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**NEW LEGISLATIVE FRAMEWORK (NLF) ALIGNMENT PACKAGE
(Implementation of the Goods Package)**

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

General context, reasons for and objectives of this proposal

This proposal is presented in the framework of the **implementation of the “goods package”** adopted in 2008. It is part of a package of proposals aligning ten product directives to Decision No 768/2008/EC establishing a common framework for the marketing of products.

Union (EU) harmonisation legislation ensuring the free movement of products has contributed considerably to the completion and operation of the Single Market. It is based on a high level of protection and provides economic operators with the means to demonstrate conformity, thus ensuring free movement through trust in the products.

Directive 94/9/EC (the ATEX Directive) is an example of that Union harmonisation legislation, ensuring the free movement of products. It sets out the essential health and safety requirements that products must comply with in order to be made available on the EU market. Manufacturers must demonstrate that a product has been designed and manufactured in compliance with the essential health and safety requirements and affix the CE marking.

Experience with the implementation of Union harmonisation legislation has shown – on a cross-sector scale - certain weaknesses and inconsistencies in the implementation and enforcement of this legislation, leading to

- the presence of non-compliant or dangerous products on the market and consequently a certain lack of trust in CE marking,
- competitive disadvantages for economic operators complying with the legislation as opposed to those circumventing the rules,
- unequal treatment in the case of non-compliant products and distortion of competition amongst economic operators due to different enforcement practices,
- differing practices in the designation of conformity assessment bodies by national authorities, and
- problems with the quality of certain notified bodies.

Furthermore the regulatory environment has become more and more complex, as frequently several pieces of legislation apply simultaneously to one and the same product. Inconsistencies in these pieces of legislation make it increasingly difficult for economic operators and authorities to correctly interpret and apply that legislation.

To remedy these horizontal shortcomings in Union harmonisation legislation observed across several industrial sectors, the "**New Legislative Framework**" was adopted in 2008 as part of the **goods package**. Its objective is to strengthen and complete the existing rules and to improve practical aspects of their application and enforcement. The New Legislative Framework (NLF) consists of two complementary instruments, **Regulation (EC) No 765/2008 on accreditation and market surveillance** and **Decision No 768/2008/EC establishing a common framework for the marketing of products**.

The NLF Regulation has introduced rules on accreditation (a tool for the evaluation of competence of conformity assessment bodies) and requirements for the organisation and performance of market surveillance and controls of products from third countries. Since 1 January 2010 these rules apply directly in all Member States.

The NLF Decision sets out a common framework for EU product harmonisation legislation. This framework consists of the provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc). These common provisions have been reinforced to ensure that the directives can be applied and enforced more effectively in practice. New elements, such as obligations on importers, have been introduced, which are crucial for improving the safety of products on the market.

The provisions of the NLF Decision and those of the NLF Regulation are complementary and closely interlinked. The NLF Decision contains the corresponding obligations for economic operators and notified bodies allowing market surveillance authorities and authorities responsible for notified bodies to properly perform the tasks imposed on them by the NLF Regulation and to ensure an effective and consistent enforcement of EU product legislation.

However, unlike the NLF Regulation, the provisions of the NLF Decision are not directly applicable. To ensure that all economic sectors subject to Union harmonisation legislation benefit from the improvements of the NLF, the provisions of the NLF Decision need to be integrated into the existing product legislation.

A survey after the adoption of the goods package in 2008 showed that a majority of Union harmonisation legislation on products was due to be revised within the following 3 years, not only to address the problems observed throughout all sectors but also for sector-specific reasons. Any such revision would automatically include an alignment of the legislation concerned to the NLF Decision since Parliament, Council and Commission have committed themselves to use its provisions as much as possible in future legislation on products in order to further the utmost coherence of the regulatory framework.

For a number of other Union harmonisation directives, including Directive 94/9/EC, no revision for sector-specific problems had been envisaged within this timeframe. To ensure that the problems in relation to non-compliance and notified bodies are nevertheless addressed in these sectors, and for the sake of consistency of the overall regulatory environment on products, it was decided to align these directives within a package to the provisions of the NLF Decision.

Consistency with other policies and objectives of the Union

This initiative is in line with the Single Market Act¹, which has stressed the need to restore consumer confidence in the quality of products on the market and the importance of reinforcing market surveillance.

Furthermore it supports the Commission's policy on Better Regulation and simplification of the regulatory environment.

¹ Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, COM(2011) 206 final.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

The alignment of the ATEX Directive 94/9/EC to the NLF Decision has been discussed with national experts responsible for the implementation of this Directive, the notified body group, the administrative cooperation group as well as the representatives of industry associations in the relevant experts working group.

From June to October 2010 a public consultation was organised that comprised all the sectors involved in this initiative. It consisted of four targeted questionnaires for economic operators, authorities, notified bodies and users and the Commission services received 300 replies. The results are published at http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm.

In addition to the general consultation a specific SME consultation was carried out. 603 SMEs were consulted through the Enterprise Europe Network in May/June 2010. The results are available at http://ec.europa.eu/enterprise/policies/single-market-goods/files/new-legislative-framework/smes_statistics_en.pdf.

The consultation process revealed widespread support for the initiative. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring Notified Bodies. Authorities fully support the exercise because it will strengthen the existing system and improve cooperation at EU level. Industry expects a more level playing field resulting from more effective actions against products that do not comply with the legislation, as well as a simplification effect from the alignment of legislation. Certain concerns were expressed on some obligations which are, however, indispensable for increasing the efficiency of market surveillance. These measures will not entail significant costs for industry, and the benefits resulting from improved market surveillance should by far outweigh the costs.

Collection and use of expertise

The impact assessment for this implementation package has largely built on the impact assessment carried out for the New Legislative Framework. In addition to the expertise collected and analysed in that context, further consultation of sector-specific experts and interest groups, as well as horizontal experts active in the area of technical harmonisation, conformity assessment, accreditation and market surveillance, has taken place.

External expertise was used to obtain some basic data on certain sectors: for the ATEX sector, the study "Market description, competitiveness analysis in the field of products and protective systems intended for use in potentially explosive atmospheres", available on http://ec.europa.eu/enterprise/sectors/mechanical/files/atex/atexcomp_finalreport_en.pdf.

Impact assessment

Based on the information collected, the Commission carried out an impact assessment which examined and compared three options.

Option 1 – No changes to the current situation

This option proposes no changes to the current directive and relies exclusively on certain improvements that can be expected from the NLF Regulation.

Option 2 – Alignment to the NLF Decision by non-legislative measures

Option 2 considers the possibility of encouraging a voluntary alignment to the provisions set out in the NLF Decision by, e.g., presenting them as best practices in guidance documents.

Option 3 – Alignment to NLF Decision by legislative measures

This option consists in integrating the provisions of the NLF Decision into the existing directives.

Option 3 was found to be the preferred option because

- it will improve the competitiveness of companies and notified bodies taking their obligations seriously, as opposed to those cheating on the system;
- it will improve the functioning of the internal market by ensuring equal treatment of all economic operators, notably importers and distributors, as well as notified bodies;
- it does not entail significant costs for economic operators and notified bodies; for those who are already acting responsibly, no extra costs or only negligible costs are expected;
- it is considered more effective than option 2: due to the lack of enforceability of option 2 it is questionable that the positive impacts would materialise under that option;
- options 1 and 2 do not provide answers to the problem of inconsistencies in the regulatory framework and therefore have no positive impact on the simplification of the regulatory environment.

3. MAIN ELEMENTS OF THE PROPOSAL

3.1. Horizontal definitions

The proposal introduces harmonised definitions of terms which are commonly used throughout Union harmonisation legislation and should therefore be given a consistent meaning throughout that legislation.

