$ $i$ = partial weighing range number $r$ = total number of partial weighing ranges				
Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value ( <sup>1</sup> ) $n = ((\text{Max}_i)/(e_{(i+1)}))$	Maximum value $n = ((\text{Max}_i)/(e_i))$
I	$0,001 \text{ g} \leq e_i$	$100 e_1$	50 000	—
II	$0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$	$20 e_1$	5 000	100 000
	$0,1 \text{ g} \leq e_i$	$50 e_1$	5 000	100 000
III	$0,1 \text{ g} \leq e_i$	$20 e_1$	500	10 000
IIII	$5 \text{ g} \leq e_i$	$10 e_1$	50	1 000

(<sup>1</sup>) For  $i = r$ , the corresponding column of Table 1 applies, with  $e$  replaced by  $e_r$ .

#### 4. Accuracy

- 4.1. On implementation of the procedures laid down in Article 13, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In the case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net value and tare value for all possible loads, excluding preset tare values.

Table 3

Maximum permissible errors				
Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
$0 \leq m \leq 50\,000 e$	$0 \leq m \leq 5\,000 e$	$0 \leq m \leq 500 e$	$0 \leq m \leq 50 e$	$\pm 0,5 e$
$50\,000 e < m \leq 200\,000 e$	$5\,000 e < m \leq 20\,000 e$	$500 e < m \leq 2\,000 e$	$50 e < m \leq 200 e$	$\pm 1,0 e$
$200\,000 e < m$	$20\,000 e < m \leq 100\,000 e$	$2\,000 e < m \leq 10\,000 e$	$200 e < m \leq 1\,000 e$	$\pm 1,5 e$

- 4.2. The maximum permissible errors in service are twice the maximum permissible errors fixed in Section 4.1.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and in accordance with other methods of balancing used.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

6. The instrument shall react to small variations in the load.

#### 7. Influence quantities and time

- 7.1. Instruments of classes II, III and IIII, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can occur in normal use.

- 7.2. The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

- (a)  $5^\circ\text{C}$  for an instrument in class I;

(b) 15 °C for an instrument in class II;

(c) 30 °C for an instrument in class III or IIII.

In the absence of a manufacturer's specification, the temperature range of – 10 °C to + 40 °C applies.

- 7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

- 7.4. Electronic instruments, except those in class I and in class II if  $e$  is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.
- 7.5. Loading an instrument in class II, III or IIII for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.
- 7.6. Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

#### **Design and construction**

##### **8. General requirements**

- 8.1. Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in an environment for which they are intended. The value of the mass must be indicated.

- 8.2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

- 8.3. The requirements of points 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating device, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

- 8.4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

- 8.5. The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

- 8.6. Instruments shall be designed to permit ready execution of the statutory controls laid down by this Directive.

##### **9. Indication of weighing results and other weight values**

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this Annex shall comply with the provisions of Directive 80/181/EEC with the addition of the symbol for the metric carat which shall be the symbol 'ct'.

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

10. *Printing of weighing results and other weight values*

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

11. *Levelling*

When appropriate, instruments shall be fitted with a levelling device and a level indicator, sufficiently sensitive to allow proper installation.

12. *Zeroing*

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

13. *Tare devices and preset tare devices*

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. *Instruments for direct sales to the public, with a maximum capacity not greater than 100 kg: additional requirements*

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications the interpretation of which is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this Section must carry near to the display the indelible marking 'Not to be used for direct sale to the public'.

15. *Price labelling instruments*

Price labelling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.

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## ANNEX II

## CONFORMITY ASSESSMENT PROCEDURES

1. **Module B: EU-type examination**

- 1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.
- 1.2. EU-type examination may be carried out in any of the following manners:
  - examination of a specimen, representative of the production envisaged, of the complete instrument (production type);
  - assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);
  - assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).
- 1.3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall contain, wherever applicable, at least the following elements:
  - (i) a general description of the instrument;
  - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
  - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
  - (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
  - (v) results of design calculations made, examinations carried out, etc.;
  - (vi) test reports;
- (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.

1.4. The notified body shall:

For the instrument:

- 1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

- 1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- 1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;
- 1.4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

- 1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

- 1.6. Where the type meets the requirements of this Directive, that apply to the instrument concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured instruments with the examined type to be evaluated and to allow for in-service control.

The EU-type examination certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each. In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of EU-type examination certificate may be limited to two years and extended by three years.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 1.7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.
- 1.8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

- 1.9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.
- 1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

## **2. Module D: Conformity to type based on quality assurance of the production process**

- 2.1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2 and 2.5, and ensures and declares on his sole responsibility that the instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

### **2.2. Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

### **2.3. Quality system**

- 2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 2.3.2. The quality system shall ensure that the instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;



- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

- 2.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2.3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 2.3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

- 2.3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 2.3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

2.4. *Surveillance under the responsibility of the notified body*

- 2.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 2.4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

- 2.4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

- 2.4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

2.5. *Conformity marking and EU declaration of conformity*

- 2.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 2.3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 2.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

- 2.6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 2.3.1;
- (b) the information relating to the change referred to in point 2.3.5, as approved;
- (c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

- 2.7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

- 2.8. *Authorised representative*

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### 3. **Module D1: Quality assurance of the production process**

- 3.1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of this Directive that apply to them.

#### 3.2. *Technical documentation*

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the instrument;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

- 3.3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

#### 3.4. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5, and shall be subject to surveillance as specified in point 3.6.

#### 3.5. *Quality system*

- 3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation referred to in point 3.2.

3.5.2. The quality system shall ensure compliance of the instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.5.2 or whether reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. *Surveillance under the responsibility of the notified body*

3.6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;
- (b) the technical documentation referred to in point 3.2;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

3.6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

3.6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

3.7. *Conformity marking and EU declaration of conformity*

3.7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

3.7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

3.8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

- (a) the documentation referred to in point 3.5.1;
- (b) the information relating to the change referred to in point 3.5.5, as approved;
- (c) the decisions and reports of the notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

3.9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

3.10. *Authorised representative*

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. **Module F: Conformity to type based on product verification**

4.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.5 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

4.3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

4.4. *Verification of conformity by examination and testing of every instrument*

- 4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

- 4.4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

4.5. *Conformity marking and EU declaration of conformity*

- 4.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 4.3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 4.5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities, for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

- 4.6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

4.7. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 4.2.

5. **Module F1: Conformity based on product verification**

- 5.1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3 and 5.6 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of this Directive that apply to them.

5.2. *Technical documentation*

- 5.2.1. The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the instrument;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

5.2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

### 5.3. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instruments with the applicable requirements of this Directive.

### 5.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of this Directive.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

### 5.5. *Verification of conformity by examination and testing of every instrument*

5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

5.5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

### 5.6. *Conformity marking and EU declaration of conformity*

5.6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

5.7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the instruments during the manufacturing process.

### 5.8. *Authorised representative*

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2.1 and 5.3.

## 6. **Module G: Conformity based on unit verification**

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 6.4, is in conformity with the requirements of this Directive that apply to it.

### 6.2. *Technical documentation*

6.2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 6.4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the instrument;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

6.2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

### 6.3. *Manufacturing*

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of this Directive.

### 6.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

### 6.5. *Conformity marking and EU declaration of conformity*

6.5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking, set out in this Directive, and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

6.5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.



6.6. *Authorised representative*

The manufacturer's obligations set out in points 6.2.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

7. **Common provisions**

7.1. The conformity assessment according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.

7.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

7.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

7.2.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

7.2.3. A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate.

7.2.4. The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

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## ANNEX III

## INSCRIPTIONS

**1. Instruments intended to be used for the applications listed in points (a) to (f) of Article 1(2)****1.1.** Those instruments shall bear visibly, legibly and indelibly the following inscriptions:

- (i) the number of the EU-type examination certificate, where appropriate;
- (ii) the manufacturer's name, registered trade name or registered trade mark;
- (iii) the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles;
- (iv) maximum capacity, in the form Max ...;
- (v) minimum capacity, in the form Min ...;
- (vi) verification scale interval, in the form  $e = \dots$ ;
- (vii) type, batch or serial number;

and when applicable:

- (viii) for instruments consisting of separate but associated units: identification mark on each unit;
- (ix) scale interval if it is different from  $e$ , in the form  $d = \dots$ ;
- (x) maximum additive tare effect, in the form  $T = + \dots$ ;
- (xi) maximum subtractive tare effect if it is different from Max, in the form  $T = - \dots$ ;
- (xii) tare interval if it is different from  $d$ , in the form  $d_T = \dots$ ;
- (xiii) maximum safe load if it is different from Max, in the form Lim ...;
- (xiv) the special temperature limits, in the form  $\dots\text{ }^{\circ}\text{C}/\dots\text{ }^{\circ}\text{C}$ ;
- (xv) ratio between load receptor and load.

**1.2.** Those instruments shall have adequate facilities for the affixing of the conformity marking and inscriptions. These shall be such that it shall be impossible to remove the conformity marking and inscriptions without damaging them, and that the conformity marking and inscriptions shall be visible when the instrument is in its regular operating position.**1.3.** Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.**1.4.** The inscriptions Max, Min,  $e$ , and  $d$ , shall also be shown near the display of the result if they are not already located there.**1.5.** Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.**2.** Instruments not intended to be used for the applications listed in points (a) to (f) of Article 1(2) shall bear visibly, legibly and indelibly:

- the manufacturer's name, registered trade name or registered trade mark;

— maximum capacity, in the form Max ....

Those instruments shall not bear the conformity marking as set out in this Directive.

3. **Restrictive use symbol referred to in Article 18**

The restrictive use symbol shall be constituted by a capital letter 'M' printed in black on a red background at least 25 mm × 25 mm square with two intersecting diagonals forming a cross.

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## ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. Instrument model/Instrument (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. The notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

\_\_\_\_\_

<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX V

## PART A

**Repealed Directive with the amendment thereto  
(referred to in Article 45)**

Directive 2009/23/EC of the European Parliament  
and of the Council

(OJ L 122, 16.5.2009, p. 6).

Regulation (EU) No 1025/2012 of the  
European Parliament and of the Council

(OJ L 316, 14.11.2012, p. 12).

Only point (i) of Article 26(1)

## PART B

**Time-limits for transposition into national law and dates of application of the Directives set out in Part B of  
Annex VII to Directive 2009/23/EC****(referred to in Article 45)**

Directive	Time-limit for transposition	Date of application
90/384/EEC	30 June 1992	1 January 1993 <sup>(1)</sup>
93/68/EEC	30 June 1994	1 January 1995 <sup>(2)</sup>

<sup>(1)</sup> In accordance with Article 15(3) of Directive 90/384/EEC Member States shall permit, during a period of 10 years from the date on which they apply the laws, regulations and administrative provisions adopted by the Member States in order to transpose that Directive into national law, the placing on the market and/or putting into service of instruments which conform to the rules in force before 1 January 1993.

<sup>(2)</sup> In accordance with Article 14(2) of Directive 93/68/EEC: 'Until 1 January 1997, Member States shall allow the placing on the market and the bringing into service of products which comply with the marking arrangements in force before 1 January 1995.'

## ANNEX VI

## CORRELATION TABLE

Directive 2009/23/EC	This Directive
Article 1(1)	Article 1(1)
Article 1(2), introductory wording	Article 1(2), introductory wording
Article 1(2), point (a)(i)	Article 1(2), point (a)
Article 1(2), point (a)(ii)	Article 1(2), point (b)
Article 1(2), point (a)(iii)	Article 1(2), point (c)
Article 1(2), point (a)(iv)	Article 1(2), point (d)
Article 1(2), point (a)(v)	Article 1(2), point (e)
Article 1(2), point (a)(vi)	Article 1(2), point (f)
Article 1(2), point (b)	Article 1(2), point (g)
Article 2(1)	Article 2(1)
Article 2(2)	Article 2(2)
Article 2(3)	—
—	Article 2(3) to (19)
Article 3	Article 3(1) and (2)
Article 4	Article 4
Article 5	Article 5
Article 6	—
Article 7	—
Article 8	—
—	Article 6
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
Article 9(1), introductory wording	Article 13(1), introductory wording
Article 9(1), point (a)	Article 13(1), point (a)
Article 9(1), point (b)	Article 13(1), point (b)
Article 9(2)	Article 13(2)
Article 9(3)	—
Article 10	—
Article 11	—
Article 12	—
—	Article 14

Directive 2009/23/EC	This Directive
—	Article 15
—	Article 16
—	Article 17(1) to (5)
—	Article 17(6)
Article 13, first sentence	Article 6(5), fourth subparagraph
Article 13, second sentence	Article 18
—	Article 19
—	Article 20
—	Article 21
—	Article 22
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28
—	Article 29
—	Article 30
—	Article 31
—	Article 32
—	Article 33
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40
—	Article 41
—	Article 42
Article 14	Article 3(3)
Article 15	—
—	Article 43
—	Article 44(1)
Article 16	Article 44(2)
Article 17	Article 45
Article 18	Article 46, first paragraph
—	Article 46, second paragraph



Directive 2009/23/EC	This Directive
Article 19	Article 47
Annex I	Annex I
Annex II, point 1	—
—	Annex II, point 1
Annex II, point 2	—
—	Annex II, point 2
—	Annex II, point 3
Annex II, point 3	—
—	Annex II, point 4
—	Annex II, point 5
Annex II, point 4	—
—	Annex II, point 6
Annex II, point 5	Annex II, point 7
Annex III	—
Annex IV	Annex III
—	Annex IV
Annex V	—
Annex VI	—
Annex VII	Annex V
Annex VIII	—
—	Annex VI

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 26 February 2014****on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2004/22/EC should be adapted to that Decision.

(4) This Directive covers measuring instruments which are new to the Union market when they are placed on the market; that is to say they are either new measuring instruments made by a manufacturer established in the Union or measuring instruments, whether new or second-hand, imported from a third country.

(5) Correct and traceable measuring instruments can be used for a variety of measurement tasks. Those responding to reasons of public interest, public health, safety and order, protection of the environment and the consumer, of levying taxes and duties and of fair trading, which directly and indirectly affect the daily life of citizens in many ways, may require the use of legally controlled measuring instruments.

(6) This Directive should apply to all forms of supply, including distance selling.

(7) Legal metrological control should not lead to barriers to the free movement of measuring instruments. The applicable provisions should be the same in all Member States and proof of conformity should be accepted throughout the Union.

(8) Legal metrological control requires conformity with specified performance requirements. The performance requirements that the measuring instruments must meet should provide a high level of protection. The conformity assessment should provide a high level of confidence.

(9) Member States should as a general rule prescribe legal metrological control. Where legal metrological control is prescribed, only measuring instruments complying with common performance requirements should be used.

(10) The principle of optionality introduced by Directive 2004/22/EC allows Member States to exercise their right to decide whether or not to prescribe the use of the measuring instruments covered by this Directive.

(1) Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products <sup>(6)</sup> lays down

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 135, 30.4.2004, p. 1.

<sup>(4)</sup> See Annex XIV, Part A.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 82.

- (11) National specifications concerning the appropriate national requirements for use should not interfere with the provisions of this Directive on 'putting into use'.
- (12) The performance of certain measuring instruments is particularly sensitive to the environment, in particular the electromagnetic environment. Immunity of measuring instruments to electromagnetic interference should form an integral part of this Directive and the immunity requirements of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility<sup>(1)</sup> should therefore not apply.
- (13) In order to ensure the free circulation of measuring instruments in the Union, Member States should not impede the placing on the market and/or putting into use of measuring instruments that carry the CE marking and supplementary metrology marking in accordance with the provisions of this Directive.
- (14) Member States should take appropriate action to prevent non-complying measuring instruments from being placed on the market and/or put into use. Adequate cooperation between the competent authorities of the Member States is therefore necessary to ensure a Union-wide effect of this objective.
- (15) Economic operators should be responsible for the compliance of measuring instruments with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the aspects of public interest covered by this Directive, and also to guarantee fair competition on the Union market.
- (16) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only measuring instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (17) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (18) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (19) It is necessary to ensure that measuring instruments from third countries entering the Union market comply with this Directive, and in particular that the appropriate conformity assessment procedures have been carried out by manufacturers with regard to those measuring instruments. Provision should therefore be made for importers to make sure that the measuring instruments they place on the market comply with the requirements of this Directive and that they do not place on the market measuring instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of measuring instruments and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (20) When placing a measuring instrument on the market, every importer should indicate on the measuring instrument his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the measuring instrument does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the measuring instrument.
- (21) The distributor makes a measuring instrument available on the market after it has been placed on the market by the manufacturer or the importer. The distributor should act with due care to ensure that its handling of the measuring instrument does not adversely affect the compliance of that instrument with this Directive.
- (22) Any economic operator that either places a measuring instrument on the market under his own name or trade mark or modifies a measuring instrument in such a way that compliance with of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (23) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the measuring instrument concerned.

<sup>(1)</sup> OJ L 390, 31.12.2004, p. 24.

- (24) Ensuring traceability of a measuring instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant measuring instruments available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a measuring instrument or to whom they have supplied a measuring instrument.
- (25) This Directive should be limited to the expression of essential requirements that do not impede technical progress, preferably performance requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for measuring instruments which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation<sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (26) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (27) The technical and performance specifications of internationally agreed normative documents may also comply, in part or in full, with the essential requirements laid down by this Directive. In those cases the use of these internationally agreed normative documents should be allowed as an alternative to the use of harmonised standards and, under specific conditions, give rise to a presumption of conformity.
- (28) Conformity with the essential requirements laid down by this Directive can also be provided by specifications that are not supplied by a harmonised standard or an internationally agreed normative document. The use of harmonised standards or internationally agreed normative documents should therefore be optional.
- (29) In order to enable economic operators to demonstrate and the competent authorities to ensure that measuring instruments made available on the market comply with the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. However, it is necessary to adapt those modules in order to reflect specific aspects of metrological control.
- (30) The conformity assessment of sub-assemblies should be carried out in accordance with this Directive. If sub-assemblies are made available on the market separately and independently of an instrument, their conformity assessment should be undertaken independently of the instrument concerned.
- (31) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measuring instrument and, where appropriate, sub-assemblies, there should be an appropriate procedure or a choice between different procedures of equivalent stringency.
- (32) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a measuring instrument with this Directive and with other relevant Union harmonisation legislation.
- (33) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (34) The CE marking and the supplementary metrology marking, indicating the conformity of a measuring instrument, are the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking and the supplementary metrology marking should be laid down in this Directive.
- (35) In order to take account of differences in climatic conditions or of different levels of consumer protection that may apply at national level, it is necessary to establish environmental or accuracy classes as essential requirements.
- (36) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

- (37) Experience has shown that the criteria set out in Directive 2004/22/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (38) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Directive.
- (39) In order to ensure a consistent level of quality in the performance of conformity assessment of measuring instruments, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (40) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (41) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (42) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the measuring instruments to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (43) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (44) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (45) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (46) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to measuring instruments covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (47) Member States should take all appropriate measures to ensure that measuring instruments may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Measuring instruments should be considered as non-compliant with the essential requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (48) Directive 2004/22/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against measuring instruments it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the view to making it more efficient and drawing on the expertise available in Member States.



- (49) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to measuring instruments presenting a risk to aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an early stage in respect of such measuring instruments.
- (50) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard or a normative document.
- (51) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers<sup>(1)</sup>.
- (52) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (53) The advisory procedure should also be used for the adoption of implementing acts with respect to the objections to the internationally agreed normative documents whose references have not yet been published in the *Official Journal of the European Union*, given that the relevant document has not yet led to the presumption of conformity with the applicable essential requirements.
- (54) The examination procedure should be used for the adoption of implementing acts with respect to the objections to the internationally agreed normative documents whose references were already published in the *Official Journal of the European Union* and which a Member State or the Commission considers justified, given that such acts could have consequences on the presumption of conformity with the applicable essential requirements.
- (55) The examination procedure should also be used for the adoption of implementing acts with respect to compliant measuring instruments which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (56) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (57) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (58) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant measuring instruments are justified or not.
- (59) In order to take into account the developments in the measurement technology, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amendments to the instrument-specific Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (60) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (61) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into use, without the need to comply with further product requirements, of measuring instruments that have already been placed on the market in accordance with Directive 2004/22/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply measuring instruments that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.



- (62) Since the objective of this Directive, namely to ensure that measuring instruments on the market fulfil the requirements providing for a high level of protection of the public interests covered by this Directive while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (63) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (64) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex XIV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

##### Subject matter

This Directive establishes the requirements that measuring instruments have to satisfy with a view to their being made available on the market and/or put into use for the measuring tasks referred to in Article 3(1).

#### Article 2

##### Scope

1. This Directive applies to the measuring instruments defined in the instrument-specific Annexes III to XII (hereinafter 'instrument-specific Annexes') concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), thermal energy meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

2. This Directive is a specific Directive in respect of requirements for electromagnetic immunity within the

meaning of Article 2(3) of Directive 2014/30/EU of the European Parliament and of the Council <sup>(1)</sup>. That Directive continues to apply with regard to emission requirements.

#### Article 3

##### Optionality

1. Member States may prescribe the use of measuring instruments for measuring tasks, where they consider it justified for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading.

2. Where Member States do not prescribe such use, they shall communicate the reasons therefor to the Commission and the other Member States.

#### Article 4

##### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'measuring instrument' means any device or system with a measurement function that is covered by Article 2(1);
- (2) 'sub-assembly' means a hardware device, mentioned as such in the instrument-specific annexes, that functions independently and makes up a measuring instrument together with other sub-assemblies with which it is compatible, or with a measuring instrument with which it is compatible;
- (3) 'legal metrological control' means the control of the measurement tasks intended for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;
- (4) 'normative document' means a document containing technical specifications adopted by the International Organisation of Legal Metrology;
- (5) 'making available on the market' means any supply of a measuring instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (6) 'placing on the market' means the first making available of a measuring instrument on the Union market;

<sup>(1)</sup> Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (see page 79 of this Official Journal).

- (7) 'putting into use' means the first use of a measuring instrument intended for the end-user for the purposes for which it was intended;
- (8) 'manufacturer' means any natural or legal person who manufactures a measuring instrument or has a measuring instrument designed or manufactured, and markets that measuring instrument under his name or trade mark or puts it into use for his own purposes;
- (9) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (10) 'importer' means any natural or legal person established within the Union who places a measuring instrument from a third country on the Union market;
- (11) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a measuring instrument available on the market;
- (12) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (13) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a measuring instrument;
- (14) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (15) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) no 765/2008;
- (16) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) no 765/2008;
- (17) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to a measuring instrument have been fulfilled;
- (18) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (19) 'recall' means any measure aimed at achieving the return of a measuring instrument that has already been made available to the end-user;
- (20) 'withdrawal' means any measure aimed at preventing a measuring instrument in the supply chain from being made available on the market;
- (21) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (22) 'CE marking' means a marking by which the manufacturer indicates that the measuring instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

#### Article 5

##### Applicability to sub-assemblies

Where instrument-specific annexes lay down the essential requirements for sub-assemblies, this Directive shall apply *mutatis mutandis* to such sub-assemblies.

Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing conformity.

#### Article 6

##### Essential requirements

A measuring instrument shall meet the essential requirements set out in Annex I and in the relevant instrument-specific Annex.

Member States may require, if it is needed for correct use of the instrument, the information referred to in point 9 of Annex I or in the relevant instrument-specific Annexes to be provided in a language which can be easily understood by end-users, as determined by the Member State in which the instrument is made available on the market.

#### Article 7

##### Making available on the market and putting into use

1. Member States shall not impede for reasons covered by this Directive the making available on the market and/or putting into use of any measuring instrument that satisfies the requirements of this Directive.

2. Member States shall take all appropriate measures to ensure that measuring instruments are made available on the market and/or put into use only if they satisfy the requirements of this Directive.

3. A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4. When different accuracy classes are defined for a measuring instrument:

- (a) the instrument-specific Annexes under the heading 'Putting into use' may indicate the accuracy classes to be used for specific applications;
- (b) in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

For the purposes of point (a) or point (b), measuring instruments of a better accuracy class may be used if the owner so chooses.

5. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not prevent the showing of measuring instruments not in conformity with this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for making available on the market and/or putting into use until they are brought into conformity.

## CHAPTER 2

### OBLIGATIONS OF ECONOMIC OPERATORS

#### Article 8

##### Obligations of manufacturers

1. When placing their measuring instruments on the market and/or putting them into use, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

2. Manufacturers shall draw up the technical documentation referred to in Article 18 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary metrology marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the measuring instrument has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the performance of a measuring instrument, manufacturers shall carry out sample testing of measuring instruments made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that measuring instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the measuring instrument does not allow it, that the required information is provided in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I.

6. Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by a copy of the EU Declaration of conformity and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

#### Article 9

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the measuring instrument has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a measuring instrument;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by measuring instruments covered by their mandate.

#### Article 10

##### Obligations of importers

1. Importers shall place only compliant measuring instruments on the market.

2. Before placing a measuring instrument on the market and/or putting a measuring instrument into use importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears the CE marking and the supplementary metrology marking and is accompanied by a copy of the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not place the measuring instrument on the market or put it into use until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the measuring instrument is accompanied by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

6. When deemed appropriate with regard to the performance of a measuring instrument, importers shall carry out sample testing of measuring instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the measuring instrument has been placed on the market keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

#### Article 11

##### Obligations of distributors

1. When making a measuring instrument available on the market and/or putting it into use, distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the EU declaration of conformity, by the required documents and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not make the measuring instrument available on the market or put it into use, until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

4. Distributors who consider or have reason to believe that a measuring instrument which they have made available on the market or put into use is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the measuring instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have made available on the market.

#### Article 12

##### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a measuring instrument on the market under his name or trade mark or modifies a measuring instrument already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 13

##### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a measuring instrument;
- (b) any economic operator to whom they have supplied a measuring instrument.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the measuring instrument and for 10 years after they have supplied the measuring instrument.

### CHAPTER 3

#### CONFORMITY OF MEASURING INSTRUMENTS

#### Article 14

##### Presumption of conformity of measuring instruments

1. Measuring instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those standards or parts thereof.

2. Measuring instruments which are in conformity with parts of normative documents, the list of which has been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents.



3. A manufacturer may choose to use any technical solution that complies with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes. In addition, to benefit from the presumption of conformity, the manufacturer must correctly apply solutions mentioned either in the relevant harmonised standards or in the normative documents referred to in paragraphs 1 and 2.

4. Member States shall presume compliance with the appropriate tests mentioned in point (i) of Article 18(3) if the corresponding test programme has been performed in accordance with the relevant documents mentioned in paragraphs 1, 2 and 3 and if the test results ensure compliance with the essential requirements.

#### Article 15

##### Publication of the references of normative documents

On request by a Member State or in its own initiative, the Commission shall, where appropriate:

- (a) identify normative documents and, in a list, indicate the parts thereof that satisfy the requirements which they cover and which are set out in Annex I and in the relevant instrument-specific Annexes;
- (b) publish the reference of the normative documents and the list referred to in point (a) in the *Official Journal of the European Union*.

#### Article 16

##### Withdrawal of the references of normative documents

1. When a Member State or the Commission considers that a normative document whose reference has been published or is intended to be published in the *Official Journal of the European Union* does not entirely satisfy the essential requirements which it covers and which are set out in Annex I and in the relevant instrument-specific Annexes, the Commission shall decide:

- (a) to publish, not to publish or to publish with restriction the references to the normative documents concerned in the *Official Journal of the European Union*;
- (b) to maintain, to maintain with restrictions or to withdraw the references to the normative documents concerned in or from the *Official Journal of the European Union*.

2. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

3. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 46(3).

#### Article 17

##### Conformity assessment procedures

Conformity assessment of a measuring instrument with the applicable essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the relevant instrument-specific Annex.

The conformity assessment procedures are set out in Annex II.

Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

#### Article 18

##### Technical documentation

1. The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the applicable requirements of this Directive.

2. The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:

- (a) the definition of the metrological characteristics;
- (b) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;
- (c) the integrity of the measuring instrument.

3. The technical documentation shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

- (a) a general description of the measuring instrument;
- (b) conceptual design and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.;
- (c) manufacturing procedures to ensure consistent production;
- (d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

- (e) descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;
  - (f) a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the *Official Journal of the European Union*;
  - (g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;
  - (h) results of design calculations, examinations, etc.;
  - (i) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:
    - the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,
    - the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;
  - (j) the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.
4. The manufacturer shall specify where seals and markings have been applied.
5. The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

#### Article 19

##### EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been demonstrated.
2. The EU declaration of conformity shall have the model structure set out in Annex XIII, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the measuring instrument is placed or made available on the market.
3. Where a measuring instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in

respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the measuring instrument with the requirements laid down in this Directive.

#### Article 20

##### Conformity marking

The conformity of a measuring instrument with this Directive shall be indicated by the presence on it of the CE marking and the supplementary metrology marking as specified in Article 21.

#### Article 21

##### General principles of the CE marking and of the supplementary metrology marking

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
2. The supplementary metrology marking shall consist of the capital letter 'M' and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.
3. The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, *mutatis mutandis*, to the supplementary metrology marking.

#### Article 22

##### Rules and conditions for affixing the CE marking and the supplementary metrology marking

1. The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate. Where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any.
2. When a measuring instrument consists of a set of devices, not being sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument's main device.
3. The CE marking and the supplementary metrology marking shall be affixed before the measuring instrument is placed on the market.
4. The CE marking and the supplementary metrology marking may be affixed to the instrument during the fabrication process, if justified.



5. The supplementary metrology marking shall immediately follow the CE marking.

The CE marking and the supplementary metrology marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase as set out in Annex II.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

The identification number of the notified body concerned shall be indelible or self destructive upon removal.

6. The CE marking, the supplementary metrology marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

7. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

#### CHAPTER 4

#### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

##### Article 23

##### Notification

1. Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

2. If a Member State has not introduced national legislation for measuring tasks referred to in Article 3, it shall retain the right to notify a body for conformity assessment tasks relating to the measuring instrument concerned.

##### Article 24

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 29.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to

in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 25. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

##### Article 25

##### Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

##### Article 26

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

##### Article 27

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the measuring instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of measuring instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the measuring instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed measuring instruments that are necessary for the operations of the conformity assessment body or the use of such measuring instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those measuring instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

The second subparagraph does not, however, preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of measuring instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 28

##### **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 27 in so far as the applicable harmonised standards cover those requirements.

#### Article 29

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

#### Article 30

##### **Accredited in-house bodies**

1. An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in point 2 (Module A2) and point 5 (Module C2) of Annex II. That body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, production, supply, installation, use or maintenance of the measuring instruments it assesses.

2. An accredited in-house body shall meet the following requirements:

(a) it shall be accredited in accordance with Regulation (EC) No 765/2008;

(b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

(d) it shall supply its services exclusively to the undertaking of which it forms a part.

3. An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

#### Article 31

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the measuring instrument or measuring instruments for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27.

#### Article 32

##### Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include information on the kind(s) of measuring instrument(s) for which each body has been designated and, where relevant, the instrument accuracy classes, the measuring range, the measurement technology, and any other instrument characteristic limiting the scope of the notification. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and measuring instrument or measuring instruments concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### Article 33

##### Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 34

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 27, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

#### Article 35

##### Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

### Article 36

#### Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the measuring instrument with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a measuring instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

### Article 37

#### Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

### Article 38

#### Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

### Article 39

#### Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

### Article 40

#### Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or those groups, directly or by means of designated representatives.

## CHAPTER 5

### UNION MARKET SURVEILLANCE, CONTROL OF MEASURING INSTRUMENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

### Article 41

#### Union market surveillance and control of measuring instruments entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to measuring instruments.

### Article 42

#### Procedure for dealing with measuring instruments presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a measuring instrument covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the measuring instrument concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.



Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the measuring instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the measuring instrument into compliance with those requirements, to withdraw the measuring instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the measuring instruments concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the measuring instrument being made available on their national market, to withdraw the measuring instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant measuring instrument, the origin of the measuring instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the measuring instrument to meet requirements relating to aspects of public interest protection laid down in this Directive; or

(b) shortcomings in the harmonised standards or normative documents referred to in Article 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the measuring instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the measuring instrument from the market, are taken in respect of the measuring instrument concerned, without delay.

#### Article 43

##### Union safeguard procedure

1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant measuring instrument is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 42(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

4. Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the normative documents referred to in point (b) of Article 42(5), the Commission shall apply the procedure provided for in Article 16.