3.2. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of manufacturers and authorised representatives and introduces obligations for importers and distributors. Importers must verify that the manufacturer has carried out the applicable conformity assessment procedure and has drawn up a technical documentation. They must also make sure with the manufacturer that this technical documentation can be made available to authorities upon request. Furthermore importers must verify that the products are correctly marked and accompanied by the required documents, instructions and safety information. They must keep a copy of the Declaration of conformity and indicate their name and address on the product, or where this is not possible on the packaging or the accompanying documentation. Distributors must verify that the product bears the CE marking, the name of the manufacturer and of the importer, if relevant, and that it is accompanied by the required documentation and instructions.

Importers and distributors must cooperate with market surveillance authorities and take appropriate actions when they have supplied non-compliant products.

Enhanced traceability obligations are introduced for all economic operators. Products have to bear the manufacturer's name and address and a number allowing to identify and link the product to its technical documentation. When a product is imported the importer's name and address must also be on the product. Furthermore every economic operator must be able to identify towards authorities the economic operator who has supplied him with a product or to whom he has supplied a product.

3.3. Harmonised standards

Compliance with harmonised standards provides a presumption of conformity with the essential requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation² that sets out a horizontal legal framework for European standardisation. The proposal for the Regulation contains inter alia provisions on standardisation requests from the Commission to the European Standardisation Organisations, on the procedure for objections to harmonised standards and on stakeholder participation in the standardisation process. Consequently the provisions of Directive 94/9/EC which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

The provisions conferring presumption of conformity to harmonised standards have been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential requirements.

3.4. Conformity assessment and CE marking

Directive 94/9/EC has selected the appropriate conformity assessment procedures which manufacturers have to apply in order to demonstrate that their products comply with the essential health and safety requirements. The proposal aligns these procedures to their updated versions set out in the NLF Decision. Sector specific elements of the procedures have been maintained.

General principles of the CE marking are set out in Article 30 of Regulation 765/2008, while the detailed provisions on the affixing of the CE marking and the specific marking of explosion protection to products have been inserted in this proposal.

3.5. Notified Bodies

The proposal reinforces the notification criteria for notified bodies. It clarifies that subsidiaries or subcontractors must also comply with the notification requirements. Specific requirements for notifying authorities are introduced, and the procedure for notification of notified bodies is revised. The competence of a notified body must be demonstrated by an accreditation certificate. Where accreditation has not been used to evaluate the competence of a notified body, the notification must comprise the documentation demonstrating how the competence of that body has been evaluated. Member States will have the possibility to object to a notification.

3.6. Market surveillance and the safeguard clause procedure

The proposal revises the existing safeguard clause procedure. It introduces a phase of information exchange between Member States, and specifies the steps to be taken by the

² COM(2011) 315 final.

authorities concerned, when a non-compliant product is found. A real safeguard clause procedure – leading to a Decision at Commission level on whether a measure is justified or not – is only launched when another Member State objects to a measure taken against a product. Where there is no disagreement on the restrictive measure taken, all Member States must take the appropriate action on their territory.

3.7. Comitology and Delegated acts

The provisions on the operation of standing committees have to be adapted to the new rules on delegated acts laid down in Article 290 of the Treaty on the Functioning of the EU and to the new provisions on implementing acts laid down in 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 the Member States of the Commission's exercise of implementing powers³.

Directive 94/9/EC provided for a standing committee. As this committee is not involved in the adoption of implementing acts provided for in Article 291 of the Treaty on the Functioning of the EU, and no need to adopt implementing acts appears under the new Directive, therefore this provision has been deleted in the proposal.

The Commission will set up an expert working group in accordance with the Communication from the President to the Commission - Framework for Commission expert groups: horizontal rules and public register (C(2010) 7649 final), that will carry out the tasks of the standing committee provided for in Directive 94/9/EC, to examine any question relating to the application of the Directive.

4. LEGAL ELEMENTS OF THE PROPOSAL

Legal basis

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union.

Subsidiarity principle

The internal market is a competence that is shared between the Union and the Member States. The subsidiarity principle arises in particular with regard to the newly added provisions aiming at the improvement of effective enforcement of Directive 94/9/EC, namely, the importer and distributor obligations, the traceability provisions, the provisions on the assessment and notification of notified bodies, and the enhanced cooperation obligations in the context of the revised market surveillance and safeguard procedures.

Experience with the enforcement of the legislation has shown that measures taken at national level have led to divergent approaches and to a different treatment of economic operators inside the EU, which undermines the objective of this directive. If actions are taken at national level to address the problems, this risks creating obstacles to the free movement of goods. Furthermore action at national level is limited to the territorial competence of a Member State. In view of the increasing internationalisation of trade, the number of cross-

³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and the general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p.13).

border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

As regards the problem of inconsistencies throughout the directives, this is a problem which can only be solved by the EU legislator.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set.

The new or modified obligations do not impose unnecessary burdens and costs on industry - especially on small and medium sized enterprises - or administrations. Where modifications have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified. A number of modifications concern the improvement of clarity of the existing Directive without introducing new requirements that entail added cost.

Legislative technique used

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 94/9/EC. To ensure the readability of the amended text the technique of recasting has been chosen in line with the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts⁴.

The changes made to the provisions of Directive 94/9/EC concern: the definitions, the obligations of economic operators, the presumption of conformity provided by harmonised standards, the declaration of conformity, CE marking, notified bodies, the safeguard clause procedure and the conformity assessment procedures.

The proposal does not change the scope of Directive and the essential health and safety requirements.

5. BUDGETARY IMPLICATIONS

This proposal does not have any implications for the EU budget.

6. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 94/9/EC.

European Economic Area

The proposal concerns the EEA and should therefore be extended to the European Economic Area.

⁴ OJ C 77, 28. 3. 2002.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the ~~approximation~~ harmonisation of the laws of the Member States
~~concerning~~ 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 ~~establishing the European Community~~ on the Functioning of the European Union , and in particular Article ~~100a~~ 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 Committee⁵,

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ new

- (1) Directive 94/9/EC of the European Parliament and 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 atmospheres⁶ has been substantially amended. Since further amendments are to be made, it 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 and repealing Regulation (EEC) No 339/93⁷ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the

⁵ OJ C [...], [Date], p. [...].

⁶ OJ L 100, 19.4.1994, p. 1.

⁷ OJ L 218, 13.8.2008, p. 30.

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, and repealing Council Decision 93/465/EEC⁸ lays down a common framework of general principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 94/9/EC should therefore be adapted to that Decision.

↓ 94/9/EC recital 1 (adapted)

- (4) ~~Whereas it~~ It is the duty of Member States to protect, on their territory, the safety and health of persons and, where appropriate, domestic animals and property and, in particular, that of workers, especially against the hazards resulting from the use of equipment and systems providing protection against potentially explosive atmospheres.

↓ 94/9/EC recital 2 (adapted)

~~Whereas mandatory provisions within the Member States determine the level of safety to be achieved by protective equipment and systems intended for use in potentially explosive atmospheres; whereas these are generally electrical and non-electrical specifications having an effect on the design and structure of equipment which can be used in potentially explosive atmospheres;~~

↓ 94/9/EC recital 3 (adapted)

~~Whereas the requirements to be met by such equipment differ from one Member State to another in respect of their extent and differing inspection procedures; whereas these differences are, therefore, likely to raise barriers to trade within the Community;~~

↓ 94/9/EC recital 4 (adapted)

~~Whereas harmonization of national legislation is the only way in which to remove these barriers to free trade; whereas this objective cannot be satisfactorily achieved by the individual Member States; whereas this Directive merely lays down the requirements vital to freedom of movement for the equipment to which it applies;~~

↓ 94/9/EC recital 5 (adapted)

~~Whereas the regulations intended to remove technical barriers to trade are required to follow the new approach provided for in the Council resolution of 7 May 1985⁹, which requires a definition of the essential requirements regarding safety and other requirements of society without reducing existing, justified levels of protection within the Member States; whereas~~

⁸ OJ L 218, 13.8.2008, p. 82.