#### Article 44

##### Compliant measuring instruments which present a risk

1. Where, having carried out an evaluation under Article 42(1), a Member State finds that although a measuring instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the measuring instrument concerned, when placed on the market, no longer presents that risk, to withdraw the measuring instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the measuring instruments concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the measuring instrument concerned, the origin and the supply chain of the measuring instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 46(3).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 45

##### Formal non-compliance

1. Without prejudice to Article 42, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 22 of this Directive;
- (b) the CE marking or the supplementary metrology marking has not been affixed;
- (c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 22 or has not been affixed;
- (d) the EU declaration of conformity does not accompany the measuring instrument;
- (e) the EU declaration of conformity has not been drawn up correctly;
- (f) technical documentation is either not available or not complete.
- (g) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;
- (h) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the measuring instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

#### CHAPTER 6

##### COMMITTEE AND DELEGATED ACTS

#### Article 46

##### Committee procedure

1. The Commission shall be assisted by the Committee on Measuring Instruments. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.



5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 47

##### Amendments of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 48 concerning the amendment of the instrument-specific Annexes, in relation to the following:

- (a) maximum permissible errors (MPEs) and accuracy classes;
- (b) rated operating conditions;
- (c) critical change values;
- (d) disturbances.

#### Article 48

##### Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 47 shall be conferred on the Commission for a period of five years from 18 April 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 47 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 47 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two

months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### CHAPTER 7

##### TRANSITIONAL AND FINAL PROVISIONS

#### Article 49

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 50

##### Transitional provisions

1. Member States shall not impede the making available on the market and/or the putting into use of measuring instruments covered by Directive 2004/22/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued under Directive 2004/22/EC shall be valid under this Directive.

2. The effects of Article 23 of Directive 2004/22/EC shall continue until 30 October 2016.

#### Article 51

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 5 to 22 of Article 4, Articles 8 to 11, 13, 14, 19 and 21, Article 22(1), (3), (5) and (6), Articles 23 to 45, 49 and 50 and Annex II. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references

to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 52

##### **Repeal**

Without prejudice to Article 50, Directive 2004/22/EC as amended by the acts listed in Annex XIV, Part A, is repealed with effect from 20 April 2016 without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law and the dates of application of the Directives set out in Annex XIV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XV.

#### Article 53

##### **Entry into force and application**

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 1, 2 and 3, points 1 to 4 of Article 4, Articles 5, 6, 7, 15 to 18 and 20, Article 22(2) and (4) and Annexes I and III to XII shall apply from 20 April 2016.

#### Article 54

##### **Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament  
The President  
M. SCHULZ

For the Council  
The President  
D. KOURKOULAS

## ANNEX I

## ESSENTIAL REQUIREMENTS

A measuring instrument shall provide a high level of metrological protection in order that any party affected can have confidence in the result of measurement, and shall be designed and manufactured to a high level of quality in respect of the measurement technology and security of the measurement data.

The essential requirements that shall be met by measuring instruments are set out below and are supplemented, where appropriate, by specific instrument requirements in Annexes III to XII that provide more detail on certain aspects of the general requirements.

The solutions adopted in the pursuit of the essential requirements shall take account of the intended use of the instrument and any foreseeable misuse thereof.

## DEFINITIONS

Measurand	The measurand is the particular quantity subject to measurement.
Influence quantity	An influence quantity is a quantity that is not the measurand but that affects the result of measurement.
Rated Operating Conditions	The rated operating conditions are the values for the measurand and influence quantities making up the normal working conditions of an instrument.
Disturbance	An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the measuring instrument. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified.
Critical change value	The critical change value is the value at which the change in the measurement result is considered undesirable.
Material Measure	A material measure is a device intended to reproduce or supply in a permanent manner during its use one or more known values of a given quantity.
Direct sales	A trading transaction is direct sales if: <ul style="list-style-type: none"> <li>— the measurement result serves as the basis for the price to pay; and</li> <li>— at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection; and</li> <li>— all the parties in the transaction accept the measurement result at that time and place.</li> </ul>
Climatic environments	Climatic environments are the conditions in which measuring instruments may be used. To cope with climatic differences between the Member States, a range of temperature limits has been defined.
Utility	A utility is regarded as a supplier of electricity, gas, thermal energy or water.

## ESSENTIAL REQUIREMENTS

## 1. Allowable Errors

- 1.1. Under rated operating conditions and in the absence of a disturbance, the error of measurement shall not exceed the maximum permissible error (MPE) value as laid down in the appropriate instrument-specific requirements.

Unless stated otherwise in the instrument-specific annexes, MPE is expressed as a bilateral value of the deviation from the true measurement value.

- 1.2. Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as laid down in the appropriate instrument-specific requirements.

Where the instrument is intended to be used in a specified permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field-amplitude modulated test shall be within MPE.

- 1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, power supply and other influence quantities likely to affect its accuracy, taking account of the requirements laid down in the appropriate instrument-specific annexes.

#### 1.3.1. Climatic environments

The manufacturer shall specify the upper temperature limit and the lower temperature limit from any of the values in Table 1 unless otherwise specified in the Annexes III to XII, and indicate whether the instrument is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Table 1

	Temperature Limits			
	30 °C	40 °C	55 °C	70 °C
Upper temperature limit				
Lower temperature limit	5 °C	– 10 °C	– 25 °C	– 40 °C

- 1.3.2. (a) Mechanical environments are classified into classes M1 to M3 as described below.

M1	This class applies to instruments used in locations with vibration and shocks of low significance, e.g. for instruments fastened to light supporting structures subject to negligible vibrations and shocks transmitted from local blasting or pile-driving activities, slamming doors, etc.
M2	This class applies to instruments used in locations with significant or high levels of vibration and shock, e.g. transmitted from machines and passing vehicles in the vicinity or adjacent to heavy machines, conveyor belts, etc.
M3	This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

- (b) The following influence quantities shall be considered in relation with mechanical environments:

- vibration;
- mechanical shock.

- 1.3.3. (a) Electromagnetic environments are classified into classes E1, E2 or E3 as described below, unless otherwise laid down in the appropriate instrument-specific annexes.

E1	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial and light industrial buildings.
E2	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in other industrial buildings.
E3	This class applies to instruments supplied by the battery of a vehicle. Such instruments shall comply with the requirements of E2 and the following additional requirements: <ul style="list-style-type: none"> <li>— voltage reductions caused by energising the starter-motor circuits of internal combustion engines,</li> <li>— load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.</li> </ul>

- (b) The following influence quantities shall be considered in relation with electromagnetic environments:

- voltage interruptions;
- short voltage reductions;
- voltage transients on supply lines and/or signal lines;
- electrostatic discharges;

- radio frequency electromagnetic fields;
- conducted radio frequency electromagnetic fields on supply lines and/or signal lines;
- surges on supply lines and/or signal lines.

1.3.4. Other influence quantities to be considered, where appropriate, are:

- voltage variation;
- mains frequency variation;
- power frequency magnetic fields;
- any other quantity likely to influence in a significant way the accuracy of the instrument.

1.4. When carrying out the tests as envisaged in this Directive, the following points shall apply:

1.4.1. Basic rules for testing and the determination of errors

Essential requirements specified in points 1.1 and 1.2 shall be verified for each relevant influence quantity. Unless otherwise specified in the appropriate instrument-specific annex, these essential requirements apply when each influence quantity is applied and its effect evaluated separately, all other influence quantities being kept relatively constant at their reference value.

Metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the instrument when that influence quantity is likely to occur.

1.4.2. Ambient humidity

- (a) According to the climatic operating environment in which the instrument is intended to be used either the damp heat-steady state (non-condensing) or damp heat cyclic (condensing) test may be appropriate.
- (b) The damp heat cyclic test is appropriate where condensation is important or when penetration of vapour will be accelerated by the effect of breathing. In conditions where non-condensing humidity is a factor the damp-heat steady state is appropriate.

2. **Reproducibility**

The application of the same measurand in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

3. **Repeatability**

The application of the same measurand under the same conditions of measurement shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

4. **Discrimination and Sensitivity**

A measuring instrument shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

5. **Durability**

A measuring instrument shall be designed to maintain an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained and used according to the manufacturer's instruction when in the environmental conditions for which it is intended.

6. **Reliability**

A measuring instrument shall be designed to reduce as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

**7. Suitability**

- 7.1. A measuring instrument shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.
- 7.2. A measuring instrument shall be suitable for its intended use taking account of the practical working conditions and shall not require unreasonable demands of the user in order to obtain a correct measurement result.
- 7.3. The errors of a utility measuring instrument at flows or currents outside the controlled range shall not be unduly biased.
- 7.4. Where a measuring instrument is designed for the measurement of values of the measurand that are constant over time, the measuring instrument shall be insensitive to small fluctuations of the value of the measurand, or shall take appropriate action.
- 7.5. A measuring instrument shall be robust and its materials of construction shall be suitable for the conditions in which it is intended to be used.
- 7.6. A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual.

When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.

**8. Protection against corruption**

- 8.1. The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.
- 8.2. A hardware component that is critical for metrological characteristics shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.
- 8.3. Software that is critical for metrological characteristics shall be identified as such and shall be secured.

Software identification shall be easily provided by the measuring instrument.

Evidence of an intervention shall be available for a reasonable period of time.

- 8.4. Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.
- 8.5. For utility measuring instruments the display of the total quantity supplied or the displays from which the total quantity supplied can be derived, whole or partial reference to which is the basis for payment, shall not be able to be reset during use.

**9. Information to be borne by and to accompany the instrument**

- 9.1. A measuring instrument shall bear the following inscriptions:

(a) manufacturer's name, registered trade name or registered trade mark;

(b) information in respect of its accuracy;

and, where applicable:

(c) information in respect of the conditions of use;

- (d) measuring capacity;
  - (e) measuring range;
  - (f) identity marking;
  - (g) number of the EU-type examination certificate or the EU design examination certificate;
  - (h) information whether or not additional devices providing metrological results comply with the provisions of this Directive on legal metrological control.
- 9.2. An instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of this Directive suitably marked.
- 9.3. The instrument shall be accompanied by information on its operation, unless the simplicity of the measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:
- (a) rated operating conditions;
  - (b) mechanical and electromagnetic environment classes;
  - (c) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;
  - (d) instructions for installation, maintenance, repairs, permissible adjustments;
  - (e) instructions for correct operation and any special conditions of use;
  - (f) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.
- 9.4. Groups of identical measuring instruments used in the same location or used for utility measurements do not necessarily require individual instruction manuals.
- 9.5. Unless specified otherwise in an instrument-specific annex, the scale interval for a measured value shall be in the form  $1 \times 10^n$ ,  $2 \times 10^n$ , or  $5 \times 10^n$ , where  $n$  is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.
- 9.6. A material measure shall be marked with a nominal value or a scale, accompanied by the unit of measurement used.
- 9.7. The units of measurement used and their symbols shall be in accordance with the provisions of Union legislation on units of measurement and their symbols.
- 9.8. All marks and inscriptions required under any requirement shall be clear, non-erasable, unambiguous and non-transferable.
- 10. Indication of result**
- 10.1. Indication of the result shall be by means of a display or hard copy.
- 10.2. The indication of any result shall be clear and unambiguous and accompanied by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown provided they cannot be confused with the metrologically controlled indications.
- 10.3. In the case of hard copy the print or record shall also be easily legible and non-erasable.
- 10.4. A measuring instrument for direct sales trading transactions shall be designed to present the measurement result to both parties in the transaction when installed as intended. When critical in case of direct sales, any ticket provided to the consumer by an ancillary device not complying with the appropriate requirements of this Directive shall bear appropriate restrictive information.



- 10.5. Whether or not a measuring instrument intended for utility measurement purposes can be remotely read it shall in any case be fitted with a metrologically controlled display accessible without tools to the consumer. The reading of this display is the measurement result that serves as the basis for the price to pay.

**11. Further processing of data to conclude the trading transaction**

- 11.1. A measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when:

- (a) the measurement is non-repeatable; and
- (b) the measuring instrument is normally intended for use in the absence of one of the trading parties.

- 11.2. Additionally, a durable proof of the measurement result and the information to identify the transaction shall be available on request at the time the measurement is concluded.

**12. Conformity evaluation**

A measuring instrument shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of this Directive.

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## ANNEX II

## MODULE A: INTERNAL PRODUCTION CONTROL

1. 'Internal production control' is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

4. **Conformity marking and EU declaration of conformity**

- 4.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual measuring instrument that satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for an instrument model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the measuring instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

1. Internal production control plus supervised instrument checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

#### 4. Instrument checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the instrument, taking into account, inter alia, the technological complexity of the instruments and the quantity of production. An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard, and/or normative document, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Directive. In the absence of a relevant harmonised standard or normative document, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.

In those cases where a relevant number of instruments in the sample do not conform to an acceptable quality level, the accredited in-house body or notified body shall take appropriate measures.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

#### 5. Conformity marking and EU declaration of conformity

- 5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual instrument that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for an instrument model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

#### 6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility provided that they are specified in the mandate.

#### MODULE B: EU- TYPE EXAMINATION

1. 'EU-type examination' is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.
2. EU-type examination may be carried out in either of the following manners:
  - (a) examination of a specimen, representative of the production envisaged, of the complete measuring instrument (production type),
  - (b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);
  - (c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

The notified body decides on the appropriate manner and the specimens required.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation as described in Article 18. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The application shall in addition contain, wherever applicable:

- (d) the specimens, representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;
- (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the instrument:

- 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and normative documents, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;
- 4.5. agree with the manufacturer on the location where the examinations and tests will be carried out.

For the other parts of the measuring instrument:

- 4.6. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.
5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis, the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined type to be evaluated and to allow for in-service control. In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:

- the metrological characteristics of the type of instrument;
- measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);
- information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;
- if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
- in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

The EU-type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
8. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.
9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.

10. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.
11. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 8 and 10, provided that they are specified in the mandate.

**MODULE C: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL**

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Conformity marking and EU declaration of conformity**

- 3.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 3.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

4. **Authorised representative**

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS**

1. Conformity to type based on internal production control plus supervised instrument checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Instrument checks**

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the instrument, taking into account, inter alia, the technological complexity of the measuring instruments and the quantity of production. An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the harmonised standards, and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instrument with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

Where a sample does not conform to an acceptable quality level, the accredited in-house body or notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the instrument performs within acceptable limits, with a view to ensuring conformity of the instrument.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

#### **4. Conformity marking and EU declaration of conformity**

- 4.1. The manufacturer shall affix the CE marking, and the supplementary metrology marking set out in this Directive to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

#### **5. Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### **MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS**

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### **2. Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### **3. Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- (b) a written declaration that the same application has not been lodged with any other notified body,
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.



All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point (e) of point 3.1, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

- (a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

## **5. Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

## **8. Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

## **MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS**

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

## **2. Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

4. **Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. **Quality system**

- 5.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation referred to in point 2.

- 5.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

- 5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

## **6. Surveillance under the responsibility of the notified body**

- 6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the technical documentation referred to in point 2;
  - (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

## **7. Conformity marking and EU declaration of conformity**

- 7.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 5.1;
  - (b) the information relating to the change referred to in point 5.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.
9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

#### 10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### MODULE E: CONFORMITY TO TYPE BASED ON INSTRUMENT QUALITY ASSURANCE

1. Conformity to type based on instrument quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### 2. **Manufacturing**

The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring instruments concerned as specified in point 3 and shall be subject to surveillance, as specified in point 4.

#### 3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) all relevant information for the instrument category envisaged;
  - (d) the documentation concerning the quality system;
  - (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
- 3.2. The quality system shall ensure compliance of the measuring instruments with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- (d) the means of monitoring the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point (e) of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**5. Conformity marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:
- (a) the documentation referred to in point 3.1;
  - (b) the information relating to the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

**8. Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**MODULE E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING**

1. Quality assurance of final instrument inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

**2. Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

**4. Manufacturing**

The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring instruments concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.



## 5. Quality system

- 5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the measuring instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the instrument category envisaged;
- (d) the documentation concerning the quality system;
- (e) the technical documentation referred to in point 2.

- 5.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- (d) the means of monitoring the effective operation of the quality system.

- 5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

- 5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **6. Surveillance under the responsibility of the notified body**

- 6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
  - (b) the technical documentation referred to in point 2;
  - (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **7. Conformity marking and EU declaration of conformity**

- 7.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:
- (a) the documentation referred to in point 5.1,
  - (b) the information relating to the change referred to in point 5.5, as approved;
  - (c) the decisions and reports from the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

#### 10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

### MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

#### 2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

#### 3. **Verification**

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the instruments with the type as described in the EU-type examination certificate and the appropriate requirements of this Directive.

The examinations and tests to verify the conformity of the measuring instruments with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 4, or by examination and testing of the measuring instruments on a statistical basis as specified in point 5.

#### 4. **Verification of conformity by examination and testing of every instrument**

- 4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

- 4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

#### 5. **Statistical verification of conformity**

- 5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

- 5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

- (a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;
- (b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

5.4. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for those measuring instruments from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

## **6. Conformity marking and EU declaration of conformity**

6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the measuring instruments.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the measuring instruments during the manufacturing process.

## **8. Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

## **MODULE F1: CONFORMITY BASED ON PRODUCT VERIFICATION**

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 6.1 and 7 and ensures and declares on his sole responsibility that the measuring instruments concerned which have been subject to the provisions of point 4, are in conformity with the requirements of this Directive that apply to them.

## 2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

## 3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the applicable requirements of this Directive.

## 4. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the measuring instruments with the applicable requirements of this Directive.

The examinations and tests to verify the conformity with the requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 5, or by examination and testing of the measuring instruments on a statistical basis as specified in point 6.

## 5. Verification of conformity by examination and testing of every instrument

5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the relevant harmonized standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

## 6. Statistical verification of conformity

6.1. The manufacturer shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

6.2. A random sample shall be taken from each lot according to the requirements of point 6.4.

6.3. All measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

6.4. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

6.5. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for those measuring instruments from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

If a lot is rejected, the notified body shall take appropriate measures to prevent that lot from being placed on the market. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

#### **7. Conformity marking and EU declaration of conformity**

- 7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.
- 7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual measuring instruments in those cases where a large number of instruments is delivered to a single user.

If the notified body referred to in point 5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the measuring instruments.

8. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the measuring instruments during the manufacturing process.

#### **9. Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2, first paragraph, point 3 and point 6.1.

#### **MODULE G: CONFORMITY BASED ON UNIT VERIFICATION**

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5 and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

#### **2. Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18 and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

#### **3. Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of this Directive.

#### 4. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or normative documents, or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

#### 5. Conformity marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with the measuring instrument.

#### 6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

#### MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

#### 2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

#### 3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) the technical documentation, as described in Article 18, for one model of each category of measuring instruments intended to be manufactured. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument,



(c) the documentation concerning the quality system, and

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point (b) of point 3.1 to verify the manufacturer's ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
  - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests;
  - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **5. Conformity marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:
- (a) the technical documentation referred to in point 3.1,
  - (b) the documentation concerning the quality system referred to in point 3.1,
  - (c) the information relating to the change referred to in point 3.5, as approved;
  - (d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to surveillance as specified in point 5.

The adequacy of the technical design of the measuring instruments shall have been examined in accordance with point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of the quality system with the notified body of his choice for the measuring instruments concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) all relevant information for the instrument category envisaged;
- (c) the documentation concerning the quality system;
- (d) a written declaration that the same application has not been lodged with any other notified body.

- 3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;
- (g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer or his authorised representative of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.6. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

#### **4. Design examination**

- 4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.
- 4.2. The application shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the requirements of this Directive that apply to it.

It shall include:

- (a) the name and address of the manufacturer;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;
- (d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

- 4.3. The notified body shall examine the application, and where the design meets the requirements of this Directive that apply to the instrument it shall issue an EU design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined design to be evaluated and to allow for in-service control. It shall allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

- (a) the metrological characteristics of the design of the instrument;
- (b) measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);
- (c) information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;
- (d) if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
- (e) in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

The notified body shall establish an evaluation report in this regard and keep it at the disposal of the Member State that designated it. Without prejudice to Article 27(10), the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

The certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

- 4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate.

- 4.5. Each notified body shall inform its notifying authority of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

- 4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

## 5. Surveillance under the responsibility of the notified body

- 5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
  - (b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;
  - (c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

## 6. Conformity marking and EU declaration of conformity

- 6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.
- 6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

7. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:
- (a) the documentation concerning the quality system referred to in point 3.1,
  - (b) the information relating to the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

## 8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX III

## WATER METERS (MI-001)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to water meters intended for the measurement of volumes of clean, cold or heated water in residential, commercial and light industrial use.

## DEFINITIONS

Water Meter	An instrument designed to measure, memorise and display the volume at metering conditions of water passing through the measurement transducer.
Minimum Flowrate ( $Q_1$ )	The lowest flowrate at which the water meter provides indications that satisfy the requirements concerning the maximum permissible errors (MPEs.)
Transitional Flowrate ( $Q_2$ )	The transitional flowrate is the flowrate value occurring between the permanent and minimum flowrates, at which the flowrate range is divided into two zones, the 'upper zone' and the 'lower zone'. Each zone has a characteristic MPE.
Permanent Flowrate ( $Q_3$ )	The highest flowrate at which the water meter operates in a satisfactory manner under normal conditions of use, i.e. under steady or intermittent flow conditions.
Overload Flowrate ( $Q_4$ )	The overload flowrate is the highest flowrate at which the meter operates in a satisfactory manner for a short period of time without deteriorating.

## SPECIFIC REQUIREMENTS

**Rated Operating Conditions**

The manufacturer shall specify the rated operating conditions for the instrument, in particular:

1. The flowrate range of the water.

The values for the flowrate range shall fulfil the following conditions:

$$Q_3/Q_1 \geq 10$$

$$Q_2/Q_1 = 1,6$$

$$Q_4/Q_3 = 1,25$$

2. The temperature range of the water.

The values for the temperature range shall fulfil the following conditions:

0,1 °C to at least 30 °C, or

30 °C to at least 90 °C.

The meter may be designed to operate over both ranges.

3. The relative pressure range of the water, the range being 0,3 bar to at least 10 bar at  $Q_3$ .
4. For the power supply: the nominal value of the AC voltage supply and/or the limits of DC supply.

**MPE**

5. The MPE, positive or negative, on volumes delivered at flowrates between the transitional flowrate ( $Q_2$ ) (included) and the overload flowrate ( $Q_4$ ) is:

2 % for water having a temperature  $\leq 30$  °C,



3 % for water having a temperature  $> 30\text{ }^{\circ}\text{C}$ .

The meter shall not exploit the MPE or systematically favour any party.

6. The MPE, positive or negative, on volumes delivered at flowrates between the minimum flowrate ( $Q_1$ ) and the transitional flowrate ( $Q_2$ ) (excluded) is 5 % for water having any temperature.

The meter shall not exploit the MPE or systematically favour any party.

#### **Permissible Effect of Disturbances**

##### **7.1. Electromagnetic immunity**

7.1.1. The effect of an electromagnetic disturbance on a water meter shall be such that:

- the change in the measurement result is no greater than the critical change value as defined in point 7.1.3, or
- the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

7.1.2. After undergoing an electromagnetic disturbance the water meter shall:

- recover to operate within MPE, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present just before the disturbance.

7.1.3. The critical change value is the smaller of the two following values:

- the volume corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;
- the volume corresponding to the MPE on the volume corresponding to one minute at flowrate  $Q_3$ .

##### **7.2. Durability**

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

7.2.1. The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed:

- 3 % of the metered volume between  $Q_1$  included and  $Q_2$  excluded;
- 1,5 % of the metered volume between  $Q_2$  included and  $Q_4$  included.

7.2.2. The error of indication for the volume metered after the durability test shall not exceed:

- $\pm 6\%$  of the metered volume between  $Q_1$  included and  $Q_2$  excluded;
- $\pm 2,5\%$  of the metered volume between  $Q_2$  included and  $Q_4$  included for water meters intended to meter water with a temperature between  $0,1\text{ }^{\circ}\text{C}$  and  $30\text{ }^{\circ}\text{C}$ ,
- $\pm 3,5\%$  of the metered volume between  $Q_2$  included and  $Q_4$  included for water meters intended to meter water with a temperature between  $30\text{ }^{\circ}\text{C}$  and  $90\text{ }^{\circ}\text{C}$ .

#### **Suitability**

8.1. The meter shall be able to be installed to operate in any position unless clearly marked otherwise.

8.2. The manufacturer shall specify whether the meter is designed to measure reverse flow. In such a case, the reverse flow volume shall either be subtracted from the cumulated volume or shall be separately recorded. The same MPE shall apply to both forward and reverse flow.

Water meters not designed to measure reverse flow shall either prevent reverse flow or shall withstand an accidental reverse flow without any deterioration or change in metrological properties.

**Units of Measurement**

9. Metered volume shall be displayed in cubic metres.

**Putting into Use**

10. The Member State shall ensure that the requirements under points 1, 2 and 3 are determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

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## ANNEX IV

## GAS METERS AND VOLUME CONVERSION DEVICES (MI-002)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to gas meters and volume conversion devices defined below, intended for residential, commercial and light industrial use.

## DEFINITIONS

Gas meter	An instrument designed to measure, memorise and display the quantity of fuel gas (volume or mass) that has passed it.
Conversion device	A device fitted to a gas meter that automatically converts the quantity measured at metering conditions into a quantity at base conditions.
Minimum flowrate ( $Q_{\min}$ )	The lowest flowrate at which the gas meter provides indications that satisfy the requirements regarding maximum permissible error (MPE).
Maximum flowrate ( $Q_{\max}$ )	The highest flowrate at which the gas meter provides indications that satisfy the requirements regarding MPE.
Transitional flowrate ( $Q_t$ )	The transitional flowrate is the flowrate occurring between the maximum and minimum flowrates at which the flowrate range is divided into two zones, the 'upper zone' and the 'lower zone'. Each zone has a characteristic MPE.
Overload Flowrate ( $Q_r$ )	The overload flowrate is the highest flowrate at which the meter operates for a short period of time without deteriorating.
Base conditions	The specified conditions to which the measured quantity of fluid is converted.

## PART I

## SPECIFIC REQUIREMENTS

## GAS METERS

1. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions of the gas meter, taking into account:

## 1.1. The flowrate range of the gas shall fulfil at least the following conditions:

Class	$Q_{\max}/Q_{\min}$	$Q_{\max}/Q_t$	$Q_t/Q_{\max}$
1,5	$\geq 150$	$\geq 10$	1,2
1,0	$\geq 20$	$\geq 5$	1,2

## 1.2. The temperature range of the gas, with a minimum range of 40 °C.

1.3. *The fuel/gas related conditions*

The gas meter shall be designed for the range of gases and supply pressures of the country of destination. In particular the manufacturer shall indicate:

- the gas family or group;
- the maximum operating pressure.

## 1.4. A minimum temperature range of 50 °C for the climatic environment.

## 1.5. The nominal value of the AC voltage supply and/or the limits of DC supply.

## 2. Maximum permissible error (MPEs)

### 2.1. Gas meter indicating the volume at metering conditions or mass

Table 1

Class	1,5	1,0
$Q_{\min} \leq Q < Q_t$	3 %	2 %
$Q_t \leq Q \leq Q_{\max}$	1,5 %	1 %

The gas meter shall not exploit the MPEs or systematically favour any party.

### 2.2. For a gas meter with temperature conversion, which only indicates the converted volume, the MPE of the meter is increased by 0,5 % in a range of 30 °C extending symmetrically around the temperature specified by the manufacturer that lies between 15 °C and 25 °C. Outside this range, an additional increase of 0,5 % is permitted in each interval of 10 °C.

## 3. Permissible effect of disturbances

### 3.1. Electromagnetic immunity

#### 3.1.1. The effect of an electromagnetic disturbance on a gas meter or volume conversion device shall be such that:

- the change in the measurement result is no greater than the critical change value as defined in point 3.1.3, or
- the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

#### 3.1.2. After undergoing a disturbance, the gas meter shall:

- recover to operate within MPE, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present just before the disturbance.

#### 3.1.3. The critical change value is the smaller of the two following values:

- the quantity corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;
- the quantity corresponding to the MPE on the quantity corresponding to one minute at maximum flowrate.

### 3.2. Effect of upstream-downstream flow disturbances

Under installation conditions specified by the manufacturer, the effect of the flow disturbances shall not exceed one third of the MPE.

## 4. Durability

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

### 4.1. Class 1,5 \$3

#### 4.1.1. The variation of the measurement result after the durability test when compared with the initial measurement result for the flow rates in the range $Q_t$ to $Q_{\max}$ shall not exceed the measurement result by more than 2 %.

#### 4.1.2. The error of indication after the durability test shall not exceed twice the MPE in point 2.

#### 4.2. Class 1,0 \$3

4.2.1. The variation of the measurement result after the durability test when compared with the initial measurement result shall not exceed one-third of the MPE in point 2.

4.2.2. The error of indication after the durability test shall not exceed the MPE in point 2.

#### 5. Suitability

5.1. A gas meter powered from the mains (AC or DC) shall be provided with an emergency power supply device or other means to ensure, during a failure of the principal power source, that all measuring functions are safeguarded.

5.2. A dedicated power source shall have a lifetime of at least five years. After 90 % of its lifetime an appropriate warning shall be shown.

5.3. An indicating device shall have a sufficient number of digits to ensure that the quantity passed during 8 000 hours at  $Q_{\max}$  does not return the digits to their initial values.

5.4. The gas meter shall be able to be installed to operate in any position declared by the manufacturer in its installation instruction.

5.5. The gas meter shall have a test element, which shall enable tests to be carried out in a reasonable time.

5.6. The gas meter shall respect the MPE in any flow direction or only in one flow direction clearly marked.

#### 6. Units

Metered quantity shall be displayed in cubic metre, or in kilogram.

### PART II

#### SPECIFIC REQUIREMENTS

##### VOLUME CONVERSION DEVICES

A volume conversion device constitutes a sub-assembly when it is together with a measuring instrument with which it is compatible.

For a volume conversion device, the essential requirements for the gas meter shall apply, if applicable. In addition, the following requirements shall apply:

#### 7. Base conditions for converted quantities

The manufacturer shall specify the base conditions for converted quantities.

#### 8. MPE

— 0,5 % at ambient temperature  $20\text{ °C} \pm 3\text{ °C}$ , ambient humidity  $60\% \pm 15\%$ , nominal values for power supply;

— 0,7 % for temperature conversion devices at rated operating conditions;

— 1 % for other conversion devices at rated operating conditions.

Note:

The error of the gas meter is not taken into account.

The volume conversion device shall not exploit the MPEs or systematically favour any party.

#### 9. Suitability

9.1. An electronic conversion device shall be capable of detecting when it is operating outside the operating range(s) stated by the manufacturer for parameters that are relevant for measurement accuracy. In such a case, the conversion device must stop integrating the converted quantity, and may totalise separately the converted quantity for the time it is operating outside the operating range(s).

9.2. An electronic conversion device shall be capable to display all relevant data for the measurement without additional equipment.

## PART III

## PUTTING INTO USE AND CONFORMITY ASSESSMENT

## Putting into use

10. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 1,5  $\pm 3$ , and by Class 1,0  $\pm 3$  which have a  $Q_{\max}/Q_{\min}$  ratio equal or greater than 150.
- (b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class 1,5  $\pm 3$ .
- (c) As regards the requirements under points 1.2 and 1.3, Member States shall ensure that the properties be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

## CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are

B + F or B + D or H1.

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## ANNEX V

## ACTIVE ELECTRICAL ENERGY METERS (MI-003)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to active electrical energy meters intended for residential, commercial and light industrial use.

Note:

Electrical energy meters may be used in combination with external instrument transformers, depending upon the measurement technique applied. However, this Annex covers only electrical energy meters but not instrument transformers.

## DEFINITIONS

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit.

I	=	the electrical current flowing through the meter;
$I_n$	=	the specified reference current for which the transformer operated meter has been designed;
$I_{st}$	=	the lowest declared value of I at which the meter registers active electrical energy at unity power factor (polyphase meters with balanced load);
$I_{min}$	=	the value of I above which the error lies within maximum permissible errors (MPEs) (polyphase meters with balanced load);
$I_{tr}$	=	the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter;
$I_{max}$	=	the maximum value of I for which the error lies within the MPEs;
U	=	the voltage of the electricity supplied to the meter;
$U_n$	=	the specified reference voltage;
f	=	the frequency of the voltage supplied to the meter;
$f_n$	=	the specified reference frequency;
PF	=	power factor = $\cos\varphi$ = the cosine of the phase difference $\varphi$ between I and U.