⁹ OJ No C 136, 4. 6. 1985, p. 1.

~~that resolution provides that a very large number of products be covered by a single Directive in order to avoid frequent amendments and the proliferation of Directives;~~

↓ 94/9/EC recitals 6 and 8
(adapted)

- (5) ~~Whereas the existing Directives~~ ☒ 94/9/EC ☒ ~~on the approximation of the laws of the Member States to electrical equipment for use in potentially explosive atmospheres have~~ ☒ has ☒ made positive steps towards ☒ effective ☒ protection against explosions via measures linked with the structure of the equipment at issue and which have helped to remove barriers to trade in this area; whereas, in parallel, a revision and expansion of the existing Directives is necessary since, more particularly, in an overall context, action must be taken to guard against the potential hazards arising from such equipment. This implies in particular that measures intended to guarantee effective protection of users and third parties must already be contemplated at the design and manufacturing stages; ☒ hazards for both mining and surface equipment. Those ☒ ~~Whereas the two groups of equipment referred to above~~ are used in a large number of commercial and industrial sectors and possess considerable economic significance.
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↓ 94/9/EC recital 7 (adapted)

~~Whereas the form taken by the hazard, the protective measures and the test methods are often very similar, if not identical, for both mining and surface equipment; whereas it is, therefore, absolutely necessary to cover by a single Directive protective equipment and systems falling within both groups;~~

↓ 94/9/EC recital 9 (adapted)

- (6) ~~Whereas~~ eCompliance with the ~~basic safety and health~~ ☒ and safety ☒ requirements is essential in order to ensure the safety of protective equipment and systems, ~~whereas~~ ~~Those requirements have been~~ ☒ should be ☒ subdivided into general and additional requirements which ~~must~~ ☒ need to ☒ be met by protective equipment and systems, ~~whereas~~, In particular, the additional requirements ~~are intended to~~ ☒ should ☒ take account of existing or potential hazards, ~~whereas~~ Protective equipment and systems ~~will~~ ☒ should ☒, therefore, embody at least one of those requirements where this is necessary for their proper functioning or is to apply to their intended use, ~~whereas~~ The notion of intended use is of prime importance for the explosion-proofing of protective equipment and systems, ~~whereas~~ It is essential that manufacturers supply full information, ~~whereas~~ Specific, clear marking of ~~said~~ ☒ that ☒ equipment, stating its use in a potentially explosive atmosphere, is also necessary.
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↓ 94/9/EC recital 10 (adapted)

~~Whereas the intention is to prepare a Directive on operations in potentially explosive atmospheres which is based on Article 118a; whereas that additional Directive will, in particular, aim at explosion hazards which derive from a given use and/or types and methods of installation;~~

↓ 94/9/EC recital 11 (adapted)

(7) ~~Whereas compliance with the essential health and safety requirements is imperative if in order to ensure the safety of equipment is to be ensured; whereas judgment will have to be exercised in~~ For the implementation of those requirements, both the technology obtained at the time of manufacture and overriding technical and economic requirements ~~in order to take~~ should be taken into account ~~of both the technology obtaining at the time of manufacture and overriding technical and economic requirements.~~

↓ 94/9/EC recital 12 (adapted)

~~Whereas, therefore, this Directive sets out essential requirements only; whereas, in order to facilitate the task of proving compliance with the essential requirements, harmonized European standards are necessary, more especially with regard to the non-electrical aspects of protection against explosions — standards relating to the design, manufacture and testing of equipment, compliance with which enables a product to be presumed to meet such essential requirements; whereas harmonized European standards are drawn up by private bodies and must retain their non-mandatory status; whereas, for this purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the bodies competent to adopt harmonized standards which follow the general guidelines for cooperation between the Commission and those two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European Standard or harmonization document) adopted by one or other of those bodies, or by both, at the prompting of the Commission pursuant to Council Directive 83/189/EEC of the 28 March 1983 providing for a procedure governing the provision of information on technical standards and regulations¹⁰ and pursuant to the general guidelines referred to above;~~

↓ 94/9/EC recital 13 (adapted)

~~Whereas the legislative framework should be improved in order to ensure that employers and workers make an effective and appropriate contribution towards the standardization process; whereas this should be completed by the time this Directive is implemented;~~

↓ 94/9/EC recital 14 (adapted)

~~Whereas, in view of the nature of the risks involved in the use of equipment in potentially explosive atmospheres it is necessary to establish procedures applying to the assessment of compliance with the basic requirements of the Directives; whereas these procedures must be devised in the light of the level of risk which may be inherent in equipment and/or against which systems must protect the immediate environment; whereas, therefore, each category of equipment conformity must be supplemented by an adequate procedure or a choice between several equivalent procedures; whereas the procedures adopted comply fully with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the~~

¹⁰ OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by Directive 88/182/EEC (OJ No L 81, 26. 3. 1988, p. 75).

~~conformity assessment procedures which are intended to be used in the technical harmonization Directives¹¹;~~

↓ 94/9/EC recital 15 (adapted)

~~Whereas the Council has provided for the affixing of the CE marking by either the manufacturer or his authorized representative within the Community; whereas that marking means that the product complies with all the basic requirements and assessment procedures provided for by the Community law applying to that product;~~

↓ 94/9/EC recital 16 (adapted)

~~Whereas it is appropriate that the Member States, as provided for by Article 100a of the Treaty, may take temporary measures to limit or prohibit the placing on the market and the use of equipment and protective systems in cases where they present a particular risk to the safety of persons and, where appropriate, domestic animals or property, provided that the measures are subject to a Community control procedure;~~

↓ 94/9/EC recital 17 (adapted)

~~Whereas the recipients of any decision taken as part of this Directive must be aware of the reasons behind that decision and the means of appeal open to them;~~

↓ 94/9/EC recital 18 (adapted)

~~Whereas, on 18 December 1985, the Council adopted a framework Directive on electrical equipment for use in potentially explosive atmospheres (76/117/EEC)¹² and, on 15 February 1982, a Directive concerning electrical equipment for use in potentially explosive atmospheres in mines susceptible to fire damp (82/130/EEC)¹³; whereas, from the outset of harmonization work, the conversion into total harmonization of the optional and partial harmonization on which these Directives are based had been contemplated; whereas this Directive fully covers the scope of the abovementioned Directives and whereas, therefore, these Directives must be repealed;~~

↓ 94/9/EC recital 19 (adapted)

~~Whereas the internal market incorporates an area without internal frontiers within which the free movement of goods, persons, services and capital is assured;~~

↓ 94/9/EC recital 20 (adapted)

~~Whereas it is necessary to provide for a transitional arrangement enabling equipment manufactured in compliance with the national regulations in force at the date of adoption of this Directive to be marketed and placed in service;~~

¹¹ OJ No L 220, 30. 8. 1993, p. 23.

¹² OJ No L 24, 31. 1. 1976, p. 45. Directive as last amended by Directive 90/487/EEC (OJ No L 270, 2. 10. 1990, p. 23).

¹³ OJ No L 59, 2. 3. 1982, p. 10.