## SPECIFIC REQUIREMENTS

## 1. Accuracy

The manufacturer shall specify the class index of the meter. The class indices are defined as: Class A, B and C.

## 2. Rated operating conditions

The manufacturer shall specify the rated operating conditions of the meter; in particular:

The values of  $f_n$ ,  $U_n$ ,  $I_n$ ,  $I_{st}$ ,  $I_{min}$ ,  $I_{tr}$  and  $I_{max}$  that apply to the meter. For the current values specified, the meter shall satisfy the conditions given in Table 1;

Table 1

	Class A	Class B	Class C
For direct-connected meters			
$I_{st}$	$\leq 0,05 \cdot I_{tr}$	$\leq 0,04 \cdot I_{tr}$	$\leq 0,04 \cdot I_{tr}$
$I_{min}$	$\leq 0,5 \cdot I_{tr}$	$\leq 0,5 \cdot I_{tr}$	$\leq 0,3 \cdot I_{tr}$
$I_{max}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$
For transformer-operated meters			
$I_{st}$	$\leq 0,06 \cdot I_{tr}$	$\leq 0,04 \cdot I_{tr}$	$\leq 0,02 \cdot I_{tr}$



	Class A	Class B	Class C
$I_{\min}$	$\leq 0,4 \cdot I_{tr}$	$\leq 0,2 \cdot I_{tr}^{(1)}$	$\leq 0,2 \cdot I_{tr}$
$I_n$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$
$I_{\max}$	$\geq 1,2 \cdot I_n$	$\geq 1,2 \cdot I_n$	$\geq 1,2 \cdot I_n$

<sup>(1)</sup> For Class B electromechanical meters  $I_{\min} \leq 0,4 \cdot I_{tr}$  shall apply.

The voltage, frequency and power factor ranges within which the meter shall satisfy the MPE requirements are specified in Table 2. These ranges shall recognise the typical characteristics of electricity supplied by public distribution systems.

The voltage and frequency ranges shall be at least:

$$0,9 \cdot U_n \leq U \leq 1,1 \cdot U_n$$

$$0,98 \cdot f_n \leq f \leq 1,02 \cdot f_n$$

power factor range at least from  $\cos\phi = 0,5$  inductive to  $\cos\phi = 0,8$  capacitive.

### 3. MPEs

The effects of the various measurands and influence quantities (a, b, c,...) are evaluated separately, all other measurands and influence quantities being kept relatively constant at their reference values. The error of measurement, that shall not exceed the MPE stated in Table 2, is calculated as:

$$\text{Error of measurement} = \sqrt{(a^2 + b^2 + c^2 \dots)}$$

When the meter is operating under varying-load current, the percentage errors shall not exceed the limits given in Table 2.

Table 2

MPEs in percent at rated operating conditions and defined load current levels and operating temperature												
	Operating temperatures			Operating temperatures			Operating temperatures			Operating temperatures		
	+ 5 °C ... + 30 °C			- 10 °C ... + 5 °C or + 30 °C ... + 40 °C			- 25 °C ... - 10 °C or + 40 °C ... + 55 °C			- 40 °C ... - 25 °C or + 55 °C ... + 70 °C		
Meter class	A	B	C	A	B	C	A	B	C	A	B	C
Single phase meter; polyphase meter if operating with balanced loads												
$I_{\min} \leq I < I_{tr}$	3,5	2	1	5	2,5	1,3	7	3,5	1,7	9	4	2
$I_{tr} \leq I \leq I_{\max}$	3,5	2	0,7	4,5	2,5	1	7	3,5	1,3	9	4	1,5
Polyphase meter if operating with single phase load												
$I_{tr} \leq I \leq I_{\max}$ , see exception below	4	2,5	1	5	3	1,3	7	4	1,7	9	4,5	2
For electromechanical polyphase meters the current range for single-phase load is limited to $5I_{tr} \leq I \leq I_{\max}$												

When a meter operates in different temperature ranges the relevant MPE values shall apply.

The meter shall not exploit the MPEs or systematically favour any party.

### 4. Permissible effect of disturbances

#### 4.1. General

As electrical energy meters are directly connected to the mains supply and as mains current is also one of the measurands, a special electromagnetic environment is used for electricity meters.

The meter shall comply with the electromagnetic environment E2 and the additional requirements in points 4.2 and 4.3.

The electromagnetic environment and permissible effects reflect the situation that there are disturbances of long duration which shall not affect the accuracy beyond the critical change values and transient disturbances, which may cause a temporary degradation or loss of function or performance but from which the meter shall recover and shall not affect the accuracy beyond the critical change values.

When there is a foreseeable high risk due to lightning or where overhead supply networks are predominant, the metrological characteristics of the meter shall be protected.

#### 4.2. *Effect of disturbances of long duration*

Table 3

Critical change values for disturbances of long duration			
Disturbance	Critical change values in percent for meters of class		
	A	B	C
Reversed phase sequence	1,5	1,5	0,3
Voltage unbalance (only applicable to polyphase meters)	4	2	1
Harmonic contents in the current circuits <sup>(1)</sup>	1	0,8	0,5
DC and harmonics in the current circuit <sup>(1)</sup>	6	3	1,5
Fast transient bursts	6	4	2
Magnetic fields; HF (radiated RF) electromagnetic field; Conducted disturbances introduced by radio-frequency fields; and Oscillatory waves immunity	3	2	1

<sup>(1)</sup> In the case of electromechanical electricity meters, no critical change values are defined for harmonic contents in the current circuits and for DC and harmonics in the current circuit.

#### 4.3. *Permissible effect of transient electromagnetic phenomena*

##### 4.3.1. The effect of an electromagnetic disturbance on an electrical energy meter shall be such that during and immediately after a disturbance:

- any output intended for testing the accuracy of the meter does not produce pulses or signals corresponding to an energy of more than the critical change value,

and in reasonable time after the disturbance the meter shall:

- recover to operate within the MPE limits, and
- have all measurement functions safeguarded, and
- allow recovery of all measurement data present prior to the disturbance, and
- not indicate a change in the registered energy of more than the critical change value.

The critical change value in kWh is  $m \cdot U_n \cdot I_{\max} \cdot 10^{-6}$

(m being the number of measuring elements of the meter,  $U_n$  in Volts and  $I_{\max}$  in Amps).

##### 4.3.2. For overcurrent the critical change value is 1,5 %.

**5. Suitability**

- 5.1. Below the rated operating voltage the positive error of the meter shall not exceed 10 %.
- 5.2. The display of the total energy shall have a sufficient number of digits to ensure that when the meter is operated for 4 000 hours at full load ( $I = I_{\max}$ ,  $U = U_n$  and  $PF = 1$ ) the indication does not return to its initial value and shall not be able to be reset during use.
- 5.3. In the event of loss of electricity in the circuit, the amounts of electrical energy measured shall remain available for reading during a period of at least 4 months.

**5.4. Running with no load**

When the voltage is applied with no current flowing in the current circuit (current circuit shall be open circuit), the meter shall not register energy at any voltage between  $0,8 \cdot U_n$  and  $1,1 U_n$ .

**5.5. Starting**

The meter shall start and continue to register at  $U_n$ ,  $PF = 1$  (polyphase meter with balanced loads) and a current which is equal to  $I_{st}$ .

**6. Units**

The electrical energy measured shall be displayed in kilowatt-hours or in megawatt-hours.

**7. Putting into use**

- (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class A meter. For specified purposes the Member State is authorised to require any Class B meter.
- (b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class B meter. For specified purposes the Member State is authorised to require any Class C meter.
- (c) The Member State shall ensure that the current range be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

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## ANNEX VI

## THERMAL ENERGY METERS (MI-004)

The relevant requirements of Annex I, the specific requirements and the conformity assessment procedures listed in this Annex, apply to thermal energy meters defined below, intended for residential, commercial and light industrial use.

## DEFINITIONS

A thermal energy meter is an instrument designed to measure the thermal energy which, in a thermal energy exchange circuit, is given up by a liquid called the thermal energy-conveying liquid.

A thermal energy meter is either a complete instrument or a combined instrument consisting of the sub-assemblies, flow sensor, temperature sensor pair, and calculator, as defined in Article 4(2), or a combination thereof

$\vartheta$	=	the temperature of the thermal energy-conveying liquid;
$\vartheta_{in}$	=	the value of $\vartheta$ at the inlet of the thermal energy exchange circuit;
$\vartheta_{out}$	=	the value of $\vartheta$ at the outlet of the thermal energy exchange circuit;
$\Delta\vartheta$	=	the temperature difference $\vartheta_{in} - \vartheta_{out}$ with $\Delta\vartheta \geq 0$ ;
$\vartheta_{max}$	=	the upper limit of $\vartheta$ for the thermal energy meter to function correctly within the MPEs;
$\vartheta_{min}$	=	the lower limit of $\vartheta$ for the thermal energy meter to function correctly within the MPEs;
$\Delta\vartheta_{max}$	=	the upper limit of $\Delta\vartheta$ for the thermal energy meter to function correctly within the MPEs;
$\Delta\vartheta_{min}$	=	the lower limit of $\Delta\vartheta$ for the thermal energy meter to function correctly within the MPEs;
$q$	=	the flow rate of the thermal energy conveying liquid;
$q_s$	=	the highest value of $q$ that is permitted for short periods of time for the thermal energy meter to function correctly;
$q_p$	=	the highest value of $q$ that is permitted permanently for the thermal energy meter to function correctly;
$q_i$	=	the lowest value of $q$ that is permitted for the thermal energy meter to function correctly;
$P$	=	the thermal power of the thermal energy exchange;
$P_s$	=	the upper limit of $P$ that is permitted for the thermal energy meter to function correctly.

## SPECIFIC REQUIREMENTS

1. **Rated operating conditions**

The values of the rated operating conditions shall be specified by the manufacturer as follows:

1.1. For the temperature of the liquid:  $\vartheta_{max}$ ,  $\vartheta_{min}$ ,

— for the temperature differences:  $\Delta\vartheta_{max}$ ,  $\Delta\vartheta_{min}$ ,

subject to the following restrictions:  $\Delta\vartheta_{max}/\Delta\vartheta_{min} \geq 10$ ;  $\Delta\vartheta_{min} = 3 \text{ K}$  or  $5 \text{ K}$  or  $10 \text{ K}$ .

1.2. For the pressure of the liquid: The maximum positive internal pressure that the thermal energy meter can withstand permanently at the upper limit of the temperature.

1.3. For the flow rates of the liquid:  $q_s$ ,  $q_p$ ,  $q_i$ , where the values of  $q_p$  and  $q_i$  are subject to the following restriction:  $q_p/q_i \geq 10$ .

1.4. For the thermal power:  $P_s$ .

## 2. Accuracy classes

The following accuracy classes are defined for thermal energy meters: 1, 2, 3.

## 3. MPEs applicable to complete thermal energy meters

The maximum permissible relative errors applicable to a complete thermal energy meter, expressed in percent of the true value for each accuracy class, are:

— For class 1:  $E = E_f + E_t + E_c$ , with  $E_f$ ,  $E_t$ ,  $E_c$  according to points 7.1 to 7.3.

— For class 2:  $E = E_f + E_t + E_c$ , with  $E_f$ ,  $E_t$ ,  $E_c$  according to points 7.1 to 7.3.

— For class 3:  $E = E_f + E_t + E_c$ , with  $E_f$ ,  $E_t$ ,  $E_c$  according to points 7.1 to 7.3.

The complete thermal energy meter shall not exploit the MPEs or systematically favour any party.

## 4. Permissible influences of electromagnetic disturbances

4.1. The instrument shall not be influenced by static magnetic fields and by electromagnetic fields at mains frequency.

4.2. The influence of an electromagnetic disturbance shall be such that the change in the measurement result is not greater than the critical change value as laid down in requirement 4.3 or the indication of the measurement result is such that it cannot be interpreted as a valid result.

4.3. The critical change value for a complete thermal energy meter is equal to the absolute value of the MPE applicable to that thermal energy meter (see point (3)).

## 5. Durability

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

5.1. Flow sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the critical change value.

5.2. Temperature sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed 0,1 °C.

## 6. Inscriptions on a thermal energy meter

— Accuracy class

— Limits of flow rate

— Limits of temperature

— Limits of temperature difference

— Place of the flow sensor installation: flow or return

— Indication of the direction of flow

## 7. Sub-assemblies

The provisions for sub-assemblies may apply to sub-assemblies manufactured by the same or different manufacturers. Where a thermal energy meter consists of sub-assemblies, the essential requirements for the thermal energy meter apply to the sub-assemblies as relevant. In addition, the following apply:

7.1. The relative MPE of the flow sensor, expressed in %, for accuracy classes:

— Class 1:  $E_f = (1 + 0,01 q_p/q)$ , but not more than 5 %,

— Class 2:  $E_f = (2 + 0,02 q_p/q)$ , but not more than 5 %,

— Class 3:  $E_f = (3 + 0,05 q_p/q)$ , but not more than 5 %,

where the error  $E_f$  relates the indicated value to the true value of the relationship between flow sensor output signal and the mass or the volume.

7.2. The relative MPE of the temperature sensor pair, expressed in %:

—  $E_t = (0,5 + 3 \cdot \Delta\vartheta_{\min}/\Delta\vartheta)$ ,

where the error  $E_t$  relates the indicated value to the true value of the relationship between temperature sensor pair output and temperature difference.

7.3. The relative MPE of the calculator, expressed in %:

—  $E_c = (0,5 + \Delta\vartheta_{\min}/\Delta\vartheta)$ ,

where the error  $E_c$  relates the value of the thermal energy indicated to the true value of the thermal energy.

7.4. The critical change value for a sub-assembly of a thermal energy meter is equal to the respective absolute value of the MPE applicable to the sub-assembly (see points 7.1, 7.2 or 7.3).

7.5. Inscriptions on the sub-assemblies

Flow sensor:	Accuracy class
	Limits of flow rate
	Limits of temperature
	Nominal meter factor (e.g. litres/pulse) or corresponding output signal
	Indication of the direction of flow
Temperature sensor pair:	Type identification (e.g. P <sub>t</sub> 100)
	Limits of temperature
	Limits of temperature difference
Calculator:	Type of temperature sensors
	— Limits of temperature
	— Limits of temperature difference
	— Required nominal meter factor (e.g. litres/pulse) or corresponding input signal coming from the flow sensor
	— Place of the flow sensor installation: flow or return

#### PUTTING INTO USE

8. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 3 meter.
- (b) Where a Member State imposes measurement of commercial and/or light industrial use, it is authorised to require any Class 2 meter.
- (c) As regards the requirements under points 1.1 to 1.4, Member States shall ensure that the properties be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

#### CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

## ANNEX VII

## MEASURING SYSTEMS FOR THE CONTINUOUS AND DYNAMIC MEASUREMENT OF QUANTITIES OF LIQUIDS OTHER THAN WATER (MI-005)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to measuring systems intended for the continuous and dynamic measurement of quantities (volumes or masses) of liquids other than water. If appropriate, the terms 'volume, and L' in this Annex can be read as: 'mass and kg'.

## DEFINITIONS

Meter	An instrument designed to measure continuously, memorise and display the quantity at metering conditions of liquid flowing through the measurement transducer in a closed, fully charged conduit.
Calculator	A part of a meter that receives the output signals from the measurement transducer(s) and possibly, from associated measuring instruments and displays the measurement results.
Associated measuring instrument	An instrument connected to the calculator for measuring certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.
Conversion Device	<p>A part of the calculator which by taking account of the characteristics of the liquid (temperature, density, etc.) measured using associated measuring instruments, or stored in a memory, automatically converts:</p> <ul style="list-style-type: none"> <li>— the volume of the liquid measured at metering conditions into a volume at base conditions and/or into mass, or</li> <li>— the mass of the liquid measured at metering conditions into a volume at metering conditions and/or into a volume at base conditions</li> </ul> <p>Note: A conversion device includes the relevant associated measuring instruments.</p>
Base conditions	The specified conditions to which the measured quantity of liquid at metering conditions is converted.
Measuring System	A system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.
Fuel dispenser	A measuring system intended for the refuelling of motor vehicles, small boats and small aircraft.
Self-service arrangement	An arrangement that allows the customer to use a measuring system for the purpose of obtaining liquid for his own use.
Self-service device	A specific device that is part of a self-service arrangement and which allows one of more measuring systems to perform in this self-service arrangement.
Minimum measured quantity (MMQ)	The smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.
Direct indication	<p>The indication, either volume or mass, corresponding to the measure and that the meter is physically capable of measuring.</p> <p>Note: The direct indication may be converted into another quantity using a conversion device.</p>
Interruptible/non-interruptible	A measuring system is considered as interruptible/non-interruptible when the liquid flow can/cannot be stopped easily and rapidly.
Flowrate range	The range between the minimum flowrate ( $Q_{\min}$ ) and maximum flowrate ( $Q_{\max}$ ).



## SPECIFIC REQUIREMENTS

1. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions for the instrument, in particular;

1.1. *The flowrate range*

The flowrate range is subject to the following conditions:

- (i) the flowrate range of a measuring system shall be within the flowrate range of each of its elements, in particular the meter.
- (ii) meter and measuring system:

Table 1

Specific measuring system	Characteristic of liquid	Minimum ratio of $Q_{\max}$ : $Q_{\min}$
Fuel dispensers	Not Liquefied gases	10: 1
	Liquefied gases	5: 1
Measuring system	Cryogenic liquids	5: 1
Measuring systems on pipeline and systems for loading ships	All liquids	Suitable for use
All other measuring systems	All liquids	4: 1

- 1.2. The properties of the liquid to be measured by the instrument by specifying the name or type of the liquid or its relevant characteristics, for example:

- Temperature range;
- Pressure range;
- Density range;
- Viscosity range.

- 1.3. The nominal value of the AC voltage supply and/or limits of the DC voltage supply.

- 1.4. The base conditions for converted values.

Note:

Point 1.4 is without prejudice to the Member States' obligations to require use of a temperature of either 15 °C in accordance with Article 12(2) of Council Directive 2003/96/EC of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity <sup>(1)</sup>.

2. **Accuracy classification and maximum permissible errors (MPEs)**

- 2.1. For quantities equal to or greater than 2 litres the MPE on indications is:

Table 2

	Accuracy Class				
	0,3	0,5	1,0	1,5	2,5
Measuring systems (A)	0,3 %	0,5 %	1,0 %	1,5 %	2,5 %
Meters (B)	0,2 %	0,3 %	0,6 %	1,0 %	1,5 %

<sup>(1)</sup> OJ L 283, 31.10.2003, p. 51.

- 2.2. For quantities less than two litres the MPE on indications is:

Table 3

Measured volume V	MPE
$V < 0,1\text{ l}$	$4 \times$ value in Table 2, applied to 0,1 L
$0,1\text{ l} \leq V < 0,2\text{ l}$	$4 \times$ value in Table 2
$0,2\text{ l} \leq V < 0,4\text{ l}$	$2 \times$ value in Table 2, applied to 0,4 L
$0,4\text{ l} \leq V < 1\text{ l}$	$2 \times$ value in Table 2
$1\text{ l} \leq V < 2\text{ l}$	Value in Table 2, applied to 2 L

- 2.3. However, no matter what the measured quantity may be, the magnitude of the MPE is given by the greater of the following two values:

- the absolute value of the MPE given in Table 2 or Table 3,
- the absolute value of the MPE for the minimum measured quantity ( $E_{\min}$ ).

- 2.4.1. For minimum measured quantities greater than or equal to 2 litres the following conditions apply:

Condition 1

$E_{\min}$  shall fulfil the condition:  $E_{\min} \geq 2 R$ , where R is the smallest scale interval of the indication device.

Condition 2

$E_{\min}$  is given by the formula:  $E_{\min} = (2MMQ) \times (A/100)$ , where:

- MMQ is the minimum measured quantity,
- A is the numerical value specified in line A of Table 2.

- 2.4.2. For minimum measured quantities of less than two litres, the above mentioned condition 1 applies and  $E_{\min}$  is twice the value specified in Table 3, and related to line A of Table 2.

2.5. *Converted indication*

In the case of a converted indication the MPEs are as in line A of Table 2.

2.6. *Conversion devices*

MPEs on converted indications due to a conversion device are equal to  $\pm (A - B)$ , A and B being the values specified in Table 2.

Parts of conversion devices that can be tested separately

(a) *Calculator*

MPEs on quantities of liquid indications applicable to calculation, positive or negative, are equal to one-tenth of the MPEs as defined in line A of Table 2.

(b) *Associated measuring instruments*

Associated measuring instruments shall have an accuracy at least as good as the values in Table 4:

Table 4

MPE on Measurements	Accuracy classes of the measuring system				
	0,3	0,5	1,0	1,5	2,5
Temperature	$\pm 0,3\text{ }^{\circ}\text{C}$	$\pm 0,5\text{ }^{\circ}\text{C}$			$\pm 1,0\text{ }^{\circ}\text{C}$

MPE on Measurements	Accuracy classes of the measuring system				
	0,3	0,5	1,0	1,5	2,5
Pressure	Less than 1 MPa: $\pm 50$ kPa From 1 to 4 MPa: $\pm 5$ % Over 4 MPa: $\pm 200$ kPa				
Density	$\pm 1$ kg/m <sup>3</sup>		$\pm 2$ kg/m <sup>3</sup>		$\pm 5$ kg/m <sup>3</sup>

These values apply to the indication of the characteristic quantities of the liquid displayed by the conversion device.

#### (c) Accuracy for calculating function

The MPE for the calculation of each characteristic quantity of the liquid, positive or negative, is equal to two fifths of the value fixed in (b).

2.7. The requirement (a) in point 2.6 applies to any calculation, not only conversion.

2.8. The measuring system shall not exploit the MPEs or systematically favour any party.

### 3. Maximum permissible effect of disturbances

3.1. The effect of an electromagnetic disturbance on a measuring system shall be one of the following:

- the change in the measurement result is not greater than the critical change value as defined in point 3.2, or
- the indication of the measurement result shows a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result. Furthermore, in the case of an interruptible system, this can also mean the impossibility to perform any measurement, or
- the change in the measurement result is greater than the critical change value, in which case the measuring system shall permit the retrieval of the measuring result just before the critical change value occurred and cut off the flow.

3.2. The critical change value is the greater of  $MPE/5$  for a particular measured quantity or  $E_{\min}$ .

### 4. Durability

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criterion shall be satisfied:

The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the value for meters specified in line B of table 2.

### 5. Suitability

5.1. For any measured quantity relating to the same measurement, the indications provided by various devices shall not deviate one from another by more than one scale interval where devices have the same scale interval. In the case where the devices have different scale intervals, the deviation shall not be more than that of the greatest scale interval.

However, in the case of a self-service arrangement the scale intervals of the main indicating device on the measuring system and the scale intervals of the self-service device shall be the same and results of measurement shall not deviate one from another.

5.2. It shall not be possible to divert the measured quantity in normal conditions of use unless it is readily apparent.

5.3. Any percentage of air or gas not easily detectable in the liquid shall not lead to a variation of error greater than:

- 0,5 % for liquids other than potable liquids and for liquids of a viscosity not exceeding 1 mPa.s, or
- 1 % for potable liquids and for liquids of a viscosity exceeding 1 mPa.s.

However, the allowed variation shall never be smaller than 1 % of MMQ. This value applies in the case of air or gas pockets.

#### 5.4. Instruments for direct sales

5.4.1. A measuring system for direct sales shall be provided with means for resetting the display to zero.

It shall not be possible to divert the measured quantity.

5.4.2. The display of the quantity on which the transaction is based shall be permanent until all parties in the transaction have accepted the measurement result.

5.4.3. Measuring systems for direct sales shall be interruptible.

5.4.4. Any percentage of air or gas in the liquid shall not lead to a variation of error greater than the values specified in point 5.3.

#### 5.5. Fuel Dispensers

5.5.1. Displays on fuel dispensers shall not be capable of being reset to zero during a measurement.

5.5.2. The start of a new measurement shall be inhibited until the display has been reset to zero.

5.5.3. Where a measuring system is fitted with a price display, the difference between the indicated price and the price calculated from the unit price and the indicated quantity shall not exceed the price corresponding to  $E_{\min}$ . However this difference need not be less than the smallest monetary value.

### 6. Power supply failure

A measuring system shall either be provided with an emergency power supply device that will safeguard all measuring functions during the failure of the main power supply device or be equipped with means to save and display the data present in order to permit the conclusion of the transaction in progress and with means to stop the flow at the moment of the failure of the main power supply device.

### 7. Putting into use

Table 5

Accuracy Class	Types of Measuring system
0,3	Measuring systems on pipeline
0,5	All measuring systems if not differently stated elsewhere in this Table, in particular: <ul style="list-style-type: none"> <li>— fuel dispensers (not for liquefied gases),</li> <li>— measuring systems on road tankers for liquids of low viscosity (&lt; 20 mPa.s)</li> <li>— measuring systems for (un)loading ships and rail and road tankers <sup>(1)</sup></li> <li>— measuring systems for milk</li> <li>— measuring systems for refuelling aircraft</li> </ul>
1,0	Measuring systems for liquefied gases under pressure measured at a temperature equal to or above – 10 °C <ul style="list-style-type: none"> <li>Measuring systems normally in class 0,3 or 0,5 but used for liquids <ul style="list-style-type: none"> <li>— whose temperature is less than – 10 °C or greater than 50 °C</li> <li>— whose dynamic viscosity is higher than 1 000 mPa.s</li> <li>— whose maximum volumetric flowrate is not higher than 20 L/h</li> </ul> </li> </ul>
1,5	Measuring systems for liquefied carbon dioxide <ul style="list-style-type: none"> <li>Measuring systems for liquefied gases under pressure measured at a temperature below – 10 °C (other than cryogenic liquids)</li> </ul>
2,5	measuring systems for cryogenic liquids (temperature below – 153 °C)

<sup>(1)</sup> However, Member States may require measuring systems of accuracy class 0,3 or 0,5 when used for the levying of duties on mineral oils when (un)loading ships and rail and road tankers.

Note: However, the manufacturer may specify a better accuracy for a certain type of measuring system.

**8. Units of measurement**

The metered quantity shall be displayed in millilitres, cubic centimetres, litres, cubic metres, grams, kilograms or tonnes.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1 or G.

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## ANNEX VIII

## AUTOMATIC WEIGHING INSTRUMENTS (MI-006)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in Chapter I of this Annex, apply to automatic weighing instruments defined below, intended to determine the mass of a body by using the action of gravity on that body.

## DEFINITIONS

Automatic weighing instrument	An instrument that determines the mass of a product without the intervention of an operator and follows a predetermined programme of automatic processes characteristic of the instrument.
Automatic catchweigher	An automatic weighing instrument that determines the mass of pre-assembled discrete loads (for example prepackages) or single loads of loose material.
Automatic checkweigher	An automatic catchweigher that subdivides articles of different mass into two or more subgroups according to the value of the difference of their mass and a nominal set-point.
Weight labeller	An automatic catchweigher that labels individual articles with the weight value.
Weight/price labeller	An automatic catchweigher that labels individual articles with the weight value, and price information.
Automatic gravimetric filling instrument	An automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk.
Discontinuous totaliser (totalising hopper weigher)	An automatic weighing instrument that determines the mass of a bulk product by dividing it into discrete loads. The mass of each discrete load is determined in sequence and summed. Each discrete load is then delivered to bulk.
Continuous totaliser	An automatic weighing instrument that continuously determines the mass of a bulk product on a conveyor belt, without systematic subdivision of the product and without interrupting the movement of the conveyor belt.
Rail-weighbridge	An automatic weighing instrument having a load receptor inclusive of rails for conveying railway vehicles.

## SPECIFIC REQUIREMENTS

## CHAPTER I

**Requirements common to all types of automatic weighing instruments****1. Rated Operating Conditions**

The manufacturer shall specify the rated operating conditions for the instrument as follows:

**1.1. For the measurand:**

The measuring range in terms of its maximum and minimum capacity.

**1.2. For the electrical supply influence quantities:**

In case of AC voltage supply	:	the nominal AC voltage supply, or the AC voltage limits.
In case of DC voltage supply	:	the nominal and minimum DC voltage supply, or the DC voltage limits.

**1.3. For the mechanical and climatic influence quantities:**

The minimum temperature range is 30 °C unless specified otherwise in the following chapters of this Annex.

The mechanical environment classes according to Annex I, point 1.3.2 are not applicable. For instruments which are used under special mechanical strain, e.g. instruments incorporated into vehicles, the manufacturer shall define the mechanical conditions of use.

- 1.4. For other influence quantities (if applicable):

The rate(s) of operation.

The characteristics of the product(s) to be weighed.

2. **Permissible effect of disturbances — Electromagnetic environment**

The required performance and the critical change value are given in the relevant Chapter of this Annex for each type of instrument.

3. **Suitability**

- 3.1. Means shall be provided to limit the effects of tilt, loading and rate of operation such that maximum permissible errors (MPEs) are not exceeded in normal operation.
- 3.2. Adequate material handling facilities shall be provided to enable the instrument to respect the MPEs during normal operation.
- 3.3. Any operator control interface shall be clear and effective.
- 3.4. The integrity of the display (where present) shall be verifiable by the operator.
- 3.5. Adequate zero setting capability shall be provided to enable the instrument to respect the MPEs during normal operation.
- 3.6. Any result outside the measurement range shall be identified as such, where a printout is possible.

4. **Conformity assessment**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

For mechanical systems:

B + D or B + E or B + F or D1 or F1 or G or H1.

For electromechanical instruments:

B + D or B + E or B + F or G or H1.

For electronic systems or systems containing software:

B + D or B + F or G or H1.

CHAPTER II

**Automatic Catchweighers**

1. **Accuracy Classes**

- 1.1. Instruments are divided into primary categories designated by:

X or Y

as specified by the manufacturer.

- 1.2. These primary categories are further divided into four accuracy classes:

XI, XII, XIII & XIII

and

Y(I), Y(II), Y(a) & Y(b)

which shall be specified by the manufacturer.



## 2. Category X Instruments

- 2.1. Category X applies to instruments used to check prepackages made up in accordance with the requirements of Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products <sup>(1)</sup> applicable to prepackages.
- 2.2. The accuracy classes are supplemented by a factor (x) that quantifies the maximum permissible standard deviation as specified in point 4.2.

The manufacturer shall specify the factor (x), where (x) shall be  $\leq 2$  and in the form  $1 \times 10^k$ ,  $2 \times 10^k$  or  $5 \times 10^k$ , where k is a negative whole number or zero.

## 3. Category Y Instruments

Category Y applies to all other automatic catchweighers.

## 4. MPE

- 4.1. *Mean error Category X/MPE Category Y instruments*

Table 1

Net Load (m) in verification scale intervals (e)								Maximum permissible mean error	Maximum permissible error
XI	Y(I)	XII	Y(II)	XIII	Y(a)	XIII	Y(b)	X	Y
$0 < m \leq 50\,000$		$0 < m \leq 5\,000$		$0 < m \leq 500$		$0 < m \leq 50$		$\pm 0,5\,e$	$\pm 1\,e$
$50\,000 < m \leq 200\,000$		$5\,000 < m \leq 20\,000$		$500 < m \leq 2\,000$		$50 < m \leq 200$		$\pm 1,0\,e$	$\pm 1,5\,e$
$200\,000 < m$		$20\,000 < m \leq 100\,000$		$2\,000 < m \leq 10\,000$		$200 < m \leq 1\,000$		$\pm 1,5\,e$	$\pm 2\,e$

- 4.2. *Standard deviation*

Maximum permissible value for the standard deviation of a class X (x) instrument is the result of the multiplication of the factor (x) by the value in Table 2 below.

Table 2

Net Load (m)	Maximum permissible standard deviation for class X(1)
$m \leq 50\,g$	0,48 %
$50\,g < m \leq 100\,g$	0,24 g
$100\,g < m \leq 200\,g$	0,24 %
$200\,g < m \leq 300\,g$	0,48 g
$300\,g < m \leq 500\,g$	0,16 %
$500\,g < m \leq 1\,000\,g$	0,8 g
$1\,000\,g < m \leq 10\,000\,g$	0,08 %
$10\,000\,g < m \leq 15\,000\,g$	8 g
$15\,000\,g < m$	0,053 %

For class XI and XII (x) shall be less than 1.