- (8) Economic operators should be responsible for the compliance of products, 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, and the protection of end-users and of the environment, 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 make available on the market only 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 operator in the supply and distribution process.
- (10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (11) It is necessary to ensure that products from third countries entering the Union market comply with the requirements of this Directive, and in particular that appropriate 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 supervisory authorities.
- (12) 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.
- (13) When placing a product on the market, every importer should indicate on the product his name and the 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.
- (14) Any economic operator that either places a product on the market under his own name or trademark or modifies a product in such a way that compliance with the requirements of 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 with all necessary information relating to the product concerned.
- (16) Ensuring traceability of a product 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 products available on the market.

- (17) 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 presumption of conformity for products which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [...] of the European Parliament and of the Council of [...] on European Standardisation and amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/105/EC and 2009/23/EC of the European Parliament and of the Council¹⁴ for the purpose of expressing detailed technical specifications of those requirements.
- (18) Regulation (EU) No [...] [on European Standardisation] provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy requirements of this Directive.
- (19) 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.
- (20) The manufacturer should draw up an EU declaration of conformity to provide detailed information on the conformity of a product with the requirements of this Directive.
- (21) 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.
- (22) 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.
- (23) 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.

¹⁴ OJ L [...], [Date], p. [...].

- (24) 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.
- (25) 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.
- (26) 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.
- (27) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity 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 this 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.
- (28) 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.
- (29) 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.
- (30) 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.
- (31) 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 must be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (32) 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.

- (33) Directive 94/9/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 clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (34) 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 and safety of persons or to other aspects of public interest protection. 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.
- (35) 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.
- (36) The Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (37) It is necessary to provide for transitional arrangements that allow making available on the market and putting into service of products that have already been placed on the market in accordance with Directive 94/9/EC.
- (38) Since the objective of this Directive, namely to ensure that products on the market fulfil the requirements providing 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 and can therefore, 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.
- (39) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with Directive 94/9/EC. The obligation to transpose the provisions which are unchanged arises under Directive 94/9/EC.
- (40) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive 94/9/EC set out in Annex X, Part B,

↓ 94/9/EC

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER ~~1~~

↓ 94/9/EC (adapted)

~~SCOPE, PLACING ON THE MARKET AND FREEDOM OF MOVEMENT~~ ☒ GENERAL PROVISIONS ☒

Article 1

☒ Scope ☒

1. This Directive ~~applies~~ ☒ shall apply ☒ to ☒ the following products: ☒

↓ 94/9/EC

(a) equipment and protective systems intended for use in potentially explosive atmospheres;

↓ 94/9/EC (adapted)

(b) ~~2. 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 are also covered by the scope of this Directive.~~

4.2. ☒ This Directive shall not apply to ☒ ~~the following are excluded from the scope of this Directive~~ ☒ products ☒ :

↓ 94/9/EC

- medical devices intended for use in a medical environment;
- equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;
- 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;
- personal protective equipment covered by Council Directive 89/686/EEC¹⁵;

¹⁵ OJ L 399, 30.12. 1989, p. 18.

- seagoing vessels and mobile offshore units together with equipment on board such vessels or units;
- 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;
- the equipment covered by Article ~~223~~346(1)(b) of the Treaty.

↓ 94/9/EC (adapted)

Article 2

~~⊗~~ Definitions ~~⊗~~

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

~~Equipment and protective systems intended for use in potentially explosive atmospheres~~

↓ 94/9/EC
 →₁ Corrigendum, OJ L 21,
 26.1.2000, p. 42

(1) ~~(a)~~ ~~E~~quipment' 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, →₁ 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~~;~~

↓ 94/9/EC
 →₁ Corrigendum, OJ L 21,
 26.1.2000, p. 42
 ⇨ new

(2) ~~(b)~~ →₁ ~~P~~rotective systems' means devices other than components of the equipment defined above which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately ~~placed~~ ⇨ made available ⇐ on the market for use as autonomous systems~~;~~ ← :

↓ 94/9/EC (adapted)

(3) ~~(c)~~ ~~C~~omponents' means any item essential to the safe functioning of equipment and protective systems but with no autonomous function~~;~~

~~Explosive atmospheres~~

(4) ~~⊗~~ 'explosive atmosphere' means a ~~⊗~~ ~~M~~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~~⊗~~;

~~Potentially explosive atmosphere~~

(5) ~~⊗~~ 'potentially explosive atmosphere' means ~~⊗~~ ~~A~~an atmosphere which could become explosive due to local and operational conditions~~⊗~~;

~~Equipment groups and categories~~

↓ 94/9/EC (adapted)
→₁ Corrigendum, OJ L 304,
5.12.2000, p. 19

(6) ~~E~~quipment group I' ~~applies~~ ~~⊗~~ means ~~⊗~~ equipment intended for use →₁ 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 categories M1 and M2 as set out in Annex I; ~~⊗~~

↓ 94/9/EC (adapted)

(7) ~~E~~quipment group II' ~~applies~~ ~~⊗~~ means ~~⊗~~ equipment intended for use in other places liable to be endangered by explosive atmospheres~~⊗~~ ~~⊗~~, comprising categories 1, 2 and 3 as set out in Annex I; ~~⊗~~

(8) ~~⊗~~ 'category of equipment' means the definition of the required levels of protection, as referred to ~~⊗~~ ~~The categories of equipment defining the required levels of protection are described~~ in Annex I~~⊗~~;

~~Equipment and protective systems may be designed for a particular explosive atmosphere. In this case, they must be marked accordingly.~~

~~Intended use~~

(9) ~~⊗~~ 'intended use' means ~~⊗~~ ~~The use of equipment, protective systems, and devices referred to in Article 1 (2)~~ ~~⊗~~ products ~~⊗~~ in accordance with the equipment group and category and with all the information supplied by the manufacturer which is required for the safe functioning of ~~equipment, protective systems and devices~~ ~~⊗~~ products; ~~⊗~~

↓ new

[Article R1 of Decision No 768/2008/EC]

(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 trademark;

(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, process or service;

(18) 'harmonised standard' means harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No [.../...] [on European Standardisation];

(19) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;

(20) 'national accreditation body' means accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;

(21) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements relating to a product, process, service or system 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) '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;

(26) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products.

Article ~~22~~ 23

~~☒~~ Making available on the market ~~☒~~

1. Member States shall take all appropriate measures to ensure that ~~the equipment, protective systems and devices referred to in Article 1 (2) to which this Directive applies~~ ☒ products ☒ may be placed ⇒ made available ⇐ on the market and put into service only if, when properly installed and maintained and used for ☒ in accordance with ☒ their intended purpose, they ~~do not endanger the health and safety of persons and, where appropriate, domestic animals or property~~ ☒ comply with this Directive ☒ .

2. ~~The provisions of~~ This Directive shall not affect Member States' entitlement to lay down, ~~in due observance of the provisions of the Treaty,~~ such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using ~~the equipment, protective systems, and devices referred to in Article 1 (2) in question~~ ☒ relevant products ☒ provided that this does not mean that such ~~equipment, protective systems, or devices~~ ☒ products ☒ are modified in a way not specified in ~~the~~ ☒ this ☒ Directive.

3. At trade fairs, exhibitions, ☒ and ☒ demonstrations, ~~etc.,~~ Member States shall not prevent the showing of ~~equipment, protective systems, or the devices referred to in Article 1 (2)~~ ☒ products ☒ which do not ~~conform to the provisions of~~ ☒ comply with ☒ this Directive, provided that a visible sign clearly indicates that such ~~equipment, protective systems, and devices referred to in Article 1 (2)~~ ☒ products ☒ do not ~~conform~~ ☒ comply ☒ and that they are not for sale until they have been brought into conformity by the manufacturer or his authorized representative established in the ~~Community~~ ☒ Union ☒ . During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

Article ~~23~~ 24

~~☒~~ Essential health and safety requirements ~~☒~~

~~Equipment, protective systems, and the devices referred to in Article 1 (2) to which this Directive applies must~~ ☒ 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.

↓ 94/9/EC (adapted)
→₁ Corrigendum, OJ L 21,
26.1.2000, p. 42
⇒ new

Article 45

⊗ Free movement ⊗

1. Member States shall not prohibit, restrict or impede the ~~placing~~ ⇒ making available ⇐ on the market and putting into service in their territory of ~~equipment, protective systems, or devices referred to in Article 1 (2)~~ ⊗ products ⊗ which comply with this Directive.

2. Member States shall not prohibit, restrict or impede the ~~placing~~ ⇒ making available ⇐ on the market of components which, →₁ accompanied by a written attestation of conformity as referred to in Article ~~8(3)~~ ← 13(3), are intended to be incorporated into ~~equipment or protective systems~~ ⊗ products ⊗ within the meaning of this Directive.

↓ 94/9/EC

Article 5

~~1. Member States shall regard as conforming to all the provisions of this Directive, including the relevant conformity assessment procedures laid down in chapter II:~~

~~equipment, protective systems, and devices referred to in Article 1 (2) accompanied by the EC declaration of conformity referred to in Annex X and bearing the CE marking provided for in Article 10;~~

~~the components referred to in Article 4 (2), accompanied by the certificate of conformity referred to in Article 8 (3).~~

~~In the absence of harmonized standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national technical standards and specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements in Annex II.~~

~~2. Where a national standard transposing a harmonized standard, the reference for which has been published in the *Official Journal of the European Communities*, covers one or more of the essential health and safety requirements, the equipment, protective system, device referred to in Article 1 (2), or the component referred to in Article 4 (2), constructed in accordance with that standard shall be presumed to comply with the relevant essential health and safety requirements.~~

~~Member States shall publish the references of national standards transposing harmonized standards.~~

~~3. Member States shall ensure that appropriate measures are taken to enable the social partners to influence the process of preparing and monitoring the harmonized standards at national level.~~

~~Article 6~~

~~1. Where a Member State or the Commission considers that the harmonized standards referred to in Article 5 (2) do not entirely satisfy the relevant essential health and safety requirements referred to in Article 3, the Commission or the Member State concerned shall bring the matter before the Committee set up under Directive 83/189/EEC, hereinafter referred to as «the Committee», giving reasons therefor. The Committee shall deliver an opinion without delay.~~

~~Upon receipt of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw those standards from the published information referred to in Article 5 (2).~~

~~2. The Commission may adopt any appropriate measure with a view to ensuring the practical application in a uniform manner of this Directive in accordance with the procedure laid down in paragraph 3.~~

↓ Regulation (EC) No 1882/2003

~~3. The Commission shall be assisted by a standing committee (hereinafter referred to as 'the Committee').~~

~~Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/486/EC¹⁶ shall apply, having regard to the provisions of Article 8 thereof.~~

~~The Committee shall adopt its rules of procedure.~~

↓ 94/9/EC

~~4. The Standing Committee may furthermore examine any question relating to the application of this Directive and raised by its chairman either on the latter's initiative, or at the request of a Member State.~~

~~Article 7~~

↓ 94/9/EC

~~1. When a Member State ascertains that equipment, protective systems or devices referred to in Article 1 (2) bearing the CE conformity marking and used in accordance with their intended use are liable to endanger the safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such equipment or protective systems from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof.~~

¹⁶ Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred to the Commission (OJ L 184, 17.7.1999, p. 23).

~~The Member State shall immediately inform the Commission of any such measure, indicating the reasons for its decision and, in particular, whether non-conformity is due to:~~

~~(a) failure to satisfy the essential requirements referred to in Article 3;~~

~~(b) incorrect application of the standards referred to in Article 5 (2);~~

~~(c) shortcomings in the standards referred to in Article 5 (2).~~

~~2. The Commission shall enter into consultation with the parties concerned without delay. Where the Commission considers, after this consultation, that the measure is justified, it shall immediately so inform the Member State which took the initiative and the other Member States. Where the Commission considers, after this consultation, that the action is unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorized representative established within the Community. Where the decision referred to in paragraph 1 is based on a shortcoming in the standards and where the Member State at the origin of the decision maintains its position, the Commission shall immediately inform the Committee in order to initiate the procedures referred to in Article 6 (1).~~

~~3. Where equipment, a protective system or a device referred to in Article 1(2) which does not comply bears the CE conformity marking, the competent Member State shall take appropriate action against the person(s) having affixed the marking and shall so inform the Commission and the other Member States.~~

~~4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.~~

↓ new

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 6 [Article R2 of Decision No 768/2008/EC]

Obligations of manufacturers

1. When placing their products on the market, 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 Annex II and carry out the relevant conformity assessment procedure referred to in Article 13 or have it carried out.

Where compliance of a product 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 specific marking of explosion protection.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least 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. Changes in a product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

5. Manufacturers shall ensure that their products 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 indicate their name and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

7. 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.

8. 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 necessary corrective measures 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 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 necessary to demonstrate the conformity of the 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 7 [Article R3 of Decision No 768/2008/EC]

Authorised representatives

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

The obligations laid down in Article 6(1) and the drawing up of technical documentation 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 surveillance authorities for at least 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 [Article R4 of Decision No 768/2008/EC]

Obligations of importers

1. Importers shall place only compliant products on the Union market.

2. Before placing a product 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 product bears the CE marking and the specific marking of explosion protection 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 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 their name and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

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, storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II.

6. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the requirements of 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 to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

7. Importers shall, for at least 10 years after the product 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 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 [Article R5 of Decision No 768/2008/EC]

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 or putting it into service distributors shall verify that the product bears the CE marking and the specific marking of explosion protection, that it is accompanied by the required documents and by instructions 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) and (6) and Article 8(3).

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, 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 the requirements of 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 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 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 [Article R6 of Decision No 768/2008/EC]

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 trademark or modifies a product already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 11 [Article R7 of Decision No 768/2008/EC]

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities, for at least 10 years after the product has been placed on the market:

- (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 a period of 10 years after they have been supplied with the product and for a period of 10 years after they have supplied the product.

CHAPTER 3

CONFORMITY OF THE PRODUCT

Article 12 [Article R8 of Decision No 768/2008/EC]

Presumption of conformity

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 covered by those standards or parts thereof, set out in Annex II.

[Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex II or in Article 21, the Commission shall publish the references of those standards in the *Official Journal of the European Union*.]

↓ 94/9/EC (adapted)

2. In the absence of harmonized standards, Member States shall take any steps which they deem necessary to bring to the attention of the parties concerned to the existing national technical standards and specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements ~~☒~~ set out ~~☒~~ in Annex II.