For class XIII (x) shall be not greater than 1.

<sup>(1)</sup> OJ L 46, 21.2.1976, p. 1.

For class XIII (x) shall be greater than 1.

#### 4.3. Verification scale interval — single interval instruments

Table 3

Accuracy classes		Verification scale interval	Number of verification scale intervals $n = \text{Max}/e$	
			Minimum	Maximum
XI	Y(I)	$0,001 \text{ g} \leq e$	50 000	—
XII	Y(II)	$0,001 \text{ g} \leq e \leq 0,05 \text{ g}$	100	100 000
		$0,1 \text{ g} \leq e$	5 000	100 000
XIII	Y(a)	$0,1 \text{ g} \leq e \leq 2 \text{ g}$	100	10 000
		$5 \text{ g} \leq e$	500	10 000
XIII	Y(b)	$5 \text{ g} \leq e$	100	1 000

#### 4.4. Verification scale interval — multi-interval instruments

Table 4

Accuracy classes		Verification scale interval	Number of verification scale intervals $n = \text{Max}/e$	
			Minimum value <sup>(1)</sup> $n = \text{Max}_i/e_{(i+1)}$	Maximum value $n = \text{Max}_i/e_i$
XI	Y(I)	$0,001 \text{ g} \leq e_i$	50 000	—
XII	Y(II)	$0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$	5 000	100 000
		$0,1 \text{ g} \leq e_i$	5 000	100 000
XIII	Y(a)	$0,1 \text{ g} \leq e_i$	500	10 000
XIII	Y(b)	$5 \text{ g} \leq e_i$	50	1 000

<sup>(1)</sup> For  $i = r$  the corresponding column of Table 3 applies with  $e$  replaced by  $e_r$ .

Where:

$i = 1, 2, \dots, r$

$i$  = partial weighing range

$r$  = total number of partial ranges

#### 5. Measurement Range

In specifying the measurement range for class Y instruments the manufacturer shall take account that the minimum capacity shall not be less than:

class Y(I)	:	100 e
class Y(II)	:	20 e for $0,001 \text{ g} \leq e \leq 0,05 \text{ g}$ , and 50 e for $0,1 \text{ g} \leq e$
class Y(a)	:	20 e
class Y(b)	:	10 e
Scales used for grading, e.g. postal scales and garbage weighers	:	5 e

## 6. **Dynamic Setting**

- 6.1. The dynamic setting facility shall operate within a load range specified by the manufacturer.
- 6.2. When fitted, a dynamic setting facility that compensates for the dynamic effects of the load in motion shall be inhibited from operating outside the load range, and shall be capable of being secured.

## 7. **Performance Under Influence Factors And Electromagnetic Disturbances**

- 7.1. The MPEs due to influence factors are:

### 7.1.1. For category X instruments:

- For automatic operation; as specified in Tables 1 and 2,
- For static weighing in non-automatic operation; as specified in Table 1.

### 7.1.2. For category Y instruments

- For each load in automatic operation; as specified in Table 1,
- For static weighing in non-automatic operation; as specified for category X in Table 1.

- 7.2. The critical change value due to a disturbance is one verification scale interval.

- 7.3. Temperature range:

- For class XI and Y(I) the minimum range is 5 °C,
- For class XII and Y(II) the minimum range is 15 °C.

## CHAPTER III

### **Automatic Gravimetric Filling Instruments**

## 1. **Accuracy classes**

- 1.1. The manufacturer shall specify both the reference accuracy class Ref(x) and the operational accuracy class(es) X(x).
- 1.2. An instrument type is designated a reference accuracy class, Ref(x), corresponding to the best possible accuracy for instruments of the type. After installation, individual instruments are designated for one or more operational accuracy classes, X(x), having taken account of the specific products to be weighed. The class designation factor (x) shall be  $\leq 2$ , and in the form  $1 \times 10^k$ ,  $2 \times 10^k$  or  $5 \times 10^k$  where k is a negative whole number or zero.
- 1.3. The reference accuracy class, Ref(x) is applicable for static loads.
- 1.4. For the operational accuracy class X(x), X is a regime relating accuracy to load weight and (x) is a multiplier for the limits of error specified for class X(1) in point 2.2.

## 2. **MPE**

### 2.1. *Static weighing error*

- 2.1.1. For static loads under rated operating conditions, the MPE for reference accuracy class Ref(x), shall be 0,312 of the maximum permissible deviation of each fill from the average; as specified in Table 5; multiplied by the class designation factor (x).
- 2.1.2. For instruments where the fill may be made up from more than one load (e.g. cumulative or selective combination weighers) the MPE for static loads shall be the accuracy required for the fill as specified in point 2.2 (i.e. not the sum of the maximum permissible deviation for the individual loads).

2.2. *Deviation from average fill*

Table 5

Value of the mass, $m$ (g), of the fills	Maximum permissible deviation of each fill from the average for class X(1)
$m \leq 50$	7,2 %
$50 < m \leq 100$	3,6 g
$100 < m \leq 200$	3,6 %
$200 < m \leq 300$	7,2 g
$300 < m \leq 500$	2,4 %
$500 < m \leq 1\,000$	12 g
$1\,000 < m \leq 10\,000$	1,2 %
$10\,000 < m \leq 15\,000$	120 g
$15\,000 < m$	0,8 %

Note:

The calculated deviation of each fill from the average may be adjusted to take account for the effect of material particle size.

2.3. *Error relative to pre-set value (setting error)*

For instruments where it is possible to pre-set a fill weight; the maximum difference between the pre-set value and the average mass of the fills shall not exceed 0,312 of the maximum permissible deviation of each fill from the average, as specified in Table 5.

3. **Performance Under Influence Factor And Electromagnetic Disturbance**

3.1. The MPE due to influence factors shall be as specified in point 2.1.

3.2. The critical change value due to a disturbance is a change of the static weight indication equal to the MPE as specified in point 2.1 calculated for the rated minimum fill, or a change that would give equivalent effect on the fill in the case of instruments where the fill consists of multiple loads. The calculated critical change value shall be rounded to the next higher scale interval (d).

3.3. The manufacturer shall specify the value of the rated minimum fill.

## CHAPTER IV

**Discontinuous Totalisers**1. **Accuracy Classes**

Instruments are divided into four accuracy classes as follows: 0,2; 0,5; 1; 2.

2. **MPEs**

Table 6

Accuracy class	MPE of totalised load
0,2	$\pm 0,10$ %
0,5	$\pm 0,25$ %
1	$\pm 0,50$ %
2	$\pm 1,00$ %

### 3. Totalisation scale interval

The totalisation scale interval ( $d_t$ ) shall be in the range:

$$0,01 \% \text{ Max} \leq d_t \leq 0,2 \% \text{ Max}$$

### 4. Minimum Totalised Load ( $\Sigma_{\min}$ )

The minimum totalised load ( $\Sigma_{\min}$ ) shall be not less than the load at which the MPE is equal to the totalisation scale interval ( $d_t$ ) and not less than the minimum load as specified by the manufacturer.

### 5. Zero Setting

Instruments that do not tare weigh after each discharge shall have a zero setting device. Automatic operation shall be inhibited if zero indication varies by:

— 1  $d_t$  on instruments with automatic zero setting device;

— 0,5  $d_t$  on instruments with a semi-automatic, or non-automatic, zero setting device.

### 6. Operator Interface

Operator adjustments and reset function shall be inhibited during automatic operation.

### 7. Printout

On instruments equipped with a printing device, the reset of the total shall be inhibited until the total is printed. The printout of the total shall occur if automatic operation is interrupted.

### 8. Performance under influence factors and electromagnetic disturbances

8.1. The MPEs due to influence factors shall be as specified in Table 7.

Table 7

Load (m) in totalisation scale intervals ( $d_t$ )	MPE
$0 < m \leq 500$	$\pm 0,5 d_t$
$500 < m \leq 2\,000$	$\pm 1,0 d_t$
$2\,000 < m \leq 10\,000$	$\pm 1,5 d_t$

8.2. The critical change value due to a disturbance is one totalisation scale interval for any weight indication and any stored total.

## CHAPTER V

### Continuous Totalisers

#### 1. Accuracy classes

Instruments are divided into three accuracy classes as follows: 0,5; 1; 2.

#### 2. Measurement Range

2.1. The manufacturer shall specify the measurement range, the ratio between the minimum net load on the weighing unit and the maximum capacity, and the minimum totalised load.

2.2. The minimum totalised load  $\Sigma_{\min}$  shall not be less than

800 d for class 0,5,

400 d for class 1,

200 d for class 2.

Where d is the totalisation scale interval of the general totalisation device.

3. **MPE**

Table 8

Accuracy class	MPE for totalised load
0,5	$\pm 0,25 \%$
1	$\pm 0,5 \%$
2	$\pm 1,0 \%$

4. **Speed of the belt**

The speed of the belt shall be specified by the manufacturer. For single-speed beltweighers, and variable-speed beltweighers having a manual speed setting control, the speed shall not vary by more than 5 % of the nominal value. The product shall not have a different speed than the speed of the belt.

5. **General Totalisation Device**

It shall not be possible to reset the general totalisation device to zero.

6. **Performance under influence factors and electromagnetic disturbances**

- 6.1. The MPE due to influence factor, for a load not less than the  $\Sigma_{\min}$ , shall be 0,7 times the appropriate value specified in Table 8, rounded to the nearest totalisation scale interval (d).
- 6.2. The critical change value due to a disturbance shall be 0,7 times the appropriate value specified in Table 8, for a load equal to  $\Sigma_{\min}$ , for the designated class of the beltweigher; rounded up to the next higher totalisation scale interval (d).

## CHAPTER VI

**Automatic Rail Weighbridges**1. **Accuracy classes**

Instruments are divided into four accuracy classes as follows:

0,2; 0,5; 1; 2.

2. **MPE**

- 2.1. The MPEs for weighing-in-motion of a single wagon or a total train are shown in Table 9.

Table 9

Accuracy class	MPE
0,2	$\pm 0,1 \%$
0,5	$\pm 0,25 \%$
1	$\pm 0,5 \%$
2	$\pm 1,0 \%$

- 2.2. The MPEs for the weight of coupled or uncoupled wagons weighing-in-motion shall be one of the following values, whichever is the greatest:

- the value calculated according to Table 9, rounded to the nearest scale interval;
- the value calculated according to Table 9, rounded to the nearest scale interval for a weight equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings);
- one scale interval (d).

- 2.3. The MPEs for the weight of train weighing-in-motion shall be one of the following values, whichever is the greatest:

- the value calculated according to Table 9, rounded to the nearest scale interval;
- the value calculated according to Table 9, for the weight of a single wagon equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings) multiplied by the number of reference wagons (not exceeding 10) in the train, and rounded to the nearest scale interval;
- one scale interval (d) for each wagon in the train, but not exceeding 10 d.

- 2.4. When weighing coupled wagons; the errors of not more than 10 % of the weighing results taken from one or more passes of the train may exceed the appropriate MPE given in point 2.2, but shall not exceed twice the MPE.

3. **Scale interval (d)**

The relationship between the accuracy class and the scale interval shall be as specified in Table 10.

Table 10

Accuracy class	Scale interval (d)
0,2	$d \leq 50 \text{ kg}$
0,5	$d \leq 100 \text{ kg}$
1	$d \leq 200 \text{ kg}$
2	$d \leq 500 \text{ kg}$

4. **Measurement range**

- 4.1. The minimum capacity shall not be less than 1 t, and not greater than the value of the result of the minimum wagon weight divided by the number of partial weighings.
- 4.2. The minimum wagon weight shall not be less than 50 d.

5. **Performance under influence factor and electromagnetic disturbance**

- 5.1. The MPE due to an influence factor shall be as specified in Table 11.

Table 11

Load (m) in verification scale intervals (d)	MPE
$0 < m \leq 500$	$\pm 0,5 \text{ d}$
$500 < m \leq 2\,000$	$\pm 1,0 \text{ d}$
$2\,000 < m \leq 10\,000$	$\pm 1,5 \text{ d}$

- 5.2. The critical change value due to a disturbance is one scale interval.



## ANNEX IX

## TAXIMETERS (MI-007)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex apply to taximeters.

## DEFINITIONS

**Taximeter**

A device that works together with a signal generator <sup>(1)</sup> to make a measuring instrument.

This device measures duration, calculates distance on the basis of a signal delivered by the distance signal generator. Additionally, it calculates and displays the fare to be paid for a trip on the basis of the calculated distance and/or the measured duration of the trip.

**Fare**

The total amount of money due for a trip based on a fixed initial hire fee and/or the length and/or the duration of the trip. The fare does not include a supplement charged for extra services.

**Cross-over speed**

The speed value found by division of a time tariff value by a distance tariff value.

**Normal calculation mode S (single application of tariff)**

Fare calculation based on application of the time tariff below the cross-over speed and application of the distance tariff above the cross-over speed.

**Normal calculation mode D (double application of tariff)**

Fare calculation based on simultaneous application of time tariff and distance tariff over the whole trip.

**Operating position**

The different modes in which a taximeter fulfils the different parts of its functioning. The operating positions are distinguished by the following indications:

'For Hire'	:	The operating position in which the fare calculation is disabled
'Hired'	:	The operating position in which the fare calculation takes place on the basis of a possible initial charge and a tariff for distance travelled and/or time of the trip
'Stopped'	:	The operating position in which the fare due for the trip is indicated and at least the fare calculation based on time is disabled.

## DESIGN REQUIREMENTS

1. The taximeter shall be designed to calculate the distance and to measure the duration of a trip.
2. The taximeter shall be designed to calculate and display the fare, incrementing in steps equal to the resolution fixed by the Member State in the operation position 'Hired'. The taximeter shall also be designed to display the final value for the trip in the operating position 'Stopped'.
3. A taximeter shall be able to apply the normal calculation modes S and D. It shall be possible to choose between these calculation modes by a secured setting.
4. A taximeter shall be able to supply the following data through an appropriate secured interface(s):
  - operation position: 'For Hire', 'Hired' or 'Stopped';
  - totaliser data according to point 15.1;

<sup>(1)</sup> The distance signal generator is outside the scope of this Directive.

- general information: constant of the distance signal generator, date of securing, taxi identifier, real time, identification of the tariff;
- fare information for a trip: total charged, fare, calculation of the fare, supplement charge, date, start time, finish time, distance travelled;
- tariff(s) information: parameters of tariff(s).

National legislation may require certain devices to be connected to the interface(s) of a taximeter. Where such a device is required; it shall be possible, by secured setting, to inhibit automatically the operation of the taximeter for reasons of the non-presence or improper functioning of the required device.

5. If relevant, it shall be possible to adjust a taximeter for the constant of the distance signal generator to which it is to be connected and to secure the adjustment.

#### RATED OPERATING CONDITIONS

- 6.1. The mechanical environment class that applies is M3.
- 6.2. The manufacturer shall specify the rated operating conditions for the instrument, in particular:
  - a minimum temperature range of 80 °C for the climatic environment;
  - the limits of the DC power supply for which the instrument has been designed.

#### MAXIMUM PERMISSIBLE ERRORS (MPEs)

7. The MPE, excluding any errors due to application of the taximeter in a taxi, are:
  - For the time elapsed:  $\pm 0,1 \%$   
  
minimum value of mpe: 0,2 s;
  - For the distance travelled:  $\pm 0,2 \%$   
  
minimum value of mpe: 4 m;
  - For the calculation of the fare:  $\pm 0,1 \%$   
  
minimum, including rounding: corresponding to the least significant digit of the fare indication.

#### PERMISSIBLE EFFECT OF DISTURBANCES

##### 8. **Electromagnetic immunity**

- 8.1. The electromagnetic class that applies is E3.
- 8.2. The MPE laid down in point 7 shall also be respected in the presence of an electromagnetic disturbance.

#### POWER SUPPLY FAILURE

9. In case of a reduction of the voltage supply to a value below the lower operating limit as specified by the manufacturer, the taximeter shall:
  - continue to work correctly or resume its correct functioning without loss of data available before the voltage drop if the voltage drop is temporary, i.e. due to restarting the engine;
  - abort an existing measurement and return to the position 'For Hire' if the voltage drop is for a longer period.

## OTHER REQUIREMENTS

10. The conditions for the compatibility between the taximeter and the distance signal generator shall be specified by the manufacturer of the taximeter.
11. If there is a supplement charge for an extra service, entered by the driver on manual command, this shall be excluded from the fare displayed. However, in that case a taximeter may display temporarily the value of the fare including the supplementary charge.
12. If the fare is calculated according to calculation mode D a taximeter may have an additional display mode in which only the total distance and duration of the trip are displayed in real time.
13. All values displayed for the passenger shall be suitably identified. These values as well as their identification shall be clearly readable under daylight and night conditions.
- 14.1. If the fare to be paid or the measures to be taken against fraudulent use can be affected by the choice of functionality from a pre-programmed setting or by free data setting, it shall be possible to secure the instrument settings and data entered.
- 14.2. The securing possibilities available in a taximeter shall be such that separate securing of the settings is possible.
- 14.3. The provisions in point 8.3 of Annex I apply also to the tariffs.
- 15.1. A taximeter shall be fitted with non-resettable totalisers for all of the following values:
  - The total distance travelled by the taxi;
  - The total distance travelled when hired;
  - The total number of hirings;
  - The total amount of money charged as supplements;
  - The total amount of money charged as fare.

The totalised values shall include the values saved according to point 9 under conditions of loss of power supply.
- 15.2. If disconnected from power, a taximeter shall allow the totalised values to be stored for one year for the purpose of reading out the values from the taximeter to another medium.
- 15.3. Adequate measures shall be taken to prevent the display of totalised values from being used to deceive passengers.
16. Automatic change of tariffs is allowed due to the:
  - distance of the trip;
  - duration of the trip;
  - time of the day;
  - date;
  - day of the week.
17. If properties of the taxi are important for the correctness of the taximeter, the taximeter shall provide means to secure the connection of the taximeter to the taxi in which it is installed.
18. For the purpose of testing after installation, the taximeter shall be equipped with the possibility to test separately the accuracy of time and distance measurement and the accuracy of the calculation.
19. A taximeter and its installation instructions specified by the manufacturer shall be such that, if installed according to the manufacturer's instructions, fraudulent alterations of the measurement signal representing the distance travelled are sufficiently excluded.

20. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of the customer, the driver, the driver's employer and the fiscal authorities are protected.
21. A taximeter shall be designed so that it can respect the MPEs without adjustment during a period of one year of normal use.
22. The taximeter shall be equipped with a real-timeclock by means of which the time of the day and the date are kept, one or both can be used for automatic change of tariffs. The requirements for the real-time clock are:
- the timekeeping shall have an accuracy of 0,02 %;
  - the correction possibility of the clock shall be not more than 2 minutes per week. Correction for summer and wintertime shall be performed automatically;
  - correction, automatic or manually, during a trip shall be prevented.
23. The values of distance travelled and time elapsed, when displayed or printed in accordance with this Directive, shall use the following units:
- Distance travelled:
- kilometres;
  - miles, in those Member States to which Article (1)(b) of Directive 80/181/EEC applies.
- Time elapsed:
- seconds, minutes or hours, as may be suitable; keeping in mind the necessary resolution and the need to prevent misunderstandings.

#### CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

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## ANNEX X

## MATERIAL MEASURES (MI-008)

## CHAPTER I

**Material measures of length**

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this chapter, apply to material measures of length defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument.

## DEFINITIONS

Material measure of length	An instrument comprising scale marks whose distances are given in legal units of length.
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## SPECIFIC REQUIREMENTS

**Reference Conditions**

- 1.1. For tapes of length equal to or greater than 5 metres, the maximum permissible errors (MPEs) are to be met when a tractive force of fifty newtons or other force values as specified by the manufacturer and marked on the tape accordingly, or in the case of rigid or semi-rigid measures no tractive force is needed, is applied.
- 1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked on the measure accordingly.

**MPEs**

2. The MPE, positive or negative in mm, between two non-consecutive scale marks is  $(a + bL)$ , where:

—  $L$  is the value of the length rounded up to the next whole metre; and

—  $a$  and  $b$  are given in Table 1 below.

When a terminal interval is bounded by a surface, the MPE for any distance beginning at this point is increased by the value  $c$  given in Table 1.

Table 1

Accuracy Class	a (mm)	b	c (mm)
I	0,1	0,1	0,1
II	0,3	0,2	0,2
III	0,6	0,4	0,3
D — special class for dipping tapes <sup>(1)</sup> Up to and including 30 m <sup>(2)</sup>	1,5	zero	zero
S — special class for tank strapping tapes For each 30 m length when the tape is supported on a flat surface	1,5	zero	zero

<sup>(1)</sup> Applies to the tape/dip weight combinations.

<sup>(2)</sup> If the nominal tape length exceeds 30 m, an additional mpe of 0,75 mm shall be permitted for each 30 m of tape length.

Dip tapes may also be of Classes I or II in which case for any length between two scale marks, one of which is on the sinker and the other on the tape, the MPE is  $\pm 0,6$  mm when application of the formula gives a value of less than 0,6 mm.

The MPE for the length between consecutive scale marks, and the maximum permissible difference between two consecutive intervals, are given in Table 2 below.

Table 2

Length $i$ of the interval	MPE or difference in millimetres according to accuracy class		
	I	II	III
$i \leq 1$ mm	0,1	0,2	0,3
$1 \text{ mm} < i \leq 1$ cm	0,2	0,4	0,6

Where a rule is of the folding type, the jointing shall be such as not to cause any errors, supplementary to those above, exceeding: 0,3 mm for Class II, and 0,5 mm for Class III.

### Materials

- 3.1. Materials used for material measures shall be such that length variations due to temperature excursions up to  $\pm 8$  °C about the reference temperature do not exceed the MPE. This does not apply to Class S and Class D measures where the manufacturer intends that thermal expansion corrections shall be applied to observed readings where necessary.
- 3.2. Measures made from material whose dimensions may alter materially when subjected to a wide range of relative humidity, may only be included in Classes II or III.

### Markings

4. The nominal value shall be marked on the measure. Millimetre scales shall be numbered every centimetre and measures with a scale interval greater than 2 cm shall have all scale marks numbered.

### CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

F 1 or D1 or B + D or H or G.

## CHAPTER II

### Capacity serving measures

The relevant essential requirements of Annex I, and the specific requirements and the conformity assessment procedures listed in this chapter, apply to capacity serving measures defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument. Also, the requirement for the instrument to bear information in respect of its accuracy shall not apply.

### DEFINITIONS

Capacity serving measure	A capacity measure (such as a drinking glass, jug or thimble measure) designed to determine a specified volume of a liquid (other than a pharmaceutical product) which is sold for immediate consumption.
Line measure	A capacity serving measure marked with a line to indicate nominal capacity.
Brim measure	A capacity serving measure for which the internal volume is equal to the nominal capacity.
Transfer measure	A capacity serving measure from which it is intended that the liquid is decanted prior to consumption.
Capacity	The capacity is the internal volume for brim measures or internal volume to a filling mark for line measures.

### SPECIFIC REQUIREMENTS

#### 1. Reference Conditions

- 1.1. Temperature: the reference temperature for measurement of capacity is 20 °C.
- 1.2. Position for correct indication: free standing on a level surface.

**2. MPEs**

Table 1

	Line	Brim
Transfer measures		
< 100 ml	$\pm 2$ ml	– 0 + 4 ml
$\geq 100$ ml	$\pm 3$ %	– 0 + 6 %
Serving measures		
< 200 ml	$\pm 5$ %	– 0 + 10 %
$\geq 200$ ml	$\pm (5 \text{ ml} + 2,5 \%)$	– 0 + 10 ml + 5 %

**3. Materials**

Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the MPE.

**4. Shape**

- 4.1. Transfer measures shall be designed so that a change of contents equal to the MPE causes a change in level of at least 2 mm at the brim or filling mark.
- 4.2. Transfer measures shall be designed so that the complete discharge of the liquid being measured will not be impeded.

**5. Marking**

- 5.1. The nominal capacity declared shall be clearly and indelibly marked on the measure.
- 5.2. Capacity serving measures may also be marked with up to three clearly distinguishable capacities, none of which shall lead to confusion one to the other.
- 5.3. All filling marks shall be sufficiently clear and durable to ensure that MPEs are not exceeded in use.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

A2 or F1 or D1 or E1 or B + E or B + D or H.



## ANNEX XI

## DIMENSIONAL MEASURING INSTRUMENTS (MI-009)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to dimensional measuring instruments of the types defined below.

## DEFINITIONS

Length measuring instrument	A length measuring instrument serves for the determination of the length of rope-type materials (e.g. textiles, bands, cables) during feed motion of the product to be measured.
Area Measuring Instruments	An area measuring instrument serves for the determination of the area of irregular shaped objects, e.g. for leather.
Multi-dimensional Measuring Instruments	A multi-dimensional measuring instrument serves for the determination of the edge length (length, height, width) of the smallest enclosing rectangular parallelepiped of a product.

## CHAPTER I

**Requirements common to all dimensional measuring instruments****Electromagnetic immunity**

- The effect of an electromagnetic disturbance on a dimensional measuring instrument shall be such that:
  - the change in measurement result is no greater than the critical change value as defined in point 2; or
  - it is impossible to perform any measurement; or
  - there are momentary variations in the measurement result that cannot be interpreted, memorised or transmitted as a measuring result; or
  - there are variations in the measurement result severe enough to be noticed by all those interested in the measurement result.
- The critical change value is equal to one scale interval.

## CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

For mechanical or electromechanical instruments:

F1 or E1 or D1 or B + F or B + E or B + D or H or H1 or G.

For electronic instruments or instruments containing software:

B + F or B + D or H1 or G.

## CHAPTER II

**Length measuring instruments****Characteristics of the product to be measured**

- Textiles are characterised by the characteristic factor K. This factor takes the stretchability and force per unit area of the product measured into account and is defined by the following formula:

K	=	$\varepsilon \cdot (G_A + 2,2 \text{ N/m}^2)$ , where $\varepsilon$ is the relative elongation of a cloth specimen 1 m wide at a tensile force of 10 N, $G_A$ is the weight force per unit area of a cloth specimen in $\text{N/m}^2$ .
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## Operating conditions

### 2.1. Range

Dimensions and K-factor, where applicable, within the range specified by the manufacturer for the instrument. The ranges of K-factor are given in Table 1:

Table 1

Group	Range of K	Product
I	$0 < K < 2 \times 10^{-2} \text{ N/m}^2$	low stretchability
II	$2 \times 10^{-2} \text{ N/m}^2 < K < 8 \times 10^{-2} \text{ N/m}^2$	medium stretchability
III	$8 \times 10^{-2} \text{ N/m}^2 < K < 24 \times 10^{-2} \text{ N/m}^2$	high stretchability
IV	$24 \times 10^{-2} \text{ N/m}^2 < K$	very high stretchability

2.2. Where the measured object is not transported by the measuring instrument, its speed must be within the range specified by the manufacturer for the instrument.

2.3. If the measurement result depends on the thickness, the surface condition and the kind of delivery (e.g. from a big roll or from a pile), corresponding limitations are specified by the manufacturer.

## MPEs

### 3. Instrument

Table 2

Accuracy class	MPE
I	0,125 %, but not less than 0,005 $L_m$
II	0,25 %, but not less than 0,01 $L_m$
III	0,5 %, but not less than 0,02 $L_m$

Where  $L_m$  is the minimum measurable length, that is to say the smallest length specified by the manufacturer for which the instrument is intended to be used.

The true length value of the different types of materials shall be measured using suitable instruments (e.g. tapes of length). Thereby, the material which is going to be measured shall be laid out on a suitable underlay (e.g. a suitable table) straight and unstretched.

## Other requirements

4. The instruments must ensure that the product is measured unstretched according to the intended stretchability for which the instrument is designed.

## CHAPTER III

### Area measuring instruments

## Operating conditions

### 1.1. Range

Dimensions within the range specified by the manufacturer for the instrument.

### 1.2. Condition of the product

The manufacturer shall specify the limitations of the instruments due to the speed, and thickness of the surface conditions if relevant, of the product.

## MPEs

### 2. Instrument

The MPE is 1,0 %, but not less than 1  $\text{dm}^2$ .

**Other requirements**3. *Presentation of the product*

In the case of pulling back or stopping the product, it shall not be possible to have an error of measurement or the display must be blanked.

4. *Scale interval*

The instruments must have a scale interval of 1,0 dm<sup>2</sup>. In addition, it must be possible to have a scale interval of 0,1 dm<sup>2</sup> for testing purposes.

## CHAPTER IV

**Multidimensional measuring instruments****Operating conditions**1.1. *Range*

Dimensions within the range specified by the manufacturer for the instrument.

1.2. *Minimum dimension*

The lower limit of the minimum dimension for all values of the scale interval is given in Table 1.

Table 1

Scale interval (d)	Minimum dimension (min) (lower limit)
$d \leq 2 \text{ cm}$	10 d
$2 \text{ cm} < d \leq 10 \text{ cm}$	20 d
$10 \text{ cm} < d$	50 d

1.3. *Speed of the product*

The speed must be within the range specified by the manufacturer for the instrument.

**MPE**2. *Instrument:*

The MPE is  $\pm 1,0 \text{ d}$ .

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## ANNEX XII

## EXHAUST GAS ANALYSERS (MI-010)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to exhaust gas analysers defined below intended for inspection and professional maintenance of motor vehicles in use.

## DEFINITIONS

Exhaust gas analyser	<p>An exhaust gas analyser is a measuring instrument that serves to determine the volume fractions of specified components of the exhaust gas of a motor vehicle engine with spark ignition at the moisture level of the sample analysed.</p> <p>These gas components are carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), oxygen (O<sub>2</sub>) and hydrocarbons (HC).</p> <p>The content of hydrocarbons has to be expressed as concentration of n-hexane (C<sub>6</sub>H<sub>14</sub>), measured with near-infrared absorption techniques.</p> <p>The volume fractions of the gas components are expressed as a percentage (% vol) for CO, CO<sub>2</sub> and O<sub>2</sub> and in parts per million (ppm vol) for HC.</p> <p>Moreover, an exhaust gas analyser calculates the lambda value from the volume fractions of the components of the exhaust gas.</p>
Lambda	Lambda is a dimensionless value representative of the burning efficiency of an engine in terms of air/fuel ratio in the exhaust gases. It is determined with a reference standardised formula.

## SPECIFIC REQUIREMENTS

## Instrument Classes

- Two classes (0 and I) are being defined for exhaust gas analysers. The relevant minimum measuring ranges for these classes are shown in Table 1.

Table 1

Classes and measuring ranges	
Parameter	Classes 0 and I
CO fraction	from 0 to 5 % vol
CO <sub>2</sub> fraction	from 0 to 16 % vol
HC fraction	from 0 to 2 000 ppm vol
O <sub>2</sub> fraction	from 0 to 21 % vol
λ	from 0,8 to 1,2

## Rated operating conditions

- The values of the operating conditions shall be specified by the manufacturer as follows:

## 2.1. For the climatic and mechanical influence quantities:

- a minimum temperature range of 35 °C for the climatic environment;
- the mechanical environment class that applies is M1.

## 2.2. For the electrical power influence quantities:

- the voltage and frequency range for the AC voltage supply;
- the limits of the DC voltage supply.

2.3. For the ambient pressure:

- the minimum and the maximum values of the ambient pressure are for both classes:  $p_{\min} \leq 860$  hPa,  $p_{\max} \geq 1\,060$  hPa.

#### Maximum permissible errors (MPEs)

3. The MPEs are defined as follows:

3.1. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to point 1.1 of Annex I is the greater of the two values shown in Table 2. Absolute values are expressed in % vol or ppm vol, percentage values are percent of the true value.

Table 2

MPEs		
Parameter	Class 0	Class I
CO fraction	$\pm 0,03$ % vol	$\pm 0,06$ % vol
	$\pm 5$ %	$\pm 5$ %
CO <sub>2</sub> fraction	$\pm 0,5$ % vol	$\pm 0,5$ % vol
	$\pm 5$ %	$\pm 5$ %
HC fraction	$\pm 10$ ppm vol	$\pm 12$ ppm vol
	$\pm 5$ %	$\pm 5$ %
O <sub>2</sub> fraction	$\pm 0,1$ % vol	$\pm 0,1$ % vol
	$\pm 5$ %	$\pm 5$ %

3.2. The MPE on lambda calculation is 0,3 %. The conventional true value is calculated according to the formula set out in point 5.3.7.3 of Regulation No 83 of the Economic Commission for Europe of the United Nations (UN/ECE) <sup>(1)</sup>.