↓ 94/9/EC (adapted)
⇒ new

Article ~~8~~13

~~☒~~ Conformity assessment procedures ~~☒~~

1. The procedures ~~☒~~ to be followed ~~☒~~ for assessing the conformity of equipment, including where necessary the devices referred to in Article 1 (2), ~~☒~~ products ~~☒~~ shall be as follows:

(a) ~~☒~~ for ~~☒~~ equipment-group I and II, equipment-category M 1 and 1 ~~☒~~, the ~~☒~~ ~~The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow the CE type examination~~ ⇒ EU-type examination ⇐ procedure ~~☒~~ (referred to in Annex III), in conjunction with ~~☒~~ either of the following procedures ~~☒~~ :

- the procedure relating to ~~production quality assurance~~ ⇒ Conformity to type based on quality assurance of the production process ⇐ ~~☒~~ (referred to in Annex IV); ~~☒~~
- the procedure relating to ~~product verification~~ ⇒ Conformity to type based on product verification ⇐ ~~☒~~ (referred to in Annex V);

(b) ~~☒~~ for ~~☒~~ ~~EE~~equipment-group I and II, equipment-category M 2 and 2;

(i) ~~in~~ in the case of internal combustion engines and electrical equipment in these groups and categories, ~~the manufacturer or his authorized representative established in the Community shall, in order to affix the CE mark, follow the EC type examination~~ ⇒ EU-type examination ⇐ procedure ~~☒~~ (referred to in Annex III), in conjunction with ~~☒~~ either of the following procedures ~~☒~~ :

- the procedure relating to ~~conformity to type~~ ⇒ Conformity to type based on internal production control plus supervised product testing ⇐ referred to in Annex VI; ~~☒~~
- the procedure relating to ~~product quality assurance~~ ⇒ Conformity to type based on product quality assurance ⇐ referred to in Annex VII;

(ii) in the case of other equipment in these groups and categories, ~~the manufacturer or his authorized representative established in the Community must, in order to affix the CE mark, follow the procedure relating to internal control of production~~ ⇒ Internal production control ⇐ ~~☒~~ (referred to in Annex VIII)

and

the communication of the dossier provided for in Annex VIII, paragraph ~~3~~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 ~~The manufacturer or his authorized representative established in the Community must, in order to affix the CE marking, follow~~ the procedure relating to ~~internal control of production~~ ⇒ Internal production control ⇐ referred to in Annex VIII;
- (d) ~~☒~~ for ~~☒~~ equipment-groups I and II, ~~in addition to the procedures referred to in paragraph 1~~ ~~☒~~ points ~~☒~~ (a), (b) and (c) ~~☒~~ of this paragraph ~~☒~~, ~~the manufacturer or his authorized representative established in the Community may also, in order to affix the CE marking, follow~~ the procedure relating to ~~CE unit verification~~ ⇒ Conformity based on unit verification ⇐ ~~☒~~ referred to in Annex IX~~2~~ ~~☒~~ may also be followed ~~☒~~.

2. ~~The provisions of 1~~ ~~☒~~ Procedure referred to in points ~~☒~~ (a) or ~~☒~~ (d) ~~☒~~ of paragraph 1 ~~☒~~ above shall be used for conformity assessment of autonomous protective systems.

↓ 94/9/EC (adapted)
→₁ Corrigendum, OJ L 21,
26.1.2000, p. 42
⇒ new

3. The procedures referred to in paragraph 1 shall be applied in respect of components as referred to in Article ~~4(2)~~⁵⁽²⁾, with the exception of the affixing of the CE marking. →₁ A written attestation ⇒ of conformity ⇐ shall be issued by the manufacturer ← or his authorized representative established in the ~~Community~~ ~~☒~~ Union ~~☒~~, declaring the conformity of the components with ~~the provisions of this Directive which apply to them~~ and stating their characteristics and how they must be incorporated into ~~equipment or protective systems~~ ~~☒~~ products ~~☒~~ to assist compliance with the essential ~~☒~~ health and safety ~~☒~~ requirements applicable to finished ~~equipment or protective systems~~ ~~☒~~ products ~~☒~~.

↓ 94/9/EC (adapted)
⇒ new

4. In addition, ~~the manufacturer or his authorized representative established in the Community may, in order to affix the CE marking, follow~~ with regard to the safety aspects referred to in point 1.2.7 of Annex II, the procedure relating to ~~internal control of production~~ ⇒ Internal production control ⇐ referred to in Annex VIII ~~☒~~ may be followed ~~☒~~.

5. ~~Notwithstanding the previous paragraphs~~ ~~☒~~ By derogation from paragraphs 1 to 4 ~~☒~~, the competent authorities may, on a duly justified request, authorize the placing on the market and putting into service on the territory of the Member State concerned of the ~~equipment, protective systems and individual devices referred to in Article 1(2)~~ ~~☒~~ products ~~☒~~ in respect of which the procedures referred to in ~~the previous~~ paragraphs ~~☒~~ 1 to 4 ~~☒~~ have not been applied and the use of which is in the interests of protection.

6. Documents and correspondence relating to the procedures referred to in ~~the abovementioned~~ paragraphs ~~☒~~ 1 to 4 ~~☒~~ shall be drawn up in ~~one of the official languages of the Member States in which those procedures are being applied or in a language accepted by the notified body~~ ☒ a language easily understood by end-users, as determined by the Member State concerned ☒ .

↓ 94/9/EC

~~7.~~

~~(a) Where the equipment, protective systems and devices referred to in Article 1(2) are subject to other Community Directives covering other aspects which also provide for the affixing of the CE marking referred to in Article 10, that marking shall indicate that the equipment, protective systems and devices referred to in Article 1(2) are also presumed to conform with the provisions of those other Directives.~~

~~(b) However, where one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer. In this case, particulars of the said Directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the equipment, protective systems and devices referred to in Article 1(2).~~

↓ new

Article 14 [Article R10 of Decision No 768/2008/EC]

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 III of Decision No 768/2008/EC, shall contain the elements specified in the relevant conformity assessment procedures set out in Annexes III to IX of this Directive and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is made available.

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 acts concerned, including the publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume the full responsibility for the compliance of the product.

Article 15 [Article R11 of Decision No 768/2008/EC]

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 [Article R12 of Decision No 768/2008/EC]

Rules and conditions for affixing the CE marking and the specific marking of explosion protection

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. It shall be accompanied by the specific marking of explosion protection , followed by the symbol of the equipment group and category, as set out in Annex II, point 1.0.5.

3. The CE marking and the specific marking and symbol referred to in paragraph 2 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, the specific marking and the symbol referred to in paragraph 2 and, where applicable, the identification number referred to in paragraph 3, may be followed by a pictogram or any other mark indicating a special risk or use.

5. Pictograms or any other mark defined in this Directive may only be used together with the CE marking.

6.

↓ 94/9/EC (adapted)

~~Equipment and protective systems may be~~  Products that are  designed for a particular explosive atmosphere. ~~In this case, they must~~  shall  be marked accordingly.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 17 [Article R13 of Decision No 768/2008/EC]

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 [Article R14 of Decision No 768/2008/EC]

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(1) to (6). 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 [Article R15 of Decision No 768/2008/EC]

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 [Article R16 of Decision No 768/2008/EC]

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 [Article R17 of Decision No 768/2008/EC]

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 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 authorised 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 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.

It 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 activities 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 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 assessment personnel shall be guaranteed.

The remuneration of the top level management and assessment personnel 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 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 assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 22 [Article R18 of Decision No 768/2008/EC]

Presumption of conformity

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 [Article R20 of Decision No 768/2008/EC]

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 IX.

Article 24 [Article R22 of Decision No 768/2008/EC]

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. That application 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 [Article R23 of Decision No 768/2008/EC]

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 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, 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 Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 26 [Article R24 of Decision No 768/2008/EC]

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 allocated to them and the activities for which they have been notified.

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

Article 27 [Article R25 of Decision No 768/2008/EC]

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 [Article R26 of Decision No 768/2008/EC]

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 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 inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 29 [Article R27 of Decision No 768/2008/EC]

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 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 provisions 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 technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

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 with the requirements laid down in this Directive, 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 decision of the notified bodies is available.

Article 31 [Article R28 of Decision No 768/2008/EC]

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 and 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 [Article R29 of Decision No 768/2008/EC]

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 [Article R30 of Decision No 768/2008/EC]

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 SAFEGUARD PROCEDURES

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.