For this purpose, the values displayed by the instrument are used for calculation.

#### Permissible effect of disturbances

4. For each of the volume fractions measured by the instrument, the critical change value is equal to the MPE for the parameter concerned.
5. The effect of an electromagnetic disturbance shall be such that:
  - either the change in the measurement result is not greater than the critical change value laid down in point 4;
  - or the presentation of the measurement result is such that it cannot be taken for a valid result.

#### Other requirements

6. The resolution shall be equal to or of one order of magnitude higher than the values shown in Table 3.

Table 3

Resolution				
	CO	CO <sub>2</sub>	O <sub>2</sub>	HC
Class 0 and class I	0,01 % vol	0,1 % vol	<sup>(1)</sup>	1 ppm vol

<sup>(1)</sup> 0,01 % vol for measurand values below or equal to 4 % vol, otherwise 0,1 % vol.

The lambda value shall be displayed with a resolution of 0,001.

<sup>(1)</sup> OJ L 42, 15.2.2012, p. 1.

7. The standard deviation of 20 measurements shall not be greater than one third of the modulus of the MPE for each applicable gas volume fraction.
8. For measuring CO, CO<sub>2</sub> and HC, the instrument, including the specified gas handling system, must indicate 95 % of the final value as determined with calibration gases within 15 seconds after changing from a gas with zero content, e.g. fresh air. For measuring O<sub>2</sub>, the instrument under similar conditions must indicate a value differing less than 0,1 % vol from zero within 60 seconds after changing from fresh air to an oxygen-free gas.
9. The components in the exhaust gas, other than the components whose values are subject to the measurement, shall not affect the measurement results by more than the half of the modulus of the MPEs when those components are present in the following maximum volume fractions:
  - 6 % vol CO,
  - 16 % vol CO<sub>2</sub>,
  - 10 % vol O<sub>2</sub>,
  - 5 % vol H<sub>2</sub>,
  - 0,3 % vol NO,
  - 2 000 ppm vol HC (as n-hexane),
  - water vapor up to saturation.
10. An exhaust gas analyser shall have an adjustment facility that provides operations for zero-setting, gas calibration and internal adjustment. The adjustment facility for zero-setting and internal adjustment shall be automatic.
11. For automatic or semi-automatic adjustment facilities, the instrument shall be unable to make a measurement as long as the adjustments have not been made.
12. An exhaust gas analyser shall detect hydrocarbon residues in the gas handling system. It shall not be possible to carry out a measurement if the hydrocarbon residues, present before any measurement, exceed 20 ppm vol.
13. An exhaust gas analyser shall have a device for automatically recognising any malfunctioning of the sensor of the oxygen channel due to wear or a break in the connecting line.
14. If the exhaust gas analyser is capable to operate with different fuels (e.g. petrol or liquefied gas), there shall be the possibility to select the suitable coefficients for the Lambda calculation without ambiguity concerning the appropriate formula.

#### CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

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## ANNEX XIII

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. Instrument model/Instrument (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards or normative documents used or references to the other technical specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

\_\_\_\_\_

<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.



## ANNEX XIV

## PART A

**Repealed Directive with list of the successive amendments thereto  
(referred to in Article 52)**

Directive 2004/22/EC of the European Parliament and of the Council  
(OJ L 135, 30.4.2004, p. 1).

Council Directive 2006/96/EC  
(OJ L 363, 20.12.2006, p. 81).

Only point B.3 of the Annex

Regulation (EC) No 1137/2008 of the European Parliament and of the Council  
(OJ L 311, 21.11.2008, p. 1).

Only point 3.8 of the Annex

Commission Directive 2009/137/EC  
(OJ L 294, 11.11.2009, p. 7).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council  
(OJ L 316, 14.11.2012, p. 12).

Only point (g) of Article 26(1)

## PART B

**Time-limits for transposition into national law and dates of application  
(referred to in Article 52)**

Directive	Time limit for transposition	Date of application
2004/22/EC	30 April 2006	30 October 2006
2006/96/EC		
2009/137/EC	1 December 2010	1 June 2011

## ANNEX XV

## CORRELATION TABLE

Directive 2004/22/EC	This Directive
Article 1	Article 2(1)
Article 2	Article 3
Article 3, first paragraph	Article 1
Article 3, second paragraph	Article 2(2)
Article 4	Article 4(1) to (4), (6) to (9)
—	Article 4(5) and (10) to (22)
Article 5	Article 5
Article 6(1)	Article 6
Article 6(2)	—
Articles 7(1)	Article 20
Article 7(2)	Article 22(4)
Article 7(3)	—
Article 7(4)	—
Article 8	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
—	Article 13
Article 9	Article 17
Article 10	Article 18
Article 11(1)	—
Article 11(2), first subparagraph	—
Article 11(2), second subparagraph	Article 23(2)
Article 12	—
Article 13(1)	—
Article 13(2)	—
—	Article 14(1)
—	Article 14(2)
Article 13(3)	Article 14(3)
Article 13(4)	Article 14(4)
Article 14	—
Article 15(1)	Article 46(1)
Article 15(2)	Article 46(3)

Directive 2004/22/EC	This Directive
Article 15(3)	—
Article 15(4)	—
Article 15(5)	—
Article 16(1)	Article 15
Article 16(2)	Article 47
Article 16(3)	Article 16
Article 16(4)	—
Article 17(1)	—
Article 17(2)	Article 21(2)
Article 17(3)	—
Article 17(4), first subparagraph	Article 22(2)
Article 17(4), second subparagraph	—
Article 17(5)	—
Article 18	—
—	Article 19
—	Article 21(1)
—	Article 22(1)
—	Article 22(3)
—	Article 22(5), second subparagraph
—	Article 22(5), third subparagraph
—	Article 22(6)
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28
—	Article 29
—	Article 31
—	Article 32
—	Article 33
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40

Directive 2004/22/EC	This Directive
Article 19(1)	—
Article 19(2)(a), first subparagraph	—
Article 19(2)(a), second subparagraph	—
Article 19(2)(a), third subparagraph	Article 43(4)
Article 19(2)(b)	—
Article 20	—
Article 21	—
Article 22	—
Article 23	—
—	Article 41
—	Article 42
—	Article 43(1)
—	Article 43(2)
—	Article 43(3)
—	Article 44
—	Article 45
—	Article 48
—	Article 49
—	Article 50
Article 24	—
—	Article 51
Article 25	—
—	Article 52
Article 26	Article 53, first paragraph
—	Article 53, second paragraph
Article 27	Article 54
Annex I	Annex I
Annex A	Annex II, point 1
Annex A1	Annex II, point 2
Annex B	Annex II, point 3
Annex C	Annex II, point 4
Annex C1	Annex II, point 5
Annex D	Annex II, point 6
Annex D1	Annex II, point 7
Annex E	Annex II, point 8
Annex E1	Annex II, point 9
Annex F	Annex II, point 10
Annex F1	Annex II, point 11

Directive 2004/22/EC	This Directive
Annex G	Annex II, point 12
Annex H	Annex II, point 13
Annex H1	Annex II, point 14
Annex MI-001	Annex III
Annex MI-002	Annex IV
Annex MI-003	Annex V
Annex MI-004	Annex VI
Annex MI-005	Annex VII
Annex MI-006	Annex VIII
Annex MI-007	Annex IX
Annex MI-008	Annex X
Annex MI-009	Annex XI
Annex MI-010	Annex XII
—	Annex XIV
—	Annex XV

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/33/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**  
**of 26 February 2014**  
**on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts**  
**(recast)**  
**(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products <sup>(6)</sup> lays down

common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 95/16/EC should be adapted to that Decision.

(4) The lifts covered by this Directive only come into existence as finished products once they have been permanently installed in buildings or constructions. Consequently, lifts cannot be imported into the Union and are only placed on the market and not subsequently made available: there are no 'importers' or 'distributors' of lifts.

(5) This Directive covers safety components for lifts which are new to the Union market when they are placed on the market; that is to say they are either new safety components made by a manufacturer in the Union or new or second-hand safety components imported from a third country.

(6) On 8 June 1995 the Commission adopted Recommendation 95/216/EC of 8 June 1995 concerning improvement of safety of existing lifts <sup>(7)</sup> to the Member States concerning improvement of safety of existing lifts.

(7) This Directive should apply to all forms of supply, including distance selling.

(8) Economic operators should be responsible for the compliance of lifts and safety components for lifts with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety of persons and, where appropriate, the safety of property, and to guarantee fair competition on the Union market.

(9) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only place on the market lifts and make available on the market safety components for lifts which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 213, 7.9.1995, p. 1.

<sup>(4)</sup> See Annex XIII, Part A.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 82.

<sup>(7)</sup> OJ L 134, 20.6.1995, p. 37.



- (10) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (11) The manufacturer and the installer, having detailed knowledge of the design and production process, are best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer or of the installer.
- (12) It is necessary to ensure that safety components for lifts from third countries entering the Union market comply with this Directive, and in particular that the appropriate conformity assessment procedures have been carried out by the manufacturer with regard to those safety components for lifts. Provision should therefore be made for importers to make sure that the safety components for lifts they place on the market comply with the requirements of this Directive and that they do not place on the market safety components for lifts which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of safety components for lifts and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (13) When placing a safety component for lifts on the market, every importer should indicate on the safety component for lifts his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the safety component for lifts does not allow it.
- (14) The distributor makes a safety component for lifts available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the safety component for lifts does not adversely affect the compliance of the safety component for lifts.
- (15) Any economic operator that either places a safety component for lifts on the market under his own name or trade mark or modifies a safety component for lifts in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (16) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the safety components for lifts concerned.
- (17) Ensuring traceability of a safety component for lifts throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant safety components for lifts available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a safety component for lifts or to whom they have supplied a safety component for lifts.
- (18) This Directive should be limited to the expression of the essential health and safety requirements. In order to facilitate conformity assessment for lifts and safety components for lifts with those requirements it is necessary to provide for a presumption of conformity for lifts and safety components for lifts which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation <sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements. The essential health and safety requirements of this Directive will guarantee the intended level of safety only if appropriate conformity assessment procedures ensure compliance therewith.
- (19) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.
- (20) The harmonised standards relevant to this Directive should also take into account the United Nations Convention on the Rights of Persons with Disabilities <sup>(2)</sup>.
- (21) In order to enable economic operators to demonstrate and the competent authorities to ensure that lifts placed on the market and safety components for lifts made available on the market conform to the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
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- <sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.
- <sup>(2)</sup> Approved by Council Decision 2010/48/EC of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities (OJ L 23, 27.1.2010, p. 35).

- (22) The installer or the manufacturer should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a lift or safety component for lifts with this Directive and with other relevant Union harmonisation legislation.
- (23) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (24) The CE marking, indicating the conformity of a lift or safety component for lifts, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (25) The conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (26) Experience has shown that the criteria set out in Directive 95/16/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (27) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive.
- (28) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (29) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (30) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (31) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the lifts and safety components for lifts to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (32) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (33) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (34) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (35) Member States should take all appropriate measures to ensure that safety components for lifts may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Safety components for lifts should be considered as non-compliant with the

essential health and safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

- (36) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to lifts and safety components for lifts covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (37) In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (38) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to lifts or safety components for lifts presenting a risk to the health or safety of persons or where appropriate, to the safety of property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such lifts and safety components for lifts.
- (39) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (40) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (41) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (42) The examination procedure should be used for the adoption of implementing acts with respect to

compliant lifts or safety components for lifts which present a risk to the health or safety of persons or to other aspects of public interest protection.

- (43) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant lifts or safety components for lifts which present a risk to the health or safety of persons, imperative grounds of urgency so require.
- (44) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (45) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (46) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant lifts or safety components for lifts are justified or not.
- (47) The Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (48) Since the objective of this Directive, namely to ensure that lifts and safety components for lifts on the market fulfil the requirements providing for a high level of protection of health and safety while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (49) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market, without the need to comply with further product requirements, of safety components for lifts that have already been placed on the market in accordance with Directive 95/16/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply safety components for lifts that have been

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.

placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

- (50) In order to monitor and ensure the correct implementation and functioning of this Directive, the Commission is invited to submit a report to the European Parliament and to the Council, exploring also the need for a new legislative proposal in this sector.
- (51) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (52) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex XIII, Part B,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

##### Scope

1. This Directive shall apply to lifts permanently serving buildings and constructions and intended for the transport of:

- (a) persons;
- (b) persons and goods;
- (c) goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.

This Directive shall also apply to the safety components for lifts listed in Annex III for use in the lifts referred to in the first subparagraph.

2. This Directive shall not apply to:

- (a) lifting appliances whose speed is not greater than 0,15 m/s;
- (b) construction site hoists;

- (c) cableways, including funicular railways;
- (d) lifts specially designed and constructed for military or police purposes;
- (e) lifting appliances from which work can be carried out;
- (f) mine winding gear;
- (g) lifting appliances intended for lifting performers during artistic performances;
- (h) lifting appliances fitted in means of transport;
- (i) lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery;
- (j) rack and pinion trains;
- (k) escalators and mechanical walkways.

3. Where, for lifts or safety components for lifts, the risks referred to in this Directive are wholly or partly covered by specific Union law, this Directive shall not apply or shall cease to apply in the case of such lifts or safety components for lifts and such risks as from the application of that specific Union law.

##### Article 2

##### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'lift' means a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, or a lifting appliance moving along a fixed course even where it does not move along rigid guides;
- (2) 'carrier' means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered;
- (3) 'model lift' means a representative lift whose technical documentation shows the way in which the essential health and safety requirements set out in Annex I will be met for lifts which conform to the model lift defined by objective parameters and which uses identical safety components for lifts;



- (4) 'making available on the market' means any supply of a safety component for lifts for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (5) 'placing on the market' means:
- the first making available on the market of a safety component for lifts, or
  - the supply of a lift for use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (6) 'installer' means the natural or legal person who takes responsibility for the design, manufacture, installation and placing on the market of the lift;
- (7) 'manufacturer' means any natural or legal person who manufactures a safety component for lifts or has a safety component for lifts designed or manufactured, and markets it under his name or trade mark;
- (8) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from an installer or a manufacturer to act on his behalf in relation to specified tasks;
- (9) 'importer' means any natural or legal person established within the Union who places a safety component for lifts from a third country on the Union market;
- (10) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a safety component for lifts available on the market;
- (11) 'economic operators' means the installer, the manufacturer, the authorised representative, the importer and the distributor;
- (12) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a lift or a safety component for lifts;
- (13) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (14) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (15) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (16) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Directive relating to a lift or a safety component for lifts have been fulfilled;
- (17) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (18) 'recall' in relation to a lift means any measure aimed at achieving the dismantling and safe disposal of a lift, and in relation to a safety component for lifts means any measure aimed at achieving the return of a safety component for lifts that has already been made available to the installer or to the end-user;
- (19) 'withdrawal' means any measure aimed at preventing a safety component for lifts in the supply chain from being made available on the market;
- (20) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (21) 'CE marking' means a marking by which the installer or the manufacturer indicates that the lift or safety component for lifts are in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

### Article 3

#### Free movement

1. Member States shall not prohibit, restrict or impede the placing on the market or putting into service of lifts or the making available on the market of safety components for lifts on their territory which comply with this Directive.
2. At trade fairs, exhibitions or demonstrations Member States shall not prevent the showing of lifts or safety components for lifts which are not in conformity with this Directive, provided that a visible sign clearly indicates that they are not in conformity and will not be placed or made available on the market until they have been brought into conformity. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.
3. This Directive shall not affect Member States' entitlement to lay down in conformity with the Union law such requirements as they may deem necessary to ensure that persons are protected when the lifts in question are put into service or used, provided that this does not mean that the lifts are modified in a way not specified in this Directive.

*Article 4***Placing on the market, making available on the market and putting into service**

1. Member States shall take all appropriate measures to ensure that the lifts covered by this Directive may be placed on the market and put into service only if they comply with this Directive, when properly installed and maintained and used for their intended purpose.

2. Member States shall take all appropriate measures to ensure that safety components for lifts covered by this Directive may be made available on the market and put into service only if they comply with this Directive when properly incorporated and maintained and used for their intended purpose.

*Article 5***Essential health and safety requirements**

1. Lifts covered by this Directive shall satisfy the essential health and safety requirements set out in Annex I.

2. Safety components for lifts covered by this Directive shall satisfy the essential health and safety requirements set out in Annex I and enable the lifts in which they are incorporated to satisfy those requirements.

*Article 6***Buildings or constructions in which lifts are installed**

1. Member States shall take all appropriate measures to ensure that the person responsible for work on the building or construction and the installer both provide each other with the necessary information and take the appropriate steps in order to ensure the proper operation and safe use of the lift.

2. Member States shall take all necessary measures to ensure that shafts intended for lifts do not contain any piping or wiring or fittings other than that necessary for the operation and safety of the lift.

## CHAPTER II

**OBLIGATIONS OF ECONOMIC OPERATORS***Article 7***Obligations of installers**

1. When placing a lift on the market, installers shall ensure that it has been designed, manufactured, installed and tested in accordance with the essential health and safety requirements set out in Annex I.

2. Installers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 16 or have it carried out.

Where compliance of the lift with the applicable essential health and safety requirements has been demonstrated by that procedure, the installer shall draw up an EU declaration of conformity, ensure that it accompanies the lift, and affix the CE marking.

3. The installer shall keep the technical documentation, the EU declaration of conformity and, where applicable, the approval decision(s) for 10 years after the lift has been placed on the market.

4. When deemed appropriate with regard to the risks presented by a lift, installers shall, to protect the health and safety of consumers, investigate, and, if necessary, keep a register of complaints, and of non-conforming lifts.

5. Installers shall ensure that lifts bear a type, batch or serial number or other element allowing their identification.

6. Installers shall indicate, on the lift, their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the installer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Installers shall ensure that the lift is accompanied by the instructions referred to in point 6.2 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State in which the lift is placed on the market. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

8. Installers who consider or have reason to believe that a lift which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that lift into conformity. Furthermore, where the lift presents a risk, installers shall immediately inform the competent national authorities of the Member States in which they placed the lift on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

9. Installers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the lift with this Directive, in a language which can be easily understood by that authority.

They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by lifts which they have placed on the market.

## Article 8

### Obligations of manufacturers

1. When placing their safety components for lifts on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with Article 5(2).

2. Manufacturers shall draw up the required technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15 or have it carried out

Where compliance of a safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity, ensure that it accompanies the safety component for lifts and affix the CE marking.

3. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, where applicable, the approval decision(s) for 10 years after the safety component for lifts has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a safety component for lifts is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a safety component for lifts, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of safety component for lifts made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming safety components for lifts and recalls of the safety components for lifts, and shall keep distributors and installers informed of any such monitoring.

5. Manufacturers shall ensure that safety components for lifts which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the safety component for lifts does not allow it, that the required information is provided on the label referred to in Article 19(1).

6. Manufacturers shall indicate on the safety component for lifts their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the label referred to in Article 19(1). The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1

of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a safety component for lifts which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the safety component for lifts presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the safety components for lifts available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the safety components for lifts with this Directive, in a language which can be easily understood by that authority.

They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have placed on the market.

## Article 9

### Authorised representatives

1. A manufacturer or an installer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 7(1) or in Article 8(1) and the obligation to draw up technical documentation referred to in Article 7(2) or in Article 8(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer or the installer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and, where applicable, the approval decision(s) relating to the manufacturer's or the installer's quality system, and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the safety component for lifts or the lift has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts or the lift;



- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the safety component for lifts or the lift covered by the authorised representative's mandate.

#### Article 10

##### **Obligations of importers**

1. Importers shall place only compliant safety components for lifts on the market.

2. Before placing a safety component for lifts on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the safety component for lifts bears the CE marking and is accompanied by the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a safety component for lifts is not in conformity with Article 5(2), he shall not place the safety component for lifts on the market until it has been brought into conformity. Furthermore, where the safety component for lifts presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the safety component for lifts their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the safety component for lifts. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1 of Annex I in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a safety component for lifts is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements referred to in Article 5(2).

6. When deemed appropriate with regard to the risks presented by a safety component for lifts, importers shall, to protect the health and safety of consumers, carry out sample testing of safety components for lifts made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming safety components for lifts and recalls of safety components for lifts, and shall keep distributors and installers informed of any such monitoring.

7. Importers who consider or have reason to believe that a safety component for lifts which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the safety component for lifts presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the safety component for lifts available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the safety component for lifts has been placed on the market, keep a copy of the EU declaration of conformity and, where applicable, of the approval decision(s) at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a safety component for lifts in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have placed on the market.

#### Article 11

##### **Obligations of distributors**

1. When making a safety component for lifts available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a safety component for lifts available on the market, distributors shall verify that the safety component for lifts bears the CE marking, that it is accompanied by the EU declaration of conformity, by the required documents and by the instructions referred to in point 6.1 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3), respectively.

Where a distributor considers or has reason to believe that a safety component for lifts is not in conformity with Article 5(2), he shall not make the safety component for lifts available on the market until it has been brought into conformity. Furthermore, where the safety component for lifts presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a safety component for lifts is under their responsibility, its storage or transport conditions do not jeopardise its compliance with Article 5(2).

4. Distributors who consider or have reason to believe that a safety component for lifts which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the safety component for lifts presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the safety component for lifts available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a safety component for lifts. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have made available on the market.

#### Article 12

#### Cases in which the obligations of manufacturers apply to importers or distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a safety component for lifts on the market under his name or trade mark or modifies a safety component for lifts already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 13

#### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a safety component for lifts;
- (b) any economic operator to whom they have supplied a safety component for lifts.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with a safety component for lifts and for 10 years after they have supplied a safety component for lifts.

#### CHAPTER III

#### CONFORMITY OF LIFTS AND SAFETY COMPONENTS FOR LIFTS

##### Article 14

#### Presumption of conformity of lifts and safety components for lifts

Lifts and safety components for lifts which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex I covered by those standards or parts thereof.

##### Article 15

#### Conformity assessment procedures for safety components for lifts

Safety components for lifts shall be subject to one of the following conformity assessment procedures:

- (a) the model of the safety component for lifts shall be submitted for EU type examination set out in Annex IV, Part A and the conformity to type shall be ensured with random checking of the safety component for lifts set out in Annex IX;
- (b) the model of the safety component for lifts shall be submitted for EU type examination set out in Annex IV, Part A and be subject to conformity to type based on product quality assurance in accordance with Annex VI;
- (c) conformity based on full quality assurance set out in Annex VII.

##### Article 16

#### Conformity assessment procedures for lifts

1. Lifts shall be subject to one of the following conformity assessment procedures:

- (a) if they are designed and manufactured in accordance with a model lift that has undergone an EU-type examination set out in Annex IV, Part B:
  - (i) final inspection for lifts set out in Annex V;
  - (ii) conformity to type based on product quality assurance for lifts set out in Annex X;
  - (iii) conformity to type based on production quality assurance for lifts set out in Annex XII;

(b) if they are designed and manufactured under a quality system approved in accordance with Annex XI;

(i) final inspection for lifts set out in Annex V;

(ii) conformity to type based on product quality assurance for lifts set out in Annex X;

(iii) conformity to type based on production quality assurance for lifts set out in Annex XII;

(c) conformity based on unit verification for lifts set out in Annex VIII;

(d) conformity based on full quality assurance plus design examination for lifts set out in Annex XI.

2. In the cases referred to in points (a) and (b) of paragraph 1, where the person responsible for the design and manufacture of the lift and the person responsible for the installation and testing of the lift are not the same, the former shall supply to the latter all the necessary documents and information to enable the latter to ensure correct and safe installation and testing of the lift.

3. All permitted variations between the model lift and the lifts forming part of the lifts derived from the model lift shall be clearly specified (with maximum and minimum values) in the technical documentation.

4. By calculation and/or on the basis of design plans it is permitted to demonstrate the similarity of a range of equipment to satisfy the essential health and safety requirements set out in Annex I.

#### Article 17

##### EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential health and safety requirements set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex II, shall contain the elements specified in the relevant Annexes V to XII, and shall be continuously updated. It shall be translated into the language or the languages required by the Member State in which the lift or the safety component for lifts is placed or made available on the market.

3. Where a lift or a safety component for lifts is subject to more than one Union act requiring an EU declaration of

conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the safety component for lifts and the installer shall assume responsibility for the compliance of the lift with the requirements laid down in this Directive.

#### Article 18

##### General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### Article 19

##### Rules and conditions for affixing the CE marking and other markings

1. The CE marking shall be affixed visibly, legibly and indelibly to each lift car and to each safety component for lifts or, where that is not possible, on a label inseparably attached to the safety component for lifts.

2. The CE marking shall be affixed before the lift or the safety component for lifts is placed on the market.

3. The CE marking on lifts shall be followed by the identification number of the notified body involved in any of the following conformity assessment procedures:

(a) the final inspection referred to in Annex V;

(b) unit verification, referred to in Annex VIII;

(c) quality assurance referred to in Annexes X, XI or XII.

4. The CE marking on safety components for lifts shall be followed by the identification number of the notified body involved in any of the following conformity assessment procedures:

(a) product quality assurance referred to in Annex VI;

(b) full quality assurance referred to in Annex VII;

(c) conformity to type with random checking for safety components for lifts referred to in Annex IX.

5. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative or by the installer or his authorised representative.

The CE marking and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

#### CHAPTER IV

#### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

##### Article 20

##### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third party conformity assessment tasks under this Directive.

##### Article 21

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

##### Article 22

##### Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

##### Article 23

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

##### Article 24

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the lifts or safety components for lifts it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of lifts or safety components for lifts which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of lifts or safety components for lifts which they assess, nor the representative of any of those parties.

This shall not preclude the use of assessed lifts or safety components for lifts that are necessary for the operations of the conformity assessment body or the use of such lifts or safety components for lifts for personal purposes.

This does not preclude the possibility of exchange of technical information between the manufacturer or the installer and the body.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those lifts or safety components for lifts, or represent the parties engaged in those activities.

They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes IV to XII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of lifts or safety components for lifts in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities for which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of its relevant national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of the conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.



9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes IV to XII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities, as well as the activities of the Coordination Group of Notified Bodies for Lifts established pursuant to Article 36. Conformity assessment bodies shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 25

##### **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

#### Article 26

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes IV to XII.

#### Article 27

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedure or procedures and the lifts or safety components for lifts for which the body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

#### Article 28

##### **Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment procedure or procedures and the lifts or the safety components for lifts concerned, and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### Article 29

##### Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 30

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

#### Article 31

##### Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention, regarding the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the

basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 42(2).

#### Article 32

##### Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Articles 15 and 16.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of lift or safety component for lifts technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the lifts or the safety components for lifts with this Directive.

3. Where a notified body finds that the essential health and safety requirements of this Directive or corresponding harmonised standards or other technical specifications have not been met by an installer or a manufacturer, it shall require the installer or the manufacturer to take appropriate corrective measures and shall not issue a certificate.

4. Where, in the course of the monitoring of conformity following the issue of a certificate or an approval decision, as appropriate, a notified body finds that a lift or a safety component for lifts no longer complies, it shall require the installer or the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decision(s), as appropriate.



*Article 33***Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

*Article 34***Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same type of lifts or the same safety components for lifts with relevant information on issues relating to negative and, on request, positive conformity assessment results.

*Article 35***Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

*Article 36***Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a Coordination Group of Notified Bodies for Lifts.

Member States shall ensure that the bodies notified by them participate in the work of that Group, directly or by means of designated representatives.

## CHAPTER V

**UNION MARKET SURVEILLANCE CONTROL OF LIFTS OR SAFETY COMPONENTS FOR LIFTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE***Article 37***Union market surveillance and control of lifts or safety components for lifts entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to lifts and safety components for lifts.

*Article 38***Procedure for dealing with lifts or safety components for lifts presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a lift or a safety component for lifts covered by this Directive presents a risk to the health or safety of persons or, where appropriate, to the safety of property, they shall carry out an evaluation in relation to the lift or the safety component for lifts concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that a lift does not comply with the requirements laid down in this Directive, they shall, without delay, require the installer to take all appropriate corrective actions to bring the lift into compliance with those requirements within a reasonable period commensurate with the nature of the risk, as they may prescribe.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that a safety component for lifts does not comply with the requirements laid down in this Directive, they shall, without delay, require the relevant economic operator to take all appropriate corrective actions to bring the safety component for lifts into compliance with those requirements, to withdraw the safety component for lifts from the market or to recall it within a reasonable period commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second and third subparagraph of this paragraph.

2. Where the market surveillance authorities consider that the non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the lifts and safety components for lifts concerned that it has placed or made available on the market throughout the Union.

4. Where the installer does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to restrict or prohibit the placing on their national market or the use of the lift concerned, or to recall it.

Where the relevant economic operator does not take adequate corrective action within the period referred to in the third subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the safety component for lifts being made available on their national market, to withdraw the safety component for lifts from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the third subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant lift or safety component for lifts, their origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operators. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the lift or the safety component for lifts to meet the essential health and safety requirements of this Directive; or
- (b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall, without delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the lift or the safety component for lifts concerned and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the third subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of a safety component for lifts

from the market, are taken, in respect of the lift or the safety component for lifts concerned, without delay.

#### Article 39

##### Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall, without delay, enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure relating to a lift is considered justified, all Member States shall take the measures necessary to ensure that the placing on the market or use of the non-compliant lift concerned is restricted or prohibited, or that the lift is recalled.

If the national measure relating to a safety component for lifts is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant safety component for lifts is withdrawn from their market.

The Member States shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the lift or the safety component for lifts is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 40

##### Compliant lifts or safety components for lifts which present a risk

1. Where, having carried out an evaluation under Article 38(1), a Member State finds that although a lift is in compliance with this Directive, it presents a risk to the health or safety of persons and, where appropriate, the safety of property, it shall require the installer to take all appropriate measures to ensure that the lift concerned no longer presents that risk or to recall the lift or restrict or prohibit its use within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

Where, having carried out an evaluation under Article 38(1), a Member State finds that, although a safety component for lifts is in compliance with this Directive, it presents a risk to the health or safety of persons and, where appropriate, the safety of property, it shall require the relevant economic operator to take all appropriate measures to ensure that the safety component for lifts concerned, when placed on the market, no longer presents that risk, to withdraw the safety component for lifts from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the lifts or safety components for lifts concerned that he has placed or made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the lifts or safety components for lifts concerned, the origin and the supply chain of the lifts or safety components for lifts, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 42(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 41

##### Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 19 of this Directive;

- (b) the CE marking has not been affixed;
- (c) the identification number of the notified body has been affixed in violation of Article 19 or has not been affixed, where required by Article 19;
- (d) the EU declaration of conformity has not been drawn up;
- (e) the EU declaration of conformity has not been drawn up correctly;
- (f) the technical documentation referred to in Annex IV, Parts A and B, and Annexes VII, VIII and XI is either not available or not complete;
- (g) the name, registered trade name or registered trade mark or the address of the installer, manufacturer or importer has not been indicated in compliance with Article 7(6), Article 8(6) or Article 10(3);
- (h) the information allowing identification of the lift or the safety component for lifts has not been indicated in compliance with Article 7(5) or Article 8(5);
- (i) the lift or the safety component for lifts is not accompanied by the documents referred to in Article 7(7) or Article 8(7) or those documents are not in compliance with the applicable requirements.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the use of the lift or to recall it, or to restrict or prohibit the making available on the market of the safety component for lifts or ensure that it is recalled or withdrawn from the market.

#### CHAPTER VI

##### COMMITTEE PROCEDURE, TRANSITIONAL AND FINAL PROVISIONS

#### Article 42

##### Committee procedure

1. The Commission shall be assisted by the Lifts Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 43

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 44

##### Transitional provisions

Member States shall not impede the putting into service of lifts or the making available on the market of safety components for lifts covered by Directive 95/16/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates and decisions issued by notified bodies under Directive 95/16/EC shall be valid under this Directive.