Article 35 [Article R31 of Decision No 768/2008/EC]

Procedure for dealing with products presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a product presents a risk to the health or safety of persons or to other aspects of public interest protection laid down in this Directive, they shall carry out an evaluation in relation to the product concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, 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 action 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.

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 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 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 any of the following:

- (a) failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Directive;
- (b) shortcomings in the harmonised standards referred to in Annex II conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure 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 notified national measure, of their objections.

7. Where, within 2 months of receipt of the information referred to in 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 product concerned without delay.

Article 36 [Article R32 of Decision No 768/2008/EC]

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 decide 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 measures necessary 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 the 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 Article 35(5)(b) of this

Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No [...] [on European Standardisation].

Article 37 [Article R33 of Decision No 768/2008/EC]

Compliant products which present a risk to health and safety

1. Where, having performed 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 other aspects of public interest protection laid down in this Directive, 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 whether the measure is justified or not, and where necessary, propose appropriate measures.

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 [Article R34 of Decision No 768/2008/EC]

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 or the specific explosion protection 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 or the specific explosion protection 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.

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.

↓ 94/9/EC

~~Article 9~~

~~1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the procedures referred to in Article 8, together with the specific tasks which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.~~

~~The Commission shall publish in the *Official Journal of the European Communities* a list of the notified bodies, with their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.~~

~~2. Member States shall apply the criteria laid down in Annex XI in assessing the bodies to be indicated in such notification. Bodies meeting the assessment criteria laid down in the relative harmonized standards shall be presumed to fulfil those criteria.~~

~~3. A Member State which has approved a body must withdraw its notification if it finds that the body no longer meets the criteria referred to in Annex XI. It shall immediately inform the Commission and the other Member States accordingly.~~

~~CHAPTER III~~

~~CE CONFORMITY MARKING~~

~~Article 10~~

~~1. The CE conformity marking shall consist of the initials «CE». The form of the marking to be used is shown in Annex X. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control stage.~~

~~2. The CE marking shall be affixed distinctly, visibly, legibly and indelibly to equipment, protective systems and devices referred to in Article 1(2), supplementary to the provisions of point 1.0.5. of Annex II.~~

~~3. The affixing of markings on the equipment, protective systems or devices referred to in Article 1(2) which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the equipment, protective systems or devices referred to in Article 1(2), provided that the visibility and legibility of the CE marking is not thereby reduced.~~

Article 11

~~Without prejudice to Article 7:~~

- ~~(a) where a Member State establishes that the CE marking has been incorrectly affixed, the manufacturer or his authorized representative established within the Community shall be obliged to bring the product into conformity as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;~~
- ~~(b) in the event of continuing non-conformity, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 7.~~

CHAPTER IV6

↓ 94/9/EC (adapted)

⊗ TRANSITIONAL AND ⊗ FINAL PROVISIONS

↓ 94/9/EC

Article 12

~~Any decision taken pursuant to this Directive which restricts or prohibits the placing on the market and/or the putting into service or requires the withdrawal from the market of equipment, a protective system, or a device referred to in Article 1 (2) shall state the exact grounds on which it is based. Such a decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.~~

Article 13

~~Member States shall ensure that all the parties involved in the application of the Directive are bound to observe confidentiality in respect of all information obtained in the performance of carrying out their tasks. This does not affect the obligations of the Member States and of the notified bodies regarding reciprocal information and the dissemination of warnings.~~

↓ new

Article 39

Penalties

Member States shall lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced.

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

Member States shall notify those provisions to the Commission by [the date set out in the second subparagraph of Article 40(1)] and shall notify it without delay of any subsequent amendment affecting them.

↓ 94/9/EC (adapted)
⇒ new

Article ~~14~~40

⊠ Transitional provisions ⊠

~~1. Directive 76/117/EEC, Directive 79/196/EEC¹⁷ and Directive 82/130/EEC shall be repealed as from 1 July 2003.~~

⇒ 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 [the date set out in the second subparagraph of Article 41(1)]. ⇐

~~2. EC Certificates of conformity to the harmonised standards obtained in accordance with the procedures laid down in the Directives referred to in paragraph 1 ⊠ issued pursuant to Article 8 of Directive 94/9/EC ⊠ shall continue to be valid ⊠ under this Directive ⊠ until 30 June 2003 unless they expire before that date. Their validity shall continue to be limited to the harmonised standards indicated in the aforementioned Directives.~~

3. Member States shall take the necessary ~~action~~ ⊠ measures ⊠ to ensure that the notified bodies which are responsible pursuant to Article ~~8 (1) to (4)~~13(1) to (4) for the assessment of the conformity of ~~electrical equipment~~ ⊠ products ⊠ placed on the market before ~~1 July 2003~~ ⇒ [Date] ⇐ take account of the results of tests and verifications already carried out under the Directives ~~referred to in paragraph 1~~ ⊠ 94/9/EC ⊠ .

¹⁷ ~~OJ No L 43, 20. 2. 1979, p. 20. Directive as last amended by Directive 90/487/EEC (OJ No L 270, 2. 10. 1990, p. 23).~~

↓ 94/9/EC (adapted)
⇒ new

Article ~~15~~41

⊗ *Transposition* ⊗

1. Member States shall adopt and publish ⊗ by ⊗ ⇒ [insert date: 2 years after adoption] ⇐ ⊗ at the latest ⊗ the laws, regulations and administrative provisions necessary to comply with ~~this Directive~~ ⊗ Article 2(2) and (10) to (26), Article 3, Articles 5 to 40 and Annexes III to IX ⊗ ~~before 1 September 1995~~. They shall forthwith ~~inform~~ ⊗ communicate to ⊗ the Commission ~~thereof~~ ⊗ the text of those provisions and a correlation table between those provisions and this Directive ⊗ .

~~The Member States~~ ⊗ They ⊗ shall apply ~~these measures~~ ⊗ those provisions ⊗ ~~with effect from 1 March 1996~~ ⊗ from [day after the date mentioned in first subparagraph] ⊗ .

When Member States adopt ~~the measures referred to in the first subparagraph~~ ⊗ those provisions ⊗, they shall contain a reference to this Directive or ~~shall~~ be accompanied by such ⊗ a ⊗ reference ~~at the time~~ ⊗ 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 94/9/EC repealed by this Directive shall be construed as references to this Directive. ⊗ ~~The methods of making such reference shall be laid down by~~ Member States ⊗ shall determine how such reference is to be made and how that statement is to be formulated ⊗ .

↓ 94/9/EC

~~2. However, Member States shall allow the placing on the market and the putting into service of equipment and protective systems conforming with the national regulations in force in their territory at the date of adoption of this Directive for the period until 30 June 2003.~~

↓ new

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 42

Repeal

Directive 94/9/EC, as amended by the Regulation listed in Annex X, Part A, is repealed with effect from [the date set out in the second subparagraph of Article 41(1)], without prejudice to

the obligations of the Member States relating to the time-limits for transposition into national law and application of the Directive 94/9/EC set out in Annex X, 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 XI.

Article 43

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, Articles 2(1) and (3) to (9), Article 4, Articles 41 to 44 and Annexes I, II, X and XI shall apply from [the date set out in the second subparagraph of Article 41(1)].

↓ 94/9/EC (adapted)

Article ~~16~~44

⊠ Addresses ⊠

This Directive is addressed to the Member States.

Done at [...],

For the European Parliament
The President

For the Council
The President

ANNEX I

CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

1. EQUIPMENT-GROUP I

- (a) 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 characterized 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 Annex II, 2.0.1.