#### Article 45

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 4 to 21 of Article 2, Articles 7 to 14, 17 and 18, Article 19(5), Articles 20 to 44, Article 45(1), Articles 47 and 48 and Annex II, Part A points (f), (k), (l), (m), Annex II, Part B points (e), (k), (l) and (m), Annex IV, Part A points 2(e), 3(c), 3(d), 3(f), points 4(b) to (e), points 5 to 9, Annex IV, Part B points 2(e), 3(c), 3(e), 3(h), points 4(c) to (e), point 6 paragraphs 2, 3 and 4, points 7 to 10, Annex V, point 3.2(b), points 5 and 6, Annex VI, points 3.1(a), (b) and (c), point 3.3 paragraphs 4 and 5, point 4.3, point 7, Annex VII, points 3.1(a), (b), (d) and (f), point 3.3, point 4.2, point 7, Annex VIII, point 3(c), (e) and (h) and point 4, Annex IX, points 3(a) to (d), Annex X, points

3.1(a), 3.1(e), point 3.4, point 6, Annex XI, points 3.1(a), (b), (c), and (e), point 3.3.4 and 3.3.5, points 3.4 and 3.5, point 5(b), point 6, Annex XII, point 3.1(a), point 3.3 and point 6. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 46

##### Review

1. Before 19 April 2018 the Commission shall submit a report to the European Parliament and the Council regarding the implementation and functioning of this Directive.

2. The report shall be based on a consultation of relevant stakeholders.

3. The report shall be accompanied, where appropriate, by a proposal for revision of this Directive.

#### Article 47

##### Repeal

Directive 95/16/EC, as amended by the acts listed in Annex XIII, Part A, is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directives set out in Annex XIII, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XIV.

#### Article 48

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, points 1 to 4 of Article 2, Articles 3 to 6, 15 and 16, Article 19(1) to (4), Article 44, Article 45(2), Article 49 and Annex I, Annex II, Part A, points (a) to (e) and (g) to (j), Annex II, Part B, points (a), (c), (d) and (f) to (j), Annex III, Annex IV, Part A, point 1, point 2(a) to (d), point 3(a) and (b), (e),(g) and (h), point 4(a) and point 10, Annex IV, Part B, point 1, point 2(a) to (d), point 3(a), (b), (d), (f), (g), (i) and (j), point 4(a) and (b), point 6, paragraph 1, point 11, Annex V, points 1 to 3.1, point 3.2(a), points 3.3 to 4, Annex VI, points 1 and 2, point 3.1(d) to (f), point 3.2, point 3.3 paragraphs 1 to 3, points 3.4 to 4.2, point 6, Annex VII, points 1 and 2, point 3.1(c) and (e), point 3.2, point 3.4, point 4.1, points 4.3 to 6, Annex VIII, points 1 and 2, point 3(a), (b), (f), (g) and (i), point 6, Annex IX, points 1 and 2, points 4 to 6, Annex X, points 1 and 2, point 3.1(b), (c) and (d), points 3.2 and 3.3, points 4 and 5, Annex XI, points 1 and 2, point 3.1(d), point 3.2, point 3.3.1, point 4, point 5(a), (c) and (d), Annex XII, points 1 and 2, points 3.1(b), (c) and (d), point 3.2, point 3.4, points 4 and 5 shall apply from 19 April 2016.

#### *Article 49*

#### **Addressees**

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

D. KOURKOULAS

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## ANNEX I

## ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

## PRELIMINARY REMARKS

1. Obligations under essential health and safety requirements apply only where the corresponding risk exists for the lift or safety component for lifts in question when used as intended by the installer or the manufacturer.
2. The essential health and safety requirements contained in the Directive are imperatives. However, given the present state of the art, the objectives which they lay down may not be attainable. In such cases, and to the greatest extent possible, the lift or safety components for lifts must be designed and constructed in such a way as to approximate to those objectives.
3. The manufacturer and the installer are under an obligation to carry out a risk assessment in order to identify all the risks which apply to their products; they must then design and construct them taking account of the assessment.

1. **General**

- 1.1. *Application of Directive 2006/42/EC*

Where the relevant risk exists and is not dealt with in this Annex, the essential health and safety requirements of Annex I to Directive 2006/42/EC of the European Parliament and of the Council <sup>(1)</sup> apply. The essential health and safety requirements of point 1.1.2 of Annex I to Directive 2006/42/EC apply in any event.

- 1.2. *Carrier*

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.

- 1.3. *Means of suspension and means of support*

The means of suspension and/or support of the car, its attachments and any terminal parts thereof must be selected and designed so as to ensure an adequate level of overall safety and to minimize the risk of the car falling, taking into account the conditions of use, the materials used and the conditions of manufacture.

Where ropes or chains are used to suspend the car, there must be at least two independent cables or chains, each with its own anchorage system. Such ropes and chains must have no joins or splices except where necessary for fixing or forming a loop.

- 1.4. *Control of loading (including overspeed)*

- 1.4.1. Lifts must be so designed, constructed and installed as to prevent normal starting if the rated load is exceeded.

- 1.4.2. Lifts must be equipped with an overspeed governor.

These requirements do not apply to lifts in which the design of the drive system prevents overspeed.

- 1.4.3. Fast lifts must be equipped with a speed-monitoring and speed-limiting device.

- 1.4.4. Lifts driven by friction pulleys must be designed so as to ensure stability of the traction cables on the pulley.

- 1.5. *Machinery*

- 1.5.1. All passenger lifts must have their own individual lift machinery. This requirement does not apply to lifts in which the counterweights are replaced by a second car.

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<sup>(1)</sup> OJ L 157, 9.6.2006, p. 24.



- 1.5.2. The installer must ensure that the lift machinery and the associated devices of a lift are not accessible except for maintenance and in emergencies.

1.6. *Controls*

- 1.6.1. The controls of lifts intended for use by unaccompanied disabled persons must be designed and located accordingly.

- 1.6.2. The function of the controls must be clearly indicated.

- 1.6.3. The call circuits of a group of lifts may be shared or interconnected.

- 1.6.4. Electrical equipment must be so installed and connected that:

- (a) there can be no possible confusion with circuits which do not have any direct connection with the lift;
- (b) the power supply can be switched while on load;
- (c) movements of the lift are dependent on electrical safety devices in a separate electrical safety circuit;
- (d) a fault in the electrical installation does not give rise to a dangerous situation.

2. **Risks for persons outside the car**

- 2.1. The lift must be designed and constructed to ensure that the space in which the car travels is inaccessible except for maintenance or in emergencies. Before a person enters that space, normal use of the lift must be made impossible.
- 2.2. The lift must be designed and constructed to prevent the risk of crushing when the car is in one of its extreme positions.

The objective will be achieved by means of free space or refuge beyond the extreme positions.

However, in specific cases, in affording Member States the possibility of giving prior approval, particularly in existing buildings, where this solution is impossible to fulfil, other appropriate means may be provided to avoid this risk.

- 2.3. The landings at the entrance and exit of the car must be equipped with landing doors of adequate mechanical resistance for the conditions of use envisaged.

An interlocking device must prevent during normal operation:

- (a) starting movement of the car, whether or not deliberately activated, unless all landing doors are shut and locked;
- (b) the opening of a landing door when the car is still moving and outside a prescribed landing zone.

However, all landing movements with the doors open shall be allowed in specified zones on condition that the levelling speed is controlled.

3. **Risks for persons in the car**

- 3.1. Lift cars must be completely enclosed by full-length walls, fitted floors and ceilings included, with the exception of ventilation apertures, and with full-length doors. These doors must be so designed and installed that the car cannot move, except for the landing movements referred to in the third subparagraph of point 2.3, unless the doors are closed, and comes to a halt if the doors are opened.

The doors of the car must remain closed and interlocked if the lift stops between two levels where there is a risk of a fall between the car and the shaft or if there is no shaft.



- 3.2. In the event of a power cut or failure of components the lift must have devices to prevent free fall or uncontrolled movements of the car.

The device preventing the free fall of the car must be independent of the means of suspension of the car.

This device must be able to stop the car at its rated load and at the maximum speed anticipated by the installer. Any stop occasioned by this device must not cause deceleration harmful to the occupants whatever the load conditions.

- 3.3. Buffers must be installed between the bottom of the shaft and the floor of the car.

In this case, the free space referred to in point 2.2 must be measured with the buffers totally compressed.

This requirement does not apply to lifts in which the car cannot enter the free space referred to in point 2.2 by reason of the design of the drive system.

- 3.4. Lifts must be so designed and constructed as to make it impossible for them to be set in motion if the device provided for in point 3.2 is not in an operational position.

#### 4. **Other risks**

- 4.1. The landing doors and car doors or the two doors together, where motorized, must be fitted with a device to prevent the risk of crushing when they are moving.
- 4.2. Landing doors, where they have to contribute to the protection of the building against fire, including those with glass parts, must be suitably resistant to fire in terms of their integrity and their properties with regard to insulation (containment of flames) and the transmission of heat (thermal radiation).
- 4.3. Counterweights must be so installed as to avoid any risk of colliding with or falling on to the car.
- 4.4. Lifts must be equipped with means enabling people trapped in the car to be released and evacuated.
- 4.5. Cars must be fitted with two-way means of communication allowing permanent contact with a rescue service.
- 4.6. Lifts must be so designed and constructed that, in the event of the temperature in the lift machine exceeding the maximum set by the installer, they can complete movements in progress but refuse new commands.
- 4.7. Cars must be designed and constructed to ensure sufficient ventilation for passengers, even in the event of a prolonged stoppage.
- 4.8. The car should be adequately lit whenever in use or whenever a door is opened; there must also be emergency lighting.
- 4.9. The means of communication referred to in point 4.5 and the emergency lighting referred to in point 4.8 must be designed and constructed so as to function even without the normal power supply. Their period of operation should be long enough to allow normal operation of the rescue procedure.
- 4.10. The control circuits of lifts which may be used in the event of fire must be designed and manufactured so that lifts may be prevented from stopping at certain levels and allow for priority control of the lift by rescue teams.

#### 5. **Marking**

- 5.1. In addition to the minimum particulars required for any machine pursuant to point 1.7.3 of Annex I to Directive 2006/42/EC, each car must bear an easily visible plate clearly showing the rated load in kilograms and the maximum number of passengers which may be carried.
- 5.2. If the lift is designed to allow people trapped in the car to escape without outside help, the relevant instructions must be clear and visible in the car.

6. **Instructions**

6.1. The safety components for lifts referred to in Annex III must be accompanied by instructions, so the following can be carried out effectively and without danger:

- (a) assembly;
- (b) connection;
- (c) adjustment;
- (d) maintenance.

6.2. Each lift must be accompanied by instructions. The instructions shall contain at least the following documents:

- (a) instructions containing the plans and diagrams necessary for normal use and relating to maintenance, inspection, repair, periodic checks and the rescue operations referred to in point 4.4;
  - (b) a logbook in which repairs and, where appropriate, periodic checks can be noted.
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## ANNEX II

## A. CONTENT OF THE EU DECLARATION OF CONFORMITY FOR SAFETY COMPONENTS FOR LIFTS

The EU declaration of conformity for safety components for lifts shall contain the following information:

- (a) business name and address of the manufacturer;
- (b) where appropriate, business name and address of the authorised representative;
- (c) description of the safety component for lifts, details of type or series and serial number (if any); it may, where necessary for the identification of the safety component for lifts, include an image;
- (d) safety function of the safety component for lifts, if not obvious from the description;
- (e) year of manufacture of the safety component for lifts;
- (f) all relevant provisions with which the safety component for lifts complies;
- (g) a statement that the safety component for lifts is in conformity with the relevant Union harmonisation legislation;
- (h) where appropriate, reference(s) to harmonised standard(s) used;
- (i) where appropriate, the name, address and identification number of the notified body which carried out the EU-type examination of safety components for lifts set out in Annex IV, Part A and Annex VI, and the reference of the EU-type examination certificate issued by that notified body;
- (j) where appropriate, the name, address and identification number of the notified body which carried out the conformity to type with random checking for safety components for lifts set out in Annex IX;
- (k) where appropriate, the name, address and identification number of the notified body which approved the quality system operated by the manufacturer in accordance with the conformity assessment procedure set out in Annex VI or VII;
- (l) the name and function of the person empowered to sign the declaration on behalf of the manufacturer or his authorised representative;
- (m) place and date of signature;
- (n) signature.

## B. CONTENT OF THE EU DECLARATION OF CONFORMITY FOR LIFTS

The EU declaration of conformity for lifts shall be drafted in the same language as the instructions referred to in Annex I, point 6.2 and contain the following information:

- (a) business name and address of the installer;
- (b) where appropriate, business name and address of the authorised representative;
- (c) description of the lift, details of the type or series, serial number and address where the lift is installed;
- (d) year of installation of the lift;
- (e) all relevant provisions to which the lift conforms;
- (f) a statement that the lift is in conformity with the relevant Union harmonisation legislation;
- (g) where appropriate, reference(s) to harmonised standard(s) used;

- (h) where appropriate, the name, address and identification number of the notified body which carried out the EU-type examination of lifts set out in Annex IV, Part B and the reference of the EU-type examination certificate issued by that notified body;
  - (i) where appropriate, the name, address and identification number of the notified body which carried out the unit verification for lifts set out in Annex VIII;
  - (j) where appropriate, the name, address and identification number of the notified body which carried out the final inspection for lifts set out in Annex V;
  - (k) where appropriate, the name, address, and identification number of the notified body which approved the quality assurance system operated by the installer in accordance with the conformity assessment procedure set out in Annex X, XI or XII;
  - (l) the name and function of the person empowered to sign the declaration on behalf of the installer or his authorised representative;
  - (m) place and date of signature;
  - (n) signature.
-

*ANNEX III*

## LIST OF SAFETY COMPONENTS FOR LIFTS

1. Devices for locking landing doors.
  2. Devices to prevent falls referred to in point 3.2 of Annex I to prevent the car from falling or uncontrolled movements.
  3. Overspeed limitation devices.
  4. (a) Energy-accumulating buffers:
    - (i) non-linear, or
    - (ii) with damping of the return movement.
  - (b) Energy-dissipating buffers.
  5. Safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls.
  6. Electric safety devices in the form of safety circuits containing electronic components.
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## ANNEX IV

## EU-TYPE EXAMINATION FOR LIFTS AND SAFETY COMPONENTS FOR LIFTS

(module B)

**A. EU-type examination of safety components for lifts**

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a safety component for lifts and verifies and attests that the technical design of the safety component for lifts satisfies the applicable essential health and safety requirements of Annex I and will enable a lift in which it is correctly incorporated to satisfy those requirements.
2. The application for EU-type examination shall be lodged by the manufacturer, or his authorised representative, with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well and the place of manufacture of the safety components for lifts;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) the technical documentation;
  - (d) a representative specimen of the safety component for lifts or details of the place where it can be examined. The notified body may request further specimens if needed for carrying out the test programme;
  - (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents, including other relevant technical specifications, that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
3. The technical documentation shall make it possible to assess whether the safety component for lifts meets the conditions referred to in point 1 and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the safety component for lifts.

The technical documentation shall contain, where applicable, the following:

- (a) a description of the safety component for lifts, including its area of use (in particular possible limits on speed, load and power) and conditions (in particular explosive environments and exposure to the elements);
- (b) design and manufacturing drawings and diagrams;
- (c) explanations necessary for the understanding of those drawings and diagrams and the operation of the safety component for lifts;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to enable the safety component for lifts to meet the conditions referred to in point 1, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations performed by or for the manufacturer;
- (f) test reports;

- (g) a copy of the instructions for the safety components for lifts;
- (h) steps taken at the manufacturing stage to ensure that series-produced safety components for lifts conform to the safety component for lifts examined.

4. The notified body shall:

- (a) examine the technical documentation and the supporting evidence to assess the adequacy of the technical design of the safety component for lifts;
- (b) agree with the applicant on a location where the examinations and tests will be carried out;
- (c) verify that the representative specimen(s) has(have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
- (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the specifications of the relevant harmonised standards, these have been applied correctly;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications enable the safety component for lifts to meet the conditions referred to in point 1.

The notified body shall draw up an evaluation report that records the examinations, verifications and tests carried out and their outcome. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

5. Where the type of the safety component for lifts meets the conditions referred to in point 1, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured safety components for lifts with the examined type to be evaluated and to allow for in-service control.

Where the type of the safety component for lifts does not satisfy the conditions referred to in point 1, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical documentation and the evaluation report, for 15 years from the date of issue of that certificate.

6. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer meet the conditions referred to in point 1 and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
7. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of any modification to the approved type that may affect the conformity of the safety component for lifts with the conditions referred to in point 1 or the conditions of validity of the EU-type examination certificate.

The notified body shall examine the modification and inform the applicant whether the EU-type examination certificate remains valid or whether further examinations, verifications or tests are needed. As appropriate, the notified body shall issue an addition to the original EU-type examination certificate or ask for a new application for an EU-type examination to be submitted.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

9. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the report on the examinations, verifications and tests carried out by the notified body.
10. The manufacturer shall keep with the technical documentation a copy of EU-type examination certificates, its annexes and additions at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market.
11. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in point 2 and fulfil the obligations set out in points 7 and 10, provided that they are specified in the mandate.

#### **B. EU-type examination of lifts**

1. EU-type examination of lifts is the part of a conformity assessment procedure in which a notified body examines the technical design of a model lift, or a lift for which there is no provision for an extension or variant, and verifies and attests that the technical design of the model lift or the lift meets the applicable essential health and safety requirements set out in Annex I.

EU-type examination of a lift includes an examination of a representative specimen of a complete lift.

2. The application for EU-type examination shall be lodged by the installer or his authorised representative with a single notified body of his choice.

The application shall include:

- (a) the name and address of the installer; and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) the technical documentation;
  - (d) details of the place where the specimen lift can be examined. The specimen lift submitted for examination shall include the terminal parts and be capable of serving at least three levels (top, middle and bottom);
  - (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents, including other relevant technical specifications that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the installer, or by another testing laboratory on his behalf and under his responsibility.
3. The technical documentation shall make it possible to assess the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.

The technical documentation shall contain, where applicable, the following:

- (a) a description of the model lift indicating clearly all the permitted variations of the model lift;
- (b) design and manufacturing drawings and diagrams;



- (c) explanations necessary for the understanding of those drawings and diagrams and of the operation of the lift;
  - (d) a list of the essential health and safety requirements taken into consideration;
  - (e) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
  - (f) a copy of the EU declarations of conformity of the safety components for lifts incorporated in the lift;
  - (g) results of design calculations performed by or for the installer;
  - (h) test reports;
  - (i) a copy of the instructions referred to in point 6.2 of Annex I;
  - (j) steps taken at the installation stage to ensure that the series-produced lift conforms to the essential health and safety requirements set out in Annex I.
4. The notified body shall:
- (a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the model lift or of the lift for which there is no provision for an extension or variant;
  - (b) agree with the installer on a location where the examinations and tests will be carried out;
  - (c) examine the specimen lift to check that it has been manufactured in accordance with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
  - (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the installer has chosen to apply the specifications of the relevant harmonised standards, these have been applied correctly;
  - (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards have not been applied, the solutions adopted by the installer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive.
5. The notified body shall draw up an evaluation report that records the examinations, verifications and tests carried out and their outcome. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the installer.
6. Where the type meets the essential health and safety requirements set out in Annex I applicable to the lift concerned, the notified body shall issue an EU-type examination certificate to the installer. That certificate shall contain the name and address of the installer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all the information necessary to enable the conformity of lifts with the approved type to be assessed during the final inspection.

Where the type does not comply with the essential health and safety requirements set out in Annex I, the notified body shall refuse to issue an EU-type examination certificate and shall inform the installer accordingly, giving detailed reasons for its refusal.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical documentation and the evaluation report for 15 years from the date of issue of that certificate.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the essential health and safety requirements set out in Annex I, and shall determine whether such changes require further investigation. If so, the notified body shall inform the installer accordingly.
8. The installer shall inform the notified body of any modifications to the approved type, including variations not specified in the original technical documentation, that may affect the conformity of the lift with the essential health and safety requirements set out in Annex I or the conditions of validity of the EU-type examination certificate.

The notified body shall examine the modification and inform the installer whether the EU-type examination certificate remains valid or whether further examinations, verifications or tests are needed. As appropriate the notified body shall issue an addition to the original EU-type examination certificate or ask for a new application for an EU-type examination to be submitted.

9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and additions thereto which it has issued.

10. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the report on the examinations, verifications and tests carried out by the notified body.
11. The installer shall keep with the technical documentation a copy of the EU-type examination certificate, including its annexes and additions, at the disposal of the national authorities for 10 years after the lift has been placed on the market.
12. Authorised representative

The installer's authorised representative may lodge the application referred to in point 2 and fulfil the obligations set out in points 8 and 11, provided that they are specified in the mandate.

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## ANNEX V

## FINAL INSPECTION FOR LIFTS

1. Final inspection is the part of a conformity assessment procedure whereby a notified body ascertains and certifies that a lift subject to an EU-type examination certificate or designed and manufactured according to an approved quality system satisfies the essential health and safety requirements set out in Annex I.

2. **Obligations of the installer**

The installer shall take all measures necessary to ensure that the lift being installed complies with the applicable essential health and safety requirements set out in Annex I and with one of the following:

- (a) an approved type described in an EU-type examination certificate;
- (b) a lift designed and manufactured in accordance with a quality system pursuant to Annex XI and the EU design examination certificate if the design is not wholly in accordance with the harmonised standards.

3. **Final inspection**

A notified body chosen by the installer shall carry out the final inspection of the lift about to be placed on the market in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.

- 3.1. The installer shall lodge an application for final inspection with a single notified body of his choice and shall provide to the notified body the following documents:

- (a) the plan of the complete lift;
- (b) the plans and diagrams necessary for final inspection, in particular control circuit diagrams;
- (c) a copy of the instructions referred to in Annex I, point 6.2;
- (d) a written declaration that the same application has not been lodged with any other notified body.

The notified body may not require detailed plans or precise information not necessary for verifying the conformity of the lift.

The appropriate examinations and tests set out in the relevant harmonised standard(s) or equivalent tests shall be carried out in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.

- 3.2. The examinations shall include at least one of the following:

- (a) examination of the documents referred to in point 3.1 to check that the lift conforms with the approved type described in the EU-type examination certificate pursuant to Annex IV, Part B;
- (b) examination of the documents referred to in point 3.1 to check that the lift conforms with the lift designed and manufactured in accordance with an approved quality system pursuant to Annex XI and if the design is not wholly in accordance with the harmonised standards, with the EU design examination certificate.

- 3.3. The tests of the lift shall include at least the following:

- (a) operation of the lift both empty and at maximum load to ensure correct installation and operation of the safety devices (end stops, locking devices, etc.);
- (b) operation of the lift at both maximum load and empty to ensure the correct functioning of the safety devices in the event of loss of power;
- (c) static test with a load equal to 1,25 times the rated load.

The rated load shall be that referred to in Annex I, point 5.

After these tests, the notified body shall check that no distortion or deterioration which could impair the use of the lift has occurred.

4. If the lift satisfies the essential health and safety requirements set out in Annex I, the notified body shall affix or have affixed its identification number adjacent to the CE marking in accordance with Articles 18 and 19 and shall issue a final inspection certificate which mentions the examinations and tests carried out.

The notified body shall fill in the corresponding pages in the logbook referred to in Annex I, point 6.2.

If the notified body refuses to issue the final inspection certificate, it shall state the detailed reasons for refusal and indicate the necessary corrective measures to be taken. Where the installer again applies for final inspection, he shall apply to the same notified body.

#### **5. CE marking and EU declaration of conformity**

- 5.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.
- 5.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity and the final inspection certificate at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
6. The Commission and the Member States may obtain a copy of the final inspection certificate on request.

#### **7. Authorised representative**

The installer's obligations set out in points 3.1 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX VI

CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE FOR SAFETY COMPONENTS FOR LIFTS  
(module E)

1. Conformity to type based on product quality assurance for safety components for lifts is the part of the conformity assessment procedure whereby a notified body assesses the quality system of a manufacturer in order to ensure that the safety components for lifts are manufactured and monitored in conformity with the type described in the EU-type examination certificate, satisfy the applicable requirements of Annex I and will enable a lift to which they are correctly incorporated to satisfy those requirements.

2. **Obligations of the manufacturer**

The manufacturer shall operate an approved quality system for final inspection and testing of the safety components for lifts as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system for the safety components for lifts concerned with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the address of the premises where final inspection and testing of the safety components for lifts are carried out;
- (d) all relevant information on the safety components for lifts to be manufactured;
- (e) the documentation concerning the quality system;
- (f) the technical documentation of the approved safety components for lifts and a copy of the EU-type examination certificate.

- 3.2. Under the quality system, each safety component for lifts shall be inspected and appropriate tests as set out in the relevant harmonised standards or equivalent tests shall be carried out in order to ensure that it meets the conditions referred to in point 1. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- (a) the quality objectives;
- (b) the organizational structure, responsibilities and powers of the management with regard to product quality;
- (c) the examinations and tests that will be carried out after manufacture;
- (d) the means of monitoring the effective operation of the quality system; and
- (e) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I.

The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1(f), in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the safety components for lifts with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer or his authorised representative shall keep the notified body which has approved the quality system informed of any intended changes of the quality system.

The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall for assessment purposes allow the notified body access to the premises where final inspection, testing and storage are carried out and provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the technical documentation;
  - (c) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.
- 4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. Additionally, the notified body may pay unexpected visits to the manufacturer's premises where final inspection and testing of safety components for lifts are carried out.

At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer, with a visit report and, if a test has been carried out, with a test report.

#### **5. CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each safety component for lifts and keep a copy of it at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market. The EU declaration of conformity shall identify the safety component for lifts for which it has been drawn up.

6. The manufacturer shall for a period ending 10 years after the safety component for lifts has been placed on the market, keep at the disposal of the national authorities:

- (a) the technical documentation referred to in point 3.1(f);
- (b) the documentation referred to in point 3.1(e);
- (c) the information relating to the change referred to in point 3.5;
- (d) the decisions and reports from the notified body which are referred to in the third paragraph of point 3.5 and in points 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decision(s) which it has refused, suspended or withdrawn and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX VII

## CONFORMITY BASED ON FULL QUALITY ASSURANCE FOR SAFETY COMPONENTS FOR LIFTS

(module H)

1. Conformity based on full quality assurance for safety components for lifts is the conformity assessment procedure whereby a notified body assesses the quality system of a manufacturer to ensure that the safety components for lifts are designed, manufactured, inspected and tested in order to satisfy the applicable requirements of Annex I and to enable a lift to which they are correctly incorporated to satisfy those requirements.

2. **Obligations of the manufacturer**

The manufacturer shall operate an approved quality system for the design, manufacture, final inspection and testing of safety components for lifts as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice. The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) the address of the premises where the safety components for lifts are designed, manufactured, inspected and tested;
- (c) all relevant information on safety components for lifts to be manufactured;
- (d) the technical documentation described in point 3 of Annex IV, Part A for one model of each category of safety component for lifts to be manufactured;
- (e) the documentation on the quality system;
- (f) a written declaration that the same application has not been lodged with any other notified body.

- 3.2. The quality system shall ensure compliance of the safety components for lifts with the conditions referred to in point 1. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- (a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and product quality;
- (b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the safety components for lifts;
- (d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1(d) to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex I and to carry out the necessary examinations with a view to ensuring compliance of the safety components for lifts with those requirements.

The decision shall be notified to the manufacturer and, where appropriate, to his authorised representative. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and maintain it so that it remains adequate and efficient.

- 3.5. The manufacturer shall keep the notified body which has approved the quality system informed of any intended change to the quality system.

The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall for assessment purposes allow the notified body access to the design, manufacture, inspection and testing, and storage locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records provided for in the design part of the quality system such as results of analyses, calculations, tests;

(c) the technical documentation for the safety components for lifts manufactured;

(d) the quality records provided for in the manufacturing part of the full quality system, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.

- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

- 4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**5. CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each safety component for lifts and keep a copy of it at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market. The EU declaration of conformity shall identify the safety component for lifts for which it has been drawn up.
6. The manufacturer shall, for a period ending 10 years after the safety component for lifts has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1(e);
  - (b) the technical documentation referred to in point 3.1(d);
  - (c) the information relating to the change referred to in the first paragraph of point 3.5;
  - (d) the decisions and reports from the notified body referred to in the third paragraph of point 3.5. and in points 4.3 and 4.4.
7. Each notified body shall inform its notifying authority of quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decisions which it has refused, suspended or withdrawn and, upon request, of approval decisions which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

The notified body shall keep a copy of the approval decision issued, its annexes and additions, as well as the technical documentation for 15 years from the date of their issue.

**8. Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX VIII

## CONFORMITY BASED ON UNIT VERIFICATION FOR LIFTS

(module G)

1. Conformity based on unit verification is the conformity assessment procedure whereby a notified body assesses whether a lift complies with the applicable essential health and safety requirements set out in Annex I.
2. **Obligations of the installer**
  - 2.1. The installer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the lift with the applicable essential health and safety requirements set out in Annex I.
  - 2.2. The installer shall apply to a single notified body of his choice for unit verification.

The application shall contain:

- (a) the name and address of the installer, and if the application is lodged by the authorised representative, his name and address as well;
  - (b) the location where the lift is installed;
  - (c) a written declaration to the effect that a similar application has not been lodged with another notified body;
  - (d) the technical documentation.
3. The technical documentation shall allow an assessment of the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.

The technical documentation shall contain at least the following elements:

- (a) a description of the lift;
  - (b) design and manufacturing drawings and diagrams;
  - (c) explanations necessary for the understanding of those drawings and diagrams and of the operation of the lift;
  - (d) a list of the essential health and safety requirements taken into consideration;
  - (e) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
  - (f) a copy of the EU-type examination certificates of the safety components for lifts incorporated in the lift;
  - (g) results of design calculations performed by or for the installer;
  - (h) test reports;
  - (i) a copy of the instructions referred to in point 6.2 of Annex I.
4. **Verification**

The notified body chosen by the installer shall examine the technical documentation and the lift and carry out the appropriate tests as set out in the relevant harmonised standard(s), or equivalent tests, to check its conformity with the applicable essential health and safety requirements set out in Annex I. The tests shall include at least the tests referred to in point 3.3 of Annex V.

If the lift meets the essential health and safety requirements set out in Annex I the notified body shall issue a certificate of conformity relating to the tests carried out.

The notified body shall fill in the corresponding pages of the logbook referred to in point 6.2 of Annex I.

If the notified body refuses to issue the certificate of conformity, it shall state in detail its reasons for refusal and indicate the necessary corrective measures to be taken. When the installer reapplies for unit verification he shall apply to the same notified body.

On request, the notified body shall provide the Commission and the Member States with a copy of the certificate of conformity.

**5. CE marking and EU declaration of conformity**

- 5.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 2.2, the latter's identification number adjacent to the CE marking in the car of each lift.
- 5.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
6. The installer shall keep with the technical documentation a copy of the certificate of conformity at the disposal of the national authorities for 10 years from the date on which the lift is placed on the market.

**7. Authorised representative**

The installer's obligations set out in points 2.2 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX IX

## CONFORMITY TO TYPE WITH RANDOM CHECKING FOR SAFETY COMPONENTS FOR LIFTS

(module C 2)

1. Conformity to type with random checking is the part of the conformity assessment procedure whereby a notified body carries out checks on safety components for lifts to ensure that they are in conformity with the approved type as described in the EU type examination certificate and satisfy the applicable requirements of Annex I and will enable a lift in which they are correctly incorporated to satisfy those requirements.

2. **Manufacturing**

The manufacturer shall take all measures necessary to ensure that the manufacturing process and its monitoring ensure that the manufactured safety components for lifts meet the conditions referred to in point 1.

3. The manufacturer shall lodge an application for random checking with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) all relevant information on the safety components for lifts manufactured;
  - (d) the address of the premises where the sample of the safety components for lifts can be taken.
4. The notified body shall carry out or have carried out checks on safety components for lifts at random intervals. An adequate sample of the final safety components for lifts, taken on site by the notified body, shall be examined and appropriate tests set out in the relevant harmonised standards, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check whether the safety components for lifts meets the conditions referred to in point 1. In cases where one or more of the safety components for lifts checked do not conform, the notified body shall take appropriate measures.

The points to be taken into account when checking the safety components for lifts will be defined by joint agreement between all the notified bodies responsible for this procedure, taking into consideration the essential characteristics of the safety components for lifts.

The notified body shall issue a certificate of conformity to type with respect to the examinations and tests carried out.

On request, the notified body shall provide the Commission and the Member States with a copy of the certificate of conformity to type.

5. **CE marking and EU declaration of conformity**

- 5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.
  - 5.2. The manufacturer shall draw up a written EU declaration of conformity for each safety component for lifts and keep a copy of it at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market. The EU declaration of conformity shall identify the safety component for lifts for which it has been drawn up.

6. **Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative shall not fulfil the manufacturer's obligations set out in point 2.

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## ANNEX X

## CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE FOR LIFTS

(module E)

1. Conformity to type based on product quality assurance is the part of the conformity assessment procedure whereby a notified body assesses the product quality system of an installer to ensure that the lifts are in conformity with the approved type as described in the EU-type examination certificate or with a lift designed and manufactured under a full quality system approved in accordance with Annex XI, and satisfy the applicable essential health and safety requirements set out in Annex I.

2. **Obligations of the installer**

The installer shall operate an approved quality system for final inspection and testing of the lift as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The installer shall lodge an application for assessment of his quality system for the lifts concerned with a single notified body of his choice.

The application shall include:

- (a) the name and address of the installer, and if the application is lodged by the authorised representative, his name and address as well;
  - (b) all relevant information on the lifts to be installed;
  - (c) the documentation on the quality system;
  - (d) the technical documentation of the lifts to be installed;
  - (e) a written declaration that the same application has not been lodged with any other notified body.
- 3.2. Under the quality system, each lift shall be examined and appropriate tests as set out in the relevant harmonised standards or equivalent tests shall be carried out in order to ensure its conformity with the applicable essential health and safety requirements set out in Annex I.

All the elements, requirements and provisions adopted by the installer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

It shall contain in particular an adequate description of:

- (a) the quality objectives;
  - (b) the organisational structure, responsibilities and powers of the management with regard to product quality;
  - (c) the examinations and tests that will be carried out before placing on the market, including at least the tests laid down in point 3.3 of Annex V;
  - (d) the means of monitoring the effective operation of the quality system;
  - (e) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I. The audit shall include an assessment visit to the premises of the installer and a visit to the installation site.



The decision shall be notified to the installer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

- 3.4.1. The installer shall keep the notified body which has approved the quality system informed of any intended change to the system.

- 3.4.2. The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 19.

#### 4. **Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The installer shall, for assessment purposes, allow the notified body access to the installation, inspection and testing locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation;

(c) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

- 4.3. The notified body shall periodically carry out audits to ensure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

- 4.4. Additionally, the notified body may pay unexpected visits to the lift installation sites.

At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system and of the lift. It shall provide the installer with a visit report and, if tests have been carried out, with a test report.

5. The installer shall, for 10 years after the last lift has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in point 3.4.1;

(d) the decisions and reports from the notified body which are referred to in the second paragraph of point 3.4.2 and in points 4.3 and 4.4.

6. Each notified body shall inform its notifying authority of quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions, refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decision(s) which it has refused, suspended or withdrawn and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

**7. CE marking and EU declaration of conformity**

- 7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.
- 7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

**8. Authorised representative**

The installer's obligations set out in points 3.1, 3.4.1, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX XI

## CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION FOR LIFTS

(module H1)

1. Conformity based on full quality assurance plus design examination for lifts is the conformity assessment procedure whereby a notified body assesses the quality system of an installer and, where appropriate, the design of the lifts, to ensure that the lifts satisfy the applicable essential health and safety requirements set out in Annex I.

2. **Obligations of the installer**

The installer shall operate an approved quality system for the design, manufacture, assembly, installation, final inspection and testing of the lifts as specified in point 3, and shall be subject to surveillance as specified in point 4. The adequacy of the technical design of the lifts shall have been examined in accordance with point 3.3.

3. **Quality system**

- 3.1. The installer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

- (a) the name and address of the installer, and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) all relevant information on the lifts to be installed, in particular information which makes for an understanding of the relationship between the design and operation of the lift;
  - (c) the documentation on the quality system;
  - (d) the technical documentation described in point 3 of Annex IV, Part B;
  - (e) a written declaration that the same application has not been lodged with any other notified body.
- 3.2. The quality system shall ensure compliance of the lifts with the applicable essential health and safety requirements set out in Annex I. All the elements, requirements and provisions adopted by the installer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

It shall contain in particular an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;
- (b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied in full, the means, including other relevant technical specifications that will be used to ensure that the applicable essential health and safety requirements set out in Annex I will be met;
- (c) the design control and design verification techniques, processes and systematic actions that will be used when designing the lifts;
- (d) the examinations and tests that will be carried out on acceptance of the supplies of materials, components and sub-assemblies;
- (e) the corresponding assembly, installation, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (f) the examinations and tests that will be carried out before (inspection of installation conditions: shaft, housing of machinery, etc.), during and after installation (including at least the tests laid down in point 3.3 of Annex V);

(g) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned;

(h) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

### 3.3. *Design examination*

3.3.1. When the design is not entirely in accordance with harmonised standards, the notified body shall ascertain whether the design conforms to the essential health and safety requirements set out in Annex I and, if it does, issue an EU design examination certificate to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.

3.3.2. Where the design does not satisfy the applicable essential health and safety requirements set out in Annex I, the notified body shall refuse to issue an EU design examination certificate and shall inform the installer accordingly, giving detailed reasons for its refusal.

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the essential health and safety requirements set out in Annex I, and shall determine whether such changes require further investigation. If so, the notified body shall inform the installer accordingly.

3.3.3. The installer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential health and safety requirements set out in Annex I or the conditions for validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EU design examination certificate — in the form of an addition to the original EU design examination certificate.

3.3.4. Each notified body shall inform its notifying authority of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of EU design examination certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of the EU design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

3.3.5. The installer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the lift has been placed on the market.

### 3.4. *Assessment of the quality system*

The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I. The audit shall include an assessment visit to the installer's premises and a visit to an installation site.

The auditing team shall review the technical documentation referred to in point 3.1(d), to verify the installer's ability to identify the applicable essential health and safety requirements set out in Annex I and to carry out the necessary examinations with a view to ensuring compliance of the lift with those requirements.

The decision shall be notified to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

- 3.5. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

The installer shall keep the notified body that has approved the quality system informed of any intended change to the system.

The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 19.

#### 4. **Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The installer shall, for assessment purposes, allow the notified body access to the design, manufacture, assembly, installation, inspection, testing and storage locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests;

(c) the quality records provided for in the part of the quality system concerning acceptance of supplies and installation, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.

- 4.3. The notified body shall carry out periodic audits to make sure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

- 4.4. Additionally, the notified body may pay unexpected visits to the premises of the installer or to the installation site of a lift. At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the installer with a visit report and, if tests have been carried out, with a test report.

5. The installer shall, keep at the disposal of the national authorities for a period ending 10 years after the lift has been placed on the market:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in the second paragraph of point 3.5;

(d) the decisions and reports from the notified body which are referred to in the fourth paragraph of point 3.5 and in points 4.3 and 4.4.

6. Each notified body shall inform its notifying authority of full quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decision(s) which it has refused, suspended or withdrawn, and, upon request, of approval decisions which it has issued.

The notified body shall keep a copy of the approval decision issued, its annexes and additions, as well as the technical documentation for 15 years from the date of their issue.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

**7. CE marking and EU declaration of conformity**

- 7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.
- 7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

**8. Authorised representative**

The installer's obligations set out in points 3.1, 3.3.3, 3.3.5, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX XII

## CONFORMITY TO TYPE BASED ON PRODUCTION QUALITY ASSURANCE FOR LIFTS

(module D)

1. Conformity to type based on production quality assurance for lifts is the part of the conformity assessment procedure whereby a notified body assesses the production quality system of an installer to ensure that the lifts installed are in conformity with the approved type as described in the EU-type examination certificate or with a lift designed and manufactured under a quality system approved in accordance with Annex XI, and satisfy the applicable essential health and safety requirements set out in Annex I.

2. **Obligations of the installer**

The installer shall operate an approved quality system for manufacture, assembly, installation, final inspection and testing of the lifts as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The installer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

- (a) the name and address of the installer, and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) all relevant information for the lifts to be installed;
  - (c) the documentation on the quality system;
  - (d) the technical documentation of the lifts to be installed;
  - (e) a written declaration that the same application has not been lodged with any other notified body.
- 3.2. The quality system shall ensure compliance of the lifts with the applicable essential health and safety requirements set out in Annex I.

All the elements, requirements and provisions adopted by the installer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

- (a) the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the product quality;
  - (b) the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
  - (c) the examinations and tests that will be carried out before, during and after installation;
  - (d) the quality records, such as inspection reports and test data, calibration data, reports on the qualification of the personnel concerned;
  - (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I.



The audit shall include an assessment visit to the installer's premises and a visit to an installation site.

The decision shall be notified to the installer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.4.1. The installer shall keep the notified body that has approved the quality system informed of any intended change to the system.
- 3.4.2. The notified body shall assess the modifications proposed and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 19.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The installer shall, for assessment purposes, allow the notified body access to the manufacture, assembly, installation, inspection, testing and storage locations, and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation;
  - (b) the technical documentation;
  - (c) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.
- 4.3. The notified body shall carry out periodic audits to make sure that the installer maintains and applies the quality system and shall provide the installer with an audit report.
- 4.4. Additionally, the notified body may pay unexpected visits to the installer. During such visits the notified body may, where necessary carry out tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the installer with a visit report and, if tests have been carried out, with a test report.
5. The installer shall, keep at the disposal of the national authorities for a period ending 10 years after the lift has been placed on the market:
  - (a) the documentation referred to in point 3.1(c);
  - (b) the technical documentation referred to in point 3.1(d);
  - (c) the information relating to the changes referred to in point 3.4.1;
  - (d) the decisions and reports from the notified body which are referred to in the second paragraph of point 3.4.2, and in points 4.3 and 4.4.
6. Each notified body shall inform its notifying authority of quality system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approval decision(s) which it has refused, suspended or withdrawn, and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of quality system approval decision(s) issued.

7. **CE marking and EU declaration of conformity**

- 7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.
- 7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. **Authorised representative**

The installer's obligations set out in points 3.1, 3.4.1, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX XIII

## PART A

**Repealed Directive with list of the successive amendments thereto**

(referred to in Article 47)

Directive 95/16/EC of the European Parliament  
and of the Council

(OJ L 213, 7.9.1995, p. 1).

Regulation (EC) No 1882/2003 of the European Parliament and of the Council

Only point 10 of Annex I

(OJ L 284, 31.10.2003, p. 1).

Directive 2006/42/EC of the European Parliament and of the Council

Only Article 24

(OJ L 157, 9.6.2006, p. 24).

Regulation (EU) No 1025/2012 of the European Parliament and of the Council

Only point (i) of Article 26(1)

(OJ L 316, 14.11.2012, p. 12).

## PART B

**Time limits for transposition into national law and dates of application**

(referred to in Article 45)

Directive	Time limit for transposition	Date of application
95/16/EC	1 January 1997	1 July 1997
2006/42/EC, Article 24	29 June 2008	29 December 2009

## ANNEX XIV

## CORRELATION TABLE

Directive 95/16/EC	This Directive
Article 1(1)	Article 1(1), first subparagraph
—	Article 1(1), second subparagraph
Article 1(2), first subparagraph	Article 2(1)
Article 1(2), second subparagraph	Article 1(1)
Article 1(2), third subparagraph	
Article 1(3)	Article 1(2)
Article 1(4), first indent of first subparagraph	Article 2(6)
Article 1(4), second indent of first subparagraph	Article 2(5)
Article 1(4), fourth indent of first subparagraph	Article 2(7)
Article 1(4), fifth indent of first subparagraph	Article 2(3)
Article 1(4), second subparagraph	Article 16(3)
Article 1(4), third subparagraph	Article 16(4)
Article 1(5)	Article 1(3)
—	Article 2(1)
Article 2(1), first indent	Article 4(1)
Article 2(1), second indent	Article 4(2)
Article 2(2)	Article 6(1)
Article 2(3)	Article 6(2)
Article 2(4)	Article 3(3)
Article 2(5)	Article 3(2)
Article 3, first paragraph	Article 5(1)
Article 3, second paragraph	Article 5(2)
Article 4(1)	Article 3(1)
Article 4(2)	—
—	Articles 7 to 14
Article 5(1)	Article 14
Article 6(1) and (2)	—
Article 6(3) and (4)	Article 42
Article 7(1), first subparagraph	Article 38(1)
Article 7(1), second subparagraph	Article 38(5)
Article 7(2), first subparagraph	Article 39(3)
Article 7(3)	
Article 7(4)	Article 40(4)

Directive 95/16/EC	This Directive
Article 8(1)(a)	Article 15
Article 8(1)(b) and (c)	—
Article 8(2)	Article 16
Article 8(3), first and third indents	Article 17(2) and Article 19(3)
Article 8(3), second indent	Article 7(3)
Article 8(4)	—
Article 8(5)	Article 12
Article 9(1)	Article 20
Article 9(2)	
Article 9(3)	Article 30(1)
	—
Article 10(1)	—
Article 10(2)	Article 19(1)
Article 10(3)	—
Article 10(4)(a)	Article 41(1)(a)
Article 10(4)(b)	—
Article 11	—
—	Article 43
Article 12	—
Article 13	—
Article 14	—
Article 15(1) and (2)	—
Article 15(3)	Article 45(2)
Article 16	Article 46
Article 17	Article 49
Annex I	Annex I
Annex II, Part A	Annex II, Part A
Annex II, Part B	Annex II, Part B
Annex III	Article 18
Annex IV	Annex III
Annex V, Part A	Annex IV, Part A
Annex V, Part B	Annex IV, Part B
Annex VI	Annex V
Annex VII	—
Annex VIII	Annex VI
Annex IX	Annex VII

Directive 95/16/EC	This Directive
Annex X	Annex VIII
Annex XI	Annex IX
Annex XII	Annex X
Annex XIII	Annex XI
Annex XIV	Annex XII
—	Annex XIII
—	Annex XIV

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/34/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 26 February 2014****on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast)****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres <sup>(3)</sup> has been substantially amended <sup>(4)</sup>. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(5)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common

framework for the marketing of products <sup>(6)</sup> lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 94/9/EC should be adapted to that Decision.

(4) This Directive covers products which are new to the Union market when they are placed on the market; that is to say they are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.

(5) This Directive should apply to all forms of supply, including distance selling.

(6) It is the duty of Member States to protect, on their territory, the health and safety of persons, especially workers, and, where appropriate, domestic animals and property, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres.

(7) Directive 94/9/EC has made positive steps towards effective protection against explosion hazards for both mining and surface equipment. Those two groups of equipment are used in a large number of commercial and industrial sectors and possess considerable economic significance.

(8) Compliance with the health and safety requirements is essential in order to ensure the safety of equipment and protective systems. Those requirements should be subdivided into general and additional requirements which need to be met by equipment and protective systems. In particular, the additional requirements should take account of existing or potential hazards. Equipment and protective systems should, therefore, meet at least one of those requirements where this is necessary for their proper functioning or is to apply to their intended use. The notion of intended use is of prime importance for the explosion-proofing of equipment and protective systems. It is essential that manufacturers supply full information. Specific, clear marking of equipment and protective systems, stating their use in a potentially explosive atmosphere, should also be necessary.

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 100, 19.4.1994, p. 1.

<sup>(4)</sup> See Annex XI, Part A.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(6)</sup> OJ L 218, 13.8.2008, p. 82.

- (9) Compliance with the essential health and safety requirements laid down in this Directive should be imperative in order to ensure the safety of equipment and protective systems. For the implementation of those requirements, both the technology obtained at the time of manufacture and overriding technical and economic requirements should be taken into account.
- (10) Economic operators should be responsible for the compliance of products with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of domestic animals and property, and to guarantee fair competition on the Union market.
- (11) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (12) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (13) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (14) It is necessary to ensure that products from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those products. Provision should therefore be made for importers to make sure that the products they place on the market comply with the requirements of this Directive and that they do not place on the market products which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (15) When placing a product on the market, every importer should indicate on the product his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the product.
- (16) The distributor makes a product available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the product does not adversely affect the compliance of the product.
- (17) Any economic operator that either places a product on the market under his own name or trade mark or modifies a product in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the product concerned.
- (19) Ensuring traceability of a product throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant products available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a product or to whom they have supplied a product.
- (20) This Directive should be limited to the expression of the essential health and safety requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for products which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation<sup>(1)</sup> for the purpose of expressing detailed technical specifications of those requirements.
- (21) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

- (22) In order to enable economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the essential health and safety requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (23) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a product with the requirements of this Directive and of other relevant Union harmonisation legislation.
- (24) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (25) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (26) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (27) Experience has shown that the criteria set out in Directive 94/9/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (28) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Directive
- (29) In order to ensure a consistent level of quality in the performance of conformity assessment, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (30) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (31) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (32) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the products to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (33) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (34) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

- (35) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (36) Member States should take all appropriate measures to ensure that products covered by this Directive may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Products covered by this Directive should be considered as non-compliant with the essential health and safety requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (37) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to products covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (38) Directive 94/9/EC already provides for a safeguard procedure which is necessary to allow the possibility for contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (39) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to products presenting a risk to the health or safety of persons, especially workers, or to domestic animals or property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.
- (40) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (41) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (42) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (43) The examination procedure should be used for the adoption of implementing acts with respect to compliant products which present a risk to the health or safety of persons or to other aspects of public interest protection.
- (44) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant products which present a risk to the health or safety of persons or to domestic animals or property, imperative grounds of urgency so require.
- (45) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (46) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (47) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant products are justified or not.
- (48) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.



(49) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into service, without the need to comply with further product requirements, of products that have already been placed on the market in accordance with Directive 94/9/EC before the date for application of national measures transposing this Directive. Distributors should therefore be able to supply products that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

(50) Since the objective of this Directive, namely to ensure that products on the market fulfil the requirements providing for a high level of protection of health and safety of persons, especially workers, and, where appropriate, protection of domestic animals and property, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(51) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(52) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directive set out in Annex XI, Part B,

HAVE ADOPTED THIS DIRECTIVE:

## CHAPTER 1

### GENERAL PROVISIONS

#### Article 1

##### Scope

1. This Directive shall apply to the following, hereinafter referred to as 'products':

- (a) equipment and protective systems intended for use in potentially explosive atmospheres;
- (b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres

but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;

- (c) components intended to be incorporated into equipment and protective systems referred to in point (a).

2. This Directive shall not apply to:

- (a) medical devices intended for use in a medical environment;
- (b) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
- (c) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;
- (d) personal protective equipment covered by Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment <sup>(1)</sup>;
- (e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
- (f) means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of this Directive;
- (g) the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

## Article 2

### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'equipment' means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;

<sup>(1)</sup> OJ L 399, 30.12.1989, p. 18.

- (2) 'protective systems' means devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems;
- (3) 'components' means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;
- (4) 'explosive atmosphere' means a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;
- (5) 'potentially explosive atmosphere' means an atmosphere which could become explosive due to local and operational conditions;
- (6) 'equipment-group I' means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M 2 as set out in Annex I;
- (7) 'equipment-group II' means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 as set out in Annex I;
- (8) 'equipment category' means the classification of equipment, within each equipment-group, specified in Annex I, determining the requisite level of protection to be ensured;
- (9) 'intended use' means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;
- (10) 'making available on the market' means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (11) 'placing on the market' means the first making available of a product on the Union market;
- (12) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trade mark or uses it for his own purposes;
- (13) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (14) 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;
- (15) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
- (16) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (17) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a product;
- (18) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (19) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (20) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (21) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Directive relating to a product have been fulfilled;
- (22) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (23) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end-user;
- (24) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (25) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(26) 'CE marking' means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

### Article 3

#### **Making available on the market and putting into service**

1. Member States shall take all appropriate measures to ensure that products may be made available on the market and put into service only if, when properly installed and maintained and used in accordance with their intended use, they comply with this Directive.

2. This Directive shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using relevant products provided that this does not mean that such products are modified in a way not specified in this Directive.

3. At trade fairs, exhibitions and demonstrations, Member States shall not prevent the showing of products which do not comply with this Directive, provided that a visible sign clearly indicates that such products do not comply with this Directive and that they are not for sale until they have been brought into conformity by the manufacturer. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

### Article 4

#### **Essential health and safety requirements**

Products shall meet the essential health and safety requirements set out in Annex II which apply to them, account being taken of their intended use.

### Article 5

#### **Free movement**

Member States shall not prohibit, restrict or impede the making available on the market and putting into service in their territory of products which comply with this Directive.

## CHAPTER 2

### **OBLIGATIONS OF ECONOMIC OPERATORS**

### Article 6

#### **Obligations of manufacturers**

1. When placing their products on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential health and safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annexes III to IX and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

Where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, manufacturers shall draw up a written attestation of conformity as referred to in Article 13(3).

Manufacturers shall ensure that each product is accompanied by a copy of the EU declaration of conformity or of the attestation of conformity, as appropriate. However, where a large number of products are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in a product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that products which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

6. Manufacturers shall ensure that products, other than components, which they have placed on the market bear the specific marking of explosion protection and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II.



7. Manufacturers shall indicate, on the product, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

8. Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

9. Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

#### Article 7

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity or, where applicable, the attestation of conformity and the technical

documentation at the disposal of national market surveillance authorities for 10 years after the product has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by the authorised representative's mandate.

#### Article 8

##### Obligations of importers

1. Importers shall place only compliant products on the market.

2. Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure referred to in Article 13 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking, where applicable, is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5), (6) and (7).

Where an importer considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Annex II, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II.

6. When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the product has been placed on the market, keep a copy of the EU declaration of conformity or, where applicable, of the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

#### Article 9

##### Obligations of distributors

1. When making a product available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a product available on the market distributors shall verify that the product bears the CE marking, where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents and by instructions and safety information, in a language which can be easily understood by end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5), (6) and (7) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Annex II, he shall not make the product

available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II.

4. Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

#### Article 10

##### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places a product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 11

##### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a product;
- (b) any economic operator to whom they have supplied a product.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the product and for 10 years after they have supplied the product.

## CHAPTER 3

**CONFORMITY OF THE PRODUCT***Article 12***Presumption of conformity of products**

1. Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.

2. In the absence of harmonised standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national standards and technical specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements set out in Annex II.

*Article 13***Conformity assessment procedures**

1. The procedures to be followed for assessing the conformity of equipment and, where necessary, the devices referred to in point (b) of Article 1(1) shall be as follows:

(a) for equipment-groups I and II, equipment-categories M 1 and 1, the EU-type examination set out in Annex III, in conjunction with either of the following:

— conformity to type based on quality assurance of the production process set out in Annex IV,

— conformity to type based on product verification set out in Annex V;

(b) for equipment-groups I and II, equipment categories M 2 and 2:

(i) in the case of internal combustion engines and electrical equipment in these groups and categories, the EU-type examination set out in Annex III, in conjunction with either of the following:

— conformity to type based on internal production control plus supervised product testing set out in Annex VI,

— conformity to type based on product quality assurance set out in Annex VII;

(ii) in the case of other equipment in these groups and categories, internal production control set out in

Annex VIII and the communication of the technical documentation provided for in Annex VIII, point 2, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

(c) for equipment-group II, equipment category 3, internal production control set out in Annex VIII;

(d) for equipment-groups I and II, in addition to the procedures referred to in points (a), (b) and (c) of this paragraph, conformity based on unit verification set out in Annex IX may also be followed.

2. The procedure referred to in point (a) or (d) of paragraph 1 shall be used for conformity assessment of protective systems.

3. The procedures referred to in paragraph 1 shall be applied in respect of components with the exception of the affixing of the CE marking and the drawing up of the EU declaration of conformity. A written attestation of conformity shall be issued by the manufacturer, declaring the conformity of the components with the applicable provisions of this Directive and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential health and safety requirements set out in Annex II applicable to finished equipment or protective systems.

4. With regard to the safety aspects referred to in point 1.2.7 of Annex II, in addition to the conformity assessment procedures referred to in paragraphs 1 and 2, the procedure referred to in Annex VIII may also be followed.

5. By derogation from paragraphs 1, 2 and 4, the competent authorities may, on a duly justified request, authorise the placing on the market and putting into service on the territory of the Member State concerned of the products other than components in respect of which the procedures referred to in paragraphs 1, 2 and 4 have not been applied and the use of which is in the interests of protection.

6. Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs 1 to 4 shall be drawn up in a language, determined by the Member State concerned.

*Article 14***EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the essential health and safety requirements set out in Annex II has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex X, shall contain the elements specified in the relevant conformity assessment procedures set out in Annexes III to IX and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market.

3. Where a product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this Directive.

#### Article 15

##### General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

#### Article 16


##### Rules and conditions for affixing the CE marking and other markings

1. The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the product is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. The CE marking and, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection , the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in point 1.0.5 of Annex II.

5. The CE marking and the markings, symbols and information referred to in paragraph 4, and, where applicable,

the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

Products that are designed for a particular explosive atmosphere shall be marked accordingly.

6. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

#### CHAPTER 4

##### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### Article 17

##### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

#### Article 18

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 23.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 is to be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 19. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### Article 19

##### Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### Article 20

##### Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

#### Article 21

##### Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity

assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III to VII and Annex IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;



- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, of the relevant provisions of Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management, and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information

obtained in carrying out their tasks under Annexes III to VII and Annex IX or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 22

##### **Presumption of conformity of notified bodies**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 21 in so far as the applicable harmonised standards cover those requirements.

#### Article 23

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 21 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes III to VII and Annex IX.

#### Article 24

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 21.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 21.

#### Article 25

##### Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 21.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the product or products concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 24(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 21.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

#### Article 26

##### Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 27

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

#### Article 28

##### Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.



4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 39(2).

#### Article 29

##### **Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III to VII and Annex IX.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the requirements of this Directive.

3. Where a notified body finds that the essential health and safety requirements set out in Annex II or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

#### Article 30

##### **Appeal against decisions of notified bodies**

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

#### Article 31

##### **Information obligation on notified bodies**

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 32

##### **Exchange of experience**

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 33

##### **Coordination of notified bodies**

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group, directly or by means of designated representatives.

#### CHAPTER 5

##### **UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE**

#### Article 34

##### **Union market surveillance and control of products entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to products covered by Article 1 of this Directive.

*Article 35***Procedure for dealing with products presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a product presents a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant

product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the product to meet requirements relating to the health or safety of persons or to the protection of domestic animals or property; or

(b) shortcomings in the harmonised standards referred to in Article 12 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the product from the market, are taken in respect of the product concerned without delay.

*Article 36***Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 35(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant product is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 35(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 37

##### Compliant products which present a risk

1. Where, having carried out an evaluation under Article 35(1), a Member State finds that although a product is in compliance with this Directive, it presents a risk to the health or safety of persons or to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 39(3).


On duly justified imperative grounds of urgency relating to the protection of health and safety of persons or to the protection of domestic animals or property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 39(4).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 38

##### Formal non-compliance

1. Without prejudice to Article 35, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of this Directive;
- (b) the CE marking, where required, has not been affixed;
- (c) the specific marking of explosion protection , the symbols of the equipment-group and category and, where applicable, the other markings and information have been affixed in violation of point 1.0.5 of Annex II or have not been affixed;
- (d) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 16 or has not been affixed;
- (e) the EU declaration of conformity or the attestation of conformity, as appropriate, does not accompany the product;
- (f) the EU declaration of conformity or, where required, the attestation of conformity has not been drawn up correctly;
- (g) technical documentation is either not available or not complete;
- (h) the information referred to in Article 6(7) or 8(3) is absent, false or incomplete;
- (i) any other administrative requirement provided for in Article 6 or 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

#### CHAPTER 6

##### COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS

#### Article 39

##### Committee procedure

1. The Commission shall be assisted by the Committee on equipment and protective systems intended for use in potentially explosive atmospheres. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 40

##### Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 41

##### Transitional provisions

1. Member States shall not impede the making available on the market or the putting into service of products covered by Directive 94/9/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

2. Certificates issued under Directive 94/9/EC shall be valid under this Directive.

#### Article 42

##### Transposition

1. Member States shall adopt and publish by 19 April 2016 the laws, regulations and administrative provisions necessary to comply with Article 1, points 2 and 8 to 26 of Article 2, Article 3, Articles 5 to 41 and Annexes III to X. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 43

##### Repeal

Directive 94/9/EC, as amended by the Regulations listed in Annex XI, Part A, is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law and the dates of application of the Directive set out in Annex XI, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XII.

#### Article 44

##### Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Points 1 and 3 to 7 of Article 2, Article 4 and Annexes I, II, XI and XII shall apply from 20 April 2016.

#### Article 45

##### Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament  
The President  
M. SCHULZ

For the Council  
The President  
D. KOURKOULAS

## ANNEX I

## CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

**1. Equipment-group I**

- (a) Equipment category M 1 comprises equipment designed and, where necessary, equipped with additional special means of protection to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines endangered by firedamp and/or combustible dust.

Equipment in this category is required to remain functional, even in the event of rare incidents relating to equipment, with an explosive atmosphere present, and is characterised by means of protection such that:

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.1 of Annex II.

- (b) Equipment category M 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines likely to be endangered by firedamp and/or combustible dust.

This equipment is intended to be de-energised in the event of an explosive atmosphere.

The means of protection relating to equipment in this category assure the requisite level of protection during normal operation and also in the case of more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.2 of Annex II.

**2. Equipment-group II**

- (a) Equipment category 1 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by mixtures of air and gases, vapours or mists or by air/dust mixtures are present continuously, for long periods or frequently.

Equipment in this category must ensure the requisite level of protection, even in the event of rare incidents relating to equipment, and is characterised by means of protection such that:

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in point 2.1 of Annex II.

- (b) Equipment category 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and of ensuring a high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists or air/dust mixtures are likely to occur occasionally.

The means of protection relating to equipment in this category ensure the requisite level of protection, even in the event of frequently occurring disturbances or equipment faults which normally have to be taken into account.

Equipment in this category must comply with the supplementary requirements referred to in point 2.2 of Annex II.

- (c) Equipment category 3 comprises equipment designed to be capable of functioning in conformity with the operating parameters established by the manufacturer and ensuring a normal level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists, or air/dust mixtures are unlikely to occur or, if they do occur, are likely to do so only infrequently and for a short period only.

Equipment in this category ensures the requisite level of protection during normal operation.

Equipment in this category must comply with the supplementary requirements referred to in point 2.3 of Annex II.

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## ANNEX II

## ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

**Preliminary observations**

- A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilised immediately.
- B. For the devices referred to in point (b) of Article 1(1), the essential health and safety requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

**1. Common requirements for Equipment and protective systems****1.0. General requirements****1.0.1. Principles of integrated explosion safety**

Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.

In this connection, the manufacturer must take measures:

- above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves,
- to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition,
- should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

**1.0.2. Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations.**

Any misuse which can reasonably be anticipated must be taken into account.

**1.0.3. Special checking and maintenance conditions**

Equipment and protective systems subject to special checking and maintenance conditions must be designed and constructed with such conditions in mind.

**1.0.4. Surrounding area conditions**


Equipment and protective systems must be so designed and constructed as to be capable of coping with actual or foreseeable surrounding area conditions.

**1.0.5. Marking**

All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars:

- name, registered trade name or registered trade mark, and address of the manufacturer,
- CE marking (see Annex II to Regulation (EC) No 765/2008),
- designation of series or type,
- batch or serial number, if any,
- year of construction,



- the specific marking of explosion protection  followed by the symbol of the equipment-group and category,
- for equipment-group II, the letter 'G' (concerning explosive atmospheres caused by gases, vapours or mists),  
and/or
- the letter 'D' (concerning explosive atmospheres caused by dust).

Furthermore, where necessary, they must also be marked with all information essential to their safe use.

#### 1.0.6. Instructions

- (a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

- a recapitulation of the information with which the equipment or protective system is marked, except for the batch or serial number (see point 1.0.5), together with any appropriate additional information to facilitate maintenance (e.g. address of the repairer, etc.);
- instructions for safe:
  - putting into service,
  - use,
  - assembling and dismantling,
  - maintenance (servicing and emergency repair),
  - installation,
  - adjustment;
- where necessary, an indication of the danger areas in front of pressure-relief devices;
- where necessary, training instructions;
- details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;
- electrical and pressure parameters, maximum surface temperatures and other limit values;
- where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;
- where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

- (b) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

- (c) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects.

#### 1.1. Selection of materials

- 1.1.1. The materials used for the construction of equipment and protective systems must not trigger off an explosion, taking into account foreseeable operational stresses.

1.1.2. Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

1.1.3. Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material's corrosion and wear resistance, electrical conductivity, mechanical strength, ageing resistance and the effects of temperature variations.

## 1.2. *Design and construction*

1.2.1. Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

1.2.2. Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

### 1.2.3. *Enclosed structures and prevention of leaks*

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only.

If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.

Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit releases of flammable materials during filling or draining.

### 1.2.4. *Dust deposits*

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited.

In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable.

The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust.

The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

### 1.2.5. *Additional means of protection*

Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection.

Equipment must withstand relevant stresses, without adverse effect on explosion protection.

### 1.2.6. *Safe opening*

If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

### 1.2.7. *Protection against other hazards*

Equipment and protective systems must be so designed and manufactured as to:

(a) avoid physical injury or other harm which might be caused by direct or indirect contact;

(b) assure that surface temperatures of accessible parts or radiation which would cause a danger, are not produced;

- (c) eliminate non-electrical dangers which are revealed by experience;
- (d) assure that foreseeable conditions of overload do not give rise to dangerous situations.

Where, for equipment and protective systems, the risks referred to in this point are wholly or partly covered by other Union legislation, this Directive shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of that specific Union legislation.

#### 1.2.8. Overloading of equipment

Dangerous overloading of equipment must be prevented at the design stage by means of integrated measurement, regulation and control devices, such as over-current cut-off switches, temperature limiters, differential pressure switches, flowmeters, time-lag relays, overspeed monitors and/or similar types of monitoring devices.

#### 1.2.9. Flameproof enclosure systems

If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

#### 1.3. Potential ignition sources

##### 1.3.1. Hazards arising from different ignition sources

Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electromagnetic waves and other ignition sources must not occur.

##### 1.3.2. Hazards arising from static electricity

Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

##### 1.3.3. Hazards arising from stray electric and leakage currents

Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

##### 1.3.4. Hazards arising from overheating

Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

##### 1.3.5. Hazards arising from pressure compensation operations

Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

#### 1.4. Hazards arising from external effects

##### 1.4.1. Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

##### 1.4.2. Equipment parts used must be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

#### 1.5. Requirements in respect of safety-related devices

##### 1.5.1. Safety devices must function independently of any measurement and/or control devices required for operation.

As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

The fail-safe principle is to be applied in general.

Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

1.5.2. In the event of a safety device failure, equipment and/or protective systems shall, wherever possible, be secured.

1.5.3. Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

1.5.4. Control and display units

Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

1.5.5. Requirements in respect of devices with a measuring function for explosion protection

In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

1.5.6. Where necessary, it must be possible to check the reading accuracy and serviceability of devices with a measuring function.

1.5.7. The design of devices with a measuring function must incorporate a safety factor which ensures that the alarm threshold lies far enough outside the explosion and/or ignition limits of the atmospheres to be registered, taking into account, in particular, the operating conditions of the installation and possible aberrations in the measuring system.

1.5.8. Risks arising from software

In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

1.6. *Integration of safety requirements relating to the system*

1.6.1. Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

This does not apply to electrochemically-stored energy.

1.6.3. Hazards arising from power failure

Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

1.6.4. Hazards arising from connections

Equipment and protective systems must be fitted with suitable cable and conduit entries.

When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

#### 1.6.5. Placing of warning devices as parts of equipment

Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

### 2. Supplementary requirements in respect of equipment

#### 2.0. Requirements applicable to equipment in equipment-group I

##### 2.0.1. Requirements applicable to equipment category M 1 of equipment-group I

###### 2.0.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

Equipment must be equipped with means of protection such that:

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

Where necessary, equipment must be equipped with additional special means of protection.

It must remain functional with an explosive atmosphere present.

###### 2.0.1.2. Where necessary, equipment must be so constructed that no dust can penetrate it.

###### 2.0.1.3. The surface temperatures of equipment parts must be kept clearly below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

###### 2.0.1.4. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

If necessary, equipment must be fitted with appropriate additional interlocking systems.

##### 2.0.2. Requirements applicable to equipment category M 2 of equipment-group I

###### 2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

The equipment is intended to be de-energised in the event of an explosive atmosphere.

###### 2.0.2.2. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

###### 2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to equipment category M 1 must be applied.

#### 2.1. Requirements applicable to equipment category 1 of equipment-group II

##### 2.1.1. Explosive atmospheres caused by gases, vapours or mists

###### 2.1.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment.

It must be equipped with means of protection such that:

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.1.2. For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

Temperature rises caused by heat build-ups and chemical reactions must also be taken into account.

2.1.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

If necessary, equipment must be fitted with appropriate additional interlocking systems.

#### 2.1.2. Explosive atmospheres caused by air/dust mixtures

2.1.2.1. Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rare incidents relating to equipment.

It must be equipped with means of protection such that

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.2.2. Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points.

This requirement must also be met by cable entries and connecting pieces.

2.1.2.3. The surface temperatures of equipment parts must be kept well below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.1.2.4. With regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

#### 2.2. Requirements applicable to equipment category 2 of equipment-group II

##### 2.2.1. Explosive atmospheres caused by gases, vapours or mists

2.2.1.1. Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

2.2.1.2. Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

2.2.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

##### 2.2.2. Explosive atmospheres caused by air/dust mixtures

2.2.2.1. Equipment must be designed and constructed so that ignition of air/dust mixtures is prevented, even in the event of frequently occurring disturbances or equipment operating faults which normally have to be taken into account.

2.2.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.2.2.3. With regard to protection against dust, requirement 2.1.2.2 applies.

2.2.2.4. With regard to the safe opening of equipment parts, requirement 2.2.1.3 applies.

### 2.3. *Requirements applicable to equipment category 3 of equipment-group II*

#### 2.3.1. Explosive atmospheres caused by gases, vapours or mists

2.3.1.1. Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

2.3.1.2. Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

#### 2.3.2. Explosive atmospheres caused by air/dust mixtures

2.3.2.1. Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

2.3.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulations inside the equipment.

### 3. **Supplementary requirements in respect of protective systems**

#### 3.0. *General requirements*

3.0.1. Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

3.0.2. Protective systems must be designed and capable of being positioned in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

3.0.3. In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

3.0.4. Protective systems must not fail due to outside interference.

#### 3.1. *Planning and design*

##### 3.1.1. Characteristics of materials

With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

3.1.2. Protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

3.1.3. Accessories connected to protective systems must be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

3.1.4. The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

##### 3.1.5. Pressure-relief systems

If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

#### 3.1.6. Explosion suppression systems

Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, with due regard to the maximum rate of pressure increase and the maximum explosion pressure.

#### 3.1.7. Explosion decoupling systems

Decoupling systems intended to disconnect specific equipment as swiftly as possible in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

#### 3.1.8. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

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## ANNEX III

## MODULE B: EU-TYPE EXAMINATION

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of this Directive that apply to it.
2. EU-type examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
  - (b) a written declaration that the same application has not been lodged with any other notified body,
  - (c) the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:
    - (i) a general description of the product,
    - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
    - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
    - (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
    - (v) results of design calculations made, examinations carried out, etc., and
    - (vi) test reports,
  - (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme.
4. The notified body shall:
    - 4.1. examine the technical documentation, verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;
    - 4.2. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
    - 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive;
    - 4.4. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of this Directive that apply to the product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential health and safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

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## ANNEX IV

## MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
  - (b) a written declaration that the same application has not been lodged with any other notified body,
  - (c) all relevant information for the product category envisaged,
  - (d) the documentation concerning the quality system,
  - (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.
- 3.2. The quality system shall ensure that the products are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
  - (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
  - (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
  - (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
  - (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
- 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
  - (a) the quality system documentation,
  - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.
- 4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **5. CE marking, EU declaration of conformity and attestation of conformity**

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.
- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

- 5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1,
  - (b) the information relating to the change referred to in point 3.5, as approved,
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX V

## MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5 and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Verification**

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out by examination and testing of every product as specified in point 4.

4. **Verification of conformity by examination and testing of every product**

- 4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

- 4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

5. **CE marking, EU declaration of conformity and attestation of conformity**

- 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product other than a component that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model other than a component and keep it at the disposal of the national authorities, for 10 years after the product, other than a component, has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product other than a component.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products other than components.

- 5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

7. **Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.

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## ANNEX VI

## MODULE C1: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Product checks**

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the type described in the EU-type examination certificate and with the corresponding requirements of this Directive. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. **CE marking, EU declaration of conformity and attestation of conformity**

- 4.1. The manufacturer shall affix the CE marking to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

- 4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model other than a component and keep it at the disposal of the national authorities for 10 years after the product, other than a component has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

- 4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX VII

## MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

- 3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the products concerned.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- (b) a written declaration that the same application has not been lodged with any other notified body,
- (c) all relevant information for the product category envisaged,
- (d) the documentation concerning the quality system, and
- (e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

- 3.2. The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- (b) the examinations and tests that will be carried out after manufacture,
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,
- (d) the means of monitoring the effective operation of the quality system.

- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

#### **4. Surveillance under the responsibility of the notified body**

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

(a) the quality system documentation,

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

#### **5. CE marking, EU declaration of conformity and attestation of conformity**

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved,

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX VIII

## MODULE A: INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

- (a) a general description of the product,
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- (e) results of design calculations made, examinations carried out, etc., and
- (f) test reports.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

4. **CE marking, EU declaration of conformity and attestation of conformity**

- 4.1. The manufacturer shall affix the CE marking to each individual product other than a component that satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model other than a component and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product, other than a component, has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product other than a component.

- 4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX IX

## MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.
2. **Technical documentation**
  - 2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:
    - (a) a general description of the product,
    - (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
    - (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
    - (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
    - (e) results of design calculations made, examinations carried out, etc., and
    - (f) test reports.
  - 2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.
3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of this Directive.
4. **Verification**

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.
5. **CE marking, EU declaration of conformity and attestation of conformity**
  - 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product other than a component that satisfies the applicable requirements of this Directive.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product, other than a component has been placed on the market. The EU declaration of conformity shall identify such product for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

- 5.3. The manufacturer shall draw up a written attestation of conformity and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. **Authorised representative**

The manufacturer's obligations set out in points 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX X

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. Product model/product (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

\_\_\_\_\_

<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX XI

## PART A

**Repealed Directive with list of the successive amendments thereto**  
**(referred to in Article 43)**

Directive 94/9/EC of the European Parliament and of the Council  
(OJ L 100, 19.4.1994, p. 1).

Regulation (EC) No 1882/2003 of the European Parliament and of the Council  
(OJ L 284, 31.10.2003, p. 1). Only point 8 of Annex I

Regulation (EU) No 1025/2012 of the European Parliament and of the Council  
(OJ L 316, 14.11.2012, p. 12). Only point (c) of Article 26(1)

## PART B

**Time limits for transposition into national law and dates of application**  
**(referred to in Article 43)**

Directive	Time limit for transposition	Date of application
94/9/EC	1 September 1995	1 March 1996

## ANNEX XII

## CORRELATION TABLE

Directive 94/9/EC	This Directive
Article 1(1)	Article 1(1)(a)
Article 1(2)	Article 1(1)(b)
—	Article 1(1)(c)
Article 1(3)	Article 2(1) to (9)
—	Article 2(10) to (26)
Article 1(4)	Article 1(2)
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5(1), first subparagraph	—
Article 5(1), second subparagraph	Article 12(2)
Article 5(2)	Article 12(1)
Article 5(3)	—
—	Articles 6 to 11
—	—
Article 6(1) and (2)	—
Article 6(3)	Article 39(1) to (4)
—	Article 39(5), first subparagraph
Article 6(4)	Article 39(5), second subparagraph
Article 7	—
Article 8(1) to (6)	Article 13(1) to (6)
Article 8(7)	—
—	Articles 14 and 15
Article 9	—
Article 10(1)	—
Article 10(2)	Article 16(1)
Article 10(3)	—
—	Article 16(2) to (6)
—	Articles 17 to 33
Article 11	—
—	Articles 34 to 38
Articles 12 and 13	—
—	Article 40

Directive 94/9/EC	This Directive
—	Article 41(1)
Article 14(1)	—
Article 14(2)	Article 41(2)
Article 14(3)	—
Article 15(1)	Article 42(1)
Article 15(2)	—
—	Article 42(2)
—	Articles 43 and 44
Article 16	Article 45
Annexes I to IX	Annexes I to IX
Annex X	—
Annex XI	—
—	Annex X
—	Annex XI
—	Annex XII

**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and insofar as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL****of 26 February 2014****on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits****(recast)****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee <sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure <sup>(2)</sup>,

Whereas:

(1) A number of amendments are to be made to Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits <sup>(3)</sup>. In the interests of clarity, that Directive should be recast.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(4)</sup> lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common

framework for the marketing of products <sup>(5)</sup> lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2006/95/EC should therefore be adapted to that Decision.

(4) This Directive covers electrical equipment designed for use within certain voltage limits which is new to the Union market when it is placed on the market; that is to say it is either new electrical equipment made by a manufacturer established in the Union or electrical equipment, whether new or second-hand, imported from a third country.

(5) This Directive should apply to all forms of supply, including distance selling.

(6) Economic operators should be responsible for the compliance of electrical equipment with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons, of domestic animals and property, and to guarantee fair competition on the Union market.

(7) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market electrical equipment which is in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(8) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(9) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer. There is no conformity assessment procedure in this Directive which requires the intervention of a notified body.

<sup>(1)</sup> OJ C 181, 21.6.2012, p. 105.

<sup>(2)</sup> Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.

<sup>(3)</sup> OJ L 374, 27.12.2006, p. 10. Directive 2006/95/EC is the codification of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 77, 26.3.1973, p. 29).

<sup>(4)</sup> OJ L 218, 13.8.2008, p. 30.

<sup>(5)</sup> OJ L 218, 13.8.2008, p. 82.

- (10) It is necessary to ensure that electrical equipment from third countries entering the Union market comply with this Directive, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to that electrical equipment. Provision should therefore be made for importers to make sure that electrical equipment they place on the market comply with the requirements of this Directive and that they do not place on the market electrical equipment which does not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of electrical equipment and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (11) When placing electrical equipment on the market, every importer should indicate on the electrical equipment his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the electrical equipment does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the electrical equipment.
- (12) The distributor makes electrical equipment available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of electrical equipment does not adversely affect the compliance of the electrical equipment.
- (13) Any economic operator that either places electrical equipment on the market under his own name or trade mark or modifies electrical equipment in such a way that compliance with this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (14) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the electrical equipment concerned.
- (15) Ensuring traceability of electrical equipment throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant electrical equipment available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with electrical equipment or to whom they have supplied electrical equipment.
- (16) This Directive should be limited to the expression of the safety objectives. In order to facilitate conformity assessment with those objectives it is necessary to provide for a presumption of conformity for electrical equipment which is in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation <sup>(1)</sup> for the purpose of expressing detailed technical specifications of those objectives.
- (17) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the safety objectives set out in this Directive.
- (18) The harmonised standards relevant to this Directive should also take into account the United Nations Convention on the Rights of Persons with Disabilities <sup>(2)</sup>.
- (19) The free movement of electrical equipment for which harmonised standards do not exist should be achieved by applying the safety provisions of the international standards laid down by the International Electrotechnical Commission or by applying national standards.
- (20) In order to enable economic operators to demonstrate and the competent authorities to ensure that electrical equipment made available on the market is in conformity with the safety objectives it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.
- (21) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of electrical equipment with this Directive and of other relevant Union harmonisation legislation.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

<sup>(2)</sup> Approved by Council Decision 2010/48/EC of 26 November 2009 concerning the conclusion, by the European Community, of the United Nations Convention on the Rights of Persons with Disabilities (OJ L 23, 27.1.2010, p. 35).



- (22) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.
- (23) The CE marking, indicating the conformity of electrical equipment, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (24) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to electrical equipment. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (25) Member States should take all appropriate measures to ensure that electrical equipment may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health and safety of persons. Electrical equipment should be considered as non-compliant with the safety objectives laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (26) Directive 2006/95/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (27) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to electrical equipment presenting a risk to the health or safety of persons or domestic animals, or to property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such electrical equipment.
- (28) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (29) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers <sup>(1)</sup>.
- (30) The examination procedure should be used for the adoption of implementing acts with respect to compliant electrical equipment which presents a risk to the health or safety of persons or to other aspects of public interest protection.
- (31) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant electrical equipment which presents a risk to the health or safety of persons, or to domestic animals or to property, imperative grounds of urgency so require.
- (32) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.
- (33) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (34) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant electrical equipment are justified or not.
- (35) Member States should lay down rules on penalties applicable to infringements of provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

<sup>(1)</sup> OJ L 55, 28.2.2011, p. 13.

- (36) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market, without the need to comply with further product requirements, of electrical equipment which has already been placed on the market in accordance with Directive 2006/95/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply electrical equipment that has been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.
- (37) Since the objective of this Directive, namely to ensure that electrical equipment on the market fulfils the safety objectives providing for a high level of protection of health and safety of persons, and of domestic animals and property, while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (38) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.
- (39) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V,

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER 1

#### GENERAL PROVISIONS

##### Article 1

##### Subject matter and scope

The purpose of this Directive is to ensure that electrical equipment on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and of domestic animals and property, while guaranteeing the functioning of the internal market.

This Directive shall apply to electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current, other than the equipment and phenomena listed in Annex II.

##### Article 2

##### Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'making available on the market' means any supply of electrical equipment for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (2) 'placing on the market' means the first making available of electrical equipment on the Union market;
- (3) 'manufacturer' means any natural or legal person who manufactures electrical equipment or has electrical equipment designed or manufactured, and markets that equipment under his name or trade mark;
- (4) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- (5) 'importer' means any natural or legal person established within the Union who places electrical equipment from a third country on the Union market;
- (6) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes electrical equipment available on the market;
- (7) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (8) 'technical specification' means a document that prescribes technical requirements to be fulfilled by an electrical equipment;
- (9) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (10) 'conformity assessment' means the process demonstrating whether the safety objectives referred to in Article 3 and set out in Annex I relating to electrical equipment have been fulfilled;
- (11) 'recall' means any measure aimed at achieving the return of electrical equipment that has already been made available to the end-user;

- (12) 'withdrawal' means any measure aimed at preventing electrical equipment in the supply chain from being made available on the market;
- (13) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (14) 'CE marking' means a marking by which the manufacturer indicates that the electrical equipment is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

#### Article 3

##### **Making available on the market and safety objectives**

Electrical equipment may be made available on the Union market only if, having been constructed in accordance with good engineering practice in safety matters in force in the Union, it does not endanger the health and safety of persons and domestic animals, or property, when properly installed and maintained and used in applications for which it was made.

The principal elements of the safety objectives are listed in Annex I.

#### Article 4

##### **Free movement**

The Member States shall not impede, for the aspects covered by this Directive, the making available on the market of electrical equipment which complies with this Directive.

#### Article 5

##### **Supply of electricity**

In relation to electrical equipment, the Member States shall ensure that stricter safety requirements than the safety objectives referred to in Article 3 and set out in Annex I are not imposed by electricity supply bodies for connection to the grid, or for the supply of electricity to users of electrical equipment.

#### CHAPTER 2

##### **OBLIGATIONS OF ECONOMIC OPERATORS**

#### Article 6

##### **Obligations of manufacturers**

1. When placing their electrical equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the safety objectives referred to in Article 3 and set out in Annex I.

2. Manufacturers shall draw up the technical documentation referred to in Annex III and carry out the conformity assessment procedure referred to in Annex III or have it carried out.

Where compliance of electrical equipment with the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated by the conformity assessment procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation referred to in Annex III and the EU declaration of conformity for 10 years after the electrical equipment has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in product design or characteristics and changes in the harmonised standards referred to in Article 12, the international or national standards referred to in Articles 13 and 14, or in other technical specifications by reference to which conformity of electrical equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by electrical equipment, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of electrical equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming electrical equipment and electrical equipment recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that electrical equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the electrical equipment does not allow it, that the required information is provided on its packaging or in a document accompanying the electrical equipment.

6. Manufacturers shall indicate on the electrical equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the electrical equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that electrical equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the electrical equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have placed on the market.

#### Article 7

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the electrical equipment has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of electrical equipment;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by electrical equipment covered by the authorised representative's mandate.

#### Article 8

##### Obligations of importers

1. Importers shall place only compliant electrical equipment on the market.

2. Before placing electrical equipment on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the electrical equipment bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).

Where an importer considers or has reason to believe that electrical equipment is not in conformity with the safety objectives referred to in Article 3 and set out in Annex I, he shall not place the electrical equipment on the market until it has been brought into conformity. Furthermore, where the electrical equipment presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the electrical equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the electrical equipment. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the electrical equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while electrical equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety objectives referred to in Article 3 and set out in Annex I.

6. When deemed appropriate with regard to the risks presented by electrical equipment, importers shall, to protect the health and safety of consumers, carry out sample testing of electrical equipment made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming electrical equipment and electrical equipment recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that electrical equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that electrical equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the electrical equipment presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the electrical equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.



8. Importers shall, for 10 years after the electrical equipment has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of electrical equipment in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have placed on the market.

#### Article 9

##### Obligations of distributors

1. When making electrical equipment available on the market distributors shall act with due care in relation to the requirements of this Directive.

2. Before making electrical equipment available on the market distributors shall verify that the electrical equipment bears the CE marking, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the electrical equipment is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that electrical equipment is not in conformity with the safety objectives referred to in Article 3 and set out in Annex I, he shall not make the electrical equipment available on the market until it has been brought into conformity. Furthermore, where the electrical equipment presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while electrical equipment is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the safety objectives referred to in Article 3 and set out in Annex I.

4. Distributors who consider or have reason to believe that electrical equipment which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that equipment into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the electrical equipment presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which

they made the electrical equipment available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of electrical equipment. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by electrical equipment which they have made available on the market.

#### Article 10

##### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 6, where he places electrical equipment on the market under his name or trade mark or modifies electrical equipment already placed on the market in such a way that compliance with this Directive may be affected.

#### Article 11

##### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with electrical equipment;
- (b) any economic operator to whom they have supplied electrical equipment.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the electrical equipment and for 10 years after they have supplied the electrical equipment.

#### CHAPTER 3

##### CONFORMITY OF THE ELECTRICAL EQUIPMENT

#### Article 12

##### Presumption of conformity on the basis of harmonised standards

Electrical equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the safety objectives referred to in Article 3 and set out in Annex I covered by those standards or parts thereof.

### Article 13

#### **Presumption of conformity on the basis of international standards**

1. Where harmonised standards referred to in Article 12 have not been drawn up and published, the Member States shall take all appropriate measures to ensure that, for the purposes of making available on the market or free movement as referred to in Articles 3 and 4 respectively, their competent authorities shall also regard as complying with the safety objectives referred to in Article 3 and set out in Annex I electrical equipment which complies with the safety provisions of the international standards set out by the International Electrotechnical Commission (IEC) in respect of which the publication procedure laid down in paragraphs 2 and 3 of this Article has been applied.

2. The safety provisions referred to in paragraph 1 shall be notified to the Member States by the Commission. The Commission, after consulting the Member States, shall state the safety provisions and in particular the variants thereof which it recommends to be published.

3. The Member States shall inform the Commission within a period of three months of any objections they may have to the safety provisions notified in accordance with paragraph 2, stating the safety grounds on account of which the provisions should not be recognised.

For purposes of information the references of the safety provisions against which no objection has been raised shall be published in the *Official Journal of the European Union*.

### Article 14

#### **Presumption of conformity on the basis of national standards**

Where harmonised standards referred to in Article 12 have not been drawn up and published and international standards referred to in Article 13 have not been published, the Member States shall take all appropriate measures to ensure that, for the purpose of making available on the market or free movement as referred to in Articles 3 and 4 respectively, their competent authorities shall also regard as complying with the safety objectives referred to in Article 3 and set out in Annex I electrical equipment manufactured in accordance with the safety provisions of the standards in force in the Member State of manufacture, if it ensures a safety level equivalent to that required in their own territory.

### Article 15

#### **EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the safety objectives referred to in Article 3 and set out in Annex I has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IV, shall contain the elements specified in Module A as set out in Annex III and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the electrical equipment is placed or made available on the market.

3. Where electrical equipment is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the electrical equipment with the requirements laid down in this Directive.

### Article 16

#### **General principles of the CE marking**

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

### Article 17

#### **Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the electrical equipment or to its data plate. Where that is not possible or not warranted on account of the nature of the electrical equipment, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the electrical equipment is placed on the market.

3. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

### CHAPTER 4

#### **UNION MARKET SURVEILLANCE, CONTROL OF ELECTRICAL EQUIPMENT ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE**

### Article 18

#### **Union market surveillance and control of electrical equipment entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to electrical equipment.

*Article 19***Procedure for dealing with electrical equipment presenting a risk at national level**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that electrical equipment covered by this Directive presents a risk to the health or safety of persons or domestic animals, or to property, they shall carry out an evaluation in relation to the electrical equipment concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the electrical equipment does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the electrical equipment into compliance with those requirements, to withdraw the electrical equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of electrical equipment concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the electrical equipment's being made available on their national market, to withdraw the electrical equipment from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the

data necessary for the identification of the non-compliant electrical equipment, the origin of the electrical equipment, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

- (a) failure of the electrical equipment to meet the safety objectives referred to in Article 3 and set out in Annex I relating to the health or safety of persons or domestic animals, or to property; or
- (b) shortcomings in the harmonised standards referred to in Article 12 or in the international or national standards referred to in Articles 13 and 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the electrical equipment concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the electrical equipment concerned such as withdrawal of the electrical equipment from the market, without delay.

*Article 20***Union safeguard procedure**

1. Where, on completion of the procedure set out in Article 19(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.



2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant electrical equipment is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the electrical equipment is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 19(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

#### Article 21

##### **Compliant electrical equipment which presents a risk**

1. Where, having carried out an evaluation under Article 19(1), a Member State finds that although electrical equipment is in compliance with this Directive, it presents a risk to the health or safety of persons, or to domestic animals or to property it shall require the relevant economic operator to take all appropriate measures to ensure that the electrical equipment concerned, when placed on the market, no longer presents that risk, to withdraw the electrical equipment from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all electrical equipment concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the electrical equipment concerned, the origin and the supply chain of the electrical equipment, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 23(2).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, or of domestic

animals or of property, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 23(3).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

#### Article 22

##### **Formal non-compliance**

1. Without prejudice to Article 19, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Directive;
- (b) the CE marking has not been affixed;
- (c) the EU declaration of conformity has not been drawn up;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) technical documentation is either not available or not complete;
- (f) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;
- (g) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the electrical equipment being made available on the market or ensure that it is recalled or withdrawn from the market.

#### CHAPTER 5

##### **COMMITTEE, TRANSITIONAL AND FINAL PROVISIONS**

#### Article 23

##### **Committee procedure**

1. The Commission shall be assisted by the Committee on Electrical Equipment. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

4. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

#### Article 24

##### Penalties

Member States shall lay down rules on penalties, applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

#### Article 25

##### Transitional provisions

Member States shall not impede the making available on the market of electrical equipment covered by Directive 2006/95/EC which is in conformity with that Directive and which was placed on the market before 20 April 2016.

#### Article 26

##### Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with Article 2, the first paragraph of Article 3, Article 4, Articles 6 to 12, Article 13(1), Articles 14 to 25 and Annexes II, III and IV. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They

shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

#### Article 27

##### Repeal

Directive 2006/95/EC is repealed with effect from 20 April 2016, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex V.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VI.

#### Article 28

##### Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 1, the second paragraph of Article 3, Article 5, Article 13(2) and (3) and Annexes I, V and VI shall apply from 20 April 2016.

#### Article 29

##### Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

## ANNEX I

## PRINCIPAL ELEMENTS OF THE SAFETY OBJECTIVES FOR ELECTRICAL EQUIPMENT DESIGNED FOR USE WITHIN CERTAIN VOLTAGE LIMITS

**1. General conditions**

- (a) the essential characteristics, the recognition and observance of which will ensure that electrical equipment will be used safely and in applications for which it was made, shall be marked on the electrical equipment, or, if this is not possible, on an accompanying document;
- (b) the electrical equipment, together with its component parts, shall be made in such a way as to ensure that it can be safely and properly assembled and connected;
- (c) the electrical equipment shall be so designed and manufactured as to ensure that protection against the hazards set out in points 2 and 3 is assured, providing that the equipment is used in applications for which it was made and is adequately maintained.

**2. Protection against hazards arising from the electrical equipment**

Measures of a technical nature shall be laid down in accordance with point 1, in order to ensure that:

- (a) persons and domestic animals are adequately protected against the danger of physical injury or other harm which might be caused by direct or indirect contact;
- (b) temperatures, arcs or radiation which would cause a danger, are not produced;
- (c) persons, domestic animals and property are adequately protected against non-electrical dangers caused by the electrical equipment which are revealed by experience;
- (d) the insulation is suitable for foreseeable conditions.

**3. Protection against hazards which may be caused by external influences on the electrical equipment**

Technical measures shall be laid down in accordance with point 1, in order to ensure that the electrical equipment:

- (a) meets the expected mechanical requirements in such a way that persons, domestic animals and property are not endangered;
  - (b) is resistant to non-mechanical influences in expected environmental conditions, in such a way that persons, domestic animals and property are not endangered;
  - (c) does not endanger persons, domestic animals and property in foreseeable conditions of overload.
-

*ANNEX II*

## EQUIPMENT AND PHENOMENA OUTSIDE THE SCOPE OF THIS DIRECTIVE

Electrical equipment for use in an explosive atmosphere

Electrical equipment for radiology and medical purposes

Electrical parts for goods and passenger lifts

Electricity meters

Plugs and socket outlets for domestic use

Electric fence controllers

Radio-electrical interference

Specialised electrical equipment, for use on ships, aircraft or railways, which complies with the safety provisions drawn up by international bodies in which the Member States participate.

Custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

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## ANNEX III

## MODULE A

**Internal production control**

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the electrical equipment concerned satisfy the requirements of this Directive that apply to it.

2. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the electrical equipment's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the electrical equipment. The technical documentation shall, where applicable, contain at least the following elements:

- (a) a general description of the electrical equipment;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the electrical equipment;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or international or national standards referred to in Articles 13 and 14 and, where those harmonised standards or international or national standards have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.; and
- (f) test reports.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured electrical equipment with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to it.

4. **CE marking and EU declaration of conformity**

- 4.1. The manufacturer shall affix the CE marking to each individual electrical equipment that satisfies the applicable requirements of this Directive.
- 4.2. The manufacturer shall draw up a written EU declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national market surveillance authorities for 10 years after the electrical equipment has been placed on the market. The EU declaration of conformity shall identify the electrical equipment for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant market surveillance authorities upon request.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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## ANNEX IV

EU DECLARATION OF CONFORMITY (No XXXX) <sup>(1)</sup>

1. Product model/product (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of electrical equipment allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the electrical equipment):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

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<sup>(1)</sup> It is optional for the manufacturer to assign a number to the declaration of conformity.

## ANNEX V

**Time-limits for transposition into national law and dates of application of the Directives set out in Part B of Annex V to Directive 2006/95/EC****(referred to in Article 27)**

Directive	Time-limit for transposition	Date of application
73/23/EEC	21 August 1974 <sup>(1)</sup>	—
93/68/EEC	1 July 1994	1 January 1995 <sup>(2)</sup>

<sup>(1)</sup> In the case of Denmark the time-limit was extended to five years, i.e. 21 February 1978. See Article 13(1) of Directive 73/23/EEC.

<sup>(2)</sup> Until 1 January 1997 Member States had to allow the placing on the market and the bringing into service of products which complied with the marking arrangements in force before 1 January 1995. See Article 14(2) of Directive 93/68/EEC.

## ANNEX VI

## CORRELATION TABLE

Directive 2006/95/EC	This Directive
Article 1	Second paragraph of Article 1
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5	Article 12
Article 6	Article 13
Article 7	Article 14
Article 8(1)	Articles 16 and 17
Article 8(2)	—
Article 8(3)	—
Article 9	Articles 18 to 20
Article 10	Articles 16 and 17
Article 11	—
Article 12	—
Article 13	Article 26(2)
Article 14	Article 27
Article 15	Article 28
Annex I	Annex I
Annex II	Annex II
Annex III	Articles 15 and 16 and Annex IV
Annex IV	Annex III
Annex V	Annex V



**STATEMENT OF THE EUROPEAN PARLIAMENT**

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.

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**Publications Office of the European Union**  
2985 Luxembourg  
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