- (b) 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-energized 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 Annex II, 2.0.2.

2. EQUIPMENT-GROUP II

- (a) 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 characterized 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 Annex II, 2.1.

- (b) 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.

↓ 94/9/EC → ₁ Corrigendum, OJ L 21, 26.1.2000, p. 42

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists or air/dust mixtures →₁ are likely to occur occasionally. ←

↓ 94/9/EC

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 Annex II, 2.2.

- (c) 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 Annex II, 2.3.

↓ 94/9/EC

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 utilized immediately.

↓ 94/9/EC (adapted)

B. For the devices referred to in Article ~~1(2)~~ 1(1)(b), 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.

↓ 94/9/EC

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 and address of the manufacturer,

↓ 94/9/EC (adapted)

- CE marking (see Annex ~~X, point A~~ II to Regulation (EC) No 765/2008),

↓ 94/9/EC

- designation of series or type,
- 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 serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (e.g. address of the importer, 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.

↓ 94/9/EC (adapted)

- (b) The instructions must be drawn up in ~~one of the Community languages~~ a language easily understood by end-users, as determined by the Member State concerned, by the manufacturer or his authorized representative established in the ~~Community~~ Union .

On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in the language or languages of the country in which the equipment or protective system is to be used and by the instructions in the original language.

This translation must be made by either the manufacturer or his authorized representative established in the ~~Community~~ Union or the person introducing the equipment or protective system into the language area in question.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his authorized representative established in the ~~Community~~ Union may be drawn up in a single ~~Community~~ Union language understood by that personnel.

↓ 94/9/EC

- (c) 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.
- (d) 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.

↓ 94/9/EC
→₁ Corrigendum, OJ L 21,
26.1.2000, p. 42

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, →₁ electrical conductivity, mechanical strength, ageing resistance ← and the effects of temperature variations.

↓ 94/9/EC

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.

↓ 94/9/EC → ₁ Corrigendum, OJ L 21, 26.1.2000, p. 42

If equipment contains openings or non-tight joints, these must as far as possible be designed in →₁ 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 →₁ so as to limit releases of flammable materials ← during filling or draining.

↓ 94/9/EC

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;

↓ 94/9/EC → ₁ Corrigendum, OJ L 21, 26.1.2000, p. 42

(d) assure that →₁ foreseeable conditions of overload do not give rise ← to dangerous situations.

↓ 94/9/EC (adapted)

Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other ~~Community~~ ☒ Union ☒ Directives, 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 those specific Directives.

↓ 94/9/EC

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

↓ 94/9/EC → ₁ Corrigendum, OJ L 21, 26.1.2000, p. 42

1.5.1. Safety devices must function →₁ 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.

→₁ The fail-safe principle ← is to be applied in general.

↓ 94/9/EC

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 category M of equipment-group I**

2.0.1. *Requirements applicable to equipment in 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, this 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 in 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-energized 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 category M 1 must be applied.

2.1. Requirements applicable to equipment in category 1 of equipment-group II

↓ 94/9/EC
→₁ Corrigendum, OJ L 21,
26.1.2000, p. 42

2.1.1. →₁ *Explosive atmospheres caused by gases, vapours or mists* ←

↓ 94/9/EC

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 for 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 in 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.

↓ 94/9/EC → ₁ Corrigendum, OJ L 21, 26.1.2000, p. 42

3.0.2. Protective systems must be designed and →₁ 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.

↓ 94/9/EC

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

↓ 94/9/EC
→₁ Corrigendum, OJ L 21,
26.1.2000, p. 42

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 →₁ to best effect, with due regard to ← the maximum rate of pressure increase and the maximum explosion pressure.

↓ 94/9/EC

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.

↓ 94/9/EC

ANNEX III

~~MODULE EC TYPE EXAMINATION~~

~~1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of the Directive.~~

~~2. The application for the EC type examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.~~

~~The application shall include:~~

~~the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition;~~

~~a written declaration that the same application has not been lodged with any other notified body;~~

~~the technical documentation, as described in point 3.~~

~~The applicant shall place at the disposal of the notified body a specimen representative of the production envisaged and hereinafter called «type». The notified body may request further specimens if needed for carrying out the test programme.~~

~~3. The technical documentation shall enable the conformity of the product with the requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:~~

~~a general type description;~~

~~design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;~~

~~descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;~~

~~a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;~~

~~results of design calculations made, examinations carried out, etc.;~~

~~test reports.~~

~~4. The notified body shall:~~

~~4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;~~

~~4.2. perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;~~

~~4.3. perform or have performed the appropriate examinations and necessary tests to check whether these have actually been applied, where the manufacturer has chosen to apply the relevant standards;~~

~~4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.~~

~~5. Where the type meets the provisions of the Directive, the notified body shall issue an EC-type examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.~~

~~A list of the significant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.~~

~~If the manufacturer or his authorized representative established in the Community is denied a type certification, the notified body shall provide detailed reasons for such denial.~~

~~Provision shall be made for an appeals procedure.~~

~~6. The applicant shall inform the notified body which holds the technical documentation concerning the EC type examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may affect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC type examination certificate.~~

~~7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC type examination certificates and additions issued and withdrawn.~~

~~8. The other notified bodies may receive copies of the EC type examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.~~

~~9. The manufacturer or his authorized representative established in the Community shall keep with the technical documentation copies of EC type examination certificates and their additions for a period ending at least 10 years after the last equipment or protective system was manufactured.~~

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.~~

↓ new

MODULE: 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:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,

- 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:
 - a general description of the product,
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
 - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
 - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - results of design calculations made, examinations carried out, etc., and
 - test reports,
- the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,
- 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 technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

4.1. 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 technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

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 and/or technical specifications, 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 and/or technical specifications have

not been applied, the solutions adopted by the manufacturer 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. The 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 certificate may have one or more annexes attached.

The 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 the 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 authorities 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 authorities the list of 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 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-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 the 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.

↓ 94/9/EC

ANNEX IV

MODULE: PRODUCTION QUALITY ASSURANCE

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorized representative established in the Community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in Section 4.~~

~~2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in Section 3 and shall be subject to monitoring as specified in Section 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 equipment concerned.~~

~~The application shall include:~~

~~all relevant information for the product category envisaged;~~

~~the documentation concerning the quality system;~~

~~technical documentation on the approved type and a copy of the EC type examination certificate.~~

~~3.2. The quality system shall ensure compliance of the equipment with the type as described in the EC type examination certificate and with the requirements of the Directive which 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 must permit a consistent interpretation of quality programmes, plans, manuals and records.~~

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

~~the quality objectives and the organizational structure, responsibilities and powers of the management with regard to equipment quality;~~

~~the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;~~

~~the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;~~

~~the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;~~

~~the means to monitor the achievement of the required equipment 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 Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard. The auditing team shall have at least one member with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 uphold the system so that it remains adequate and efficient.~~

~~The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.~~

~~The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.~~

~~It shall notify its decision to the manufacturer. 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 inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular~~

~~the quality system documentation~~

~~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 manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.~~

~~4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.~~

~~5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:~~

~~the documentation referred to in the second indent of Section 3.1;~~

~~the updating referred to in the second paragraph of Section 3.4;~~

~~the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.~~

~~6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.~~

↓ new

MODULE: 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:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information for the product category envisaged,
- the documentation concerning the quality system,
- 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:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- 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 national standard that implements the relevant harmonised standard and/or technical specifications.

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, fifth indent, 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:

- the quality system documentation,
- 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. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity markings 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 product 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 declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

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

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- the documentation referred to in point 3.1,
- the change referred to in point 3.5, as approved,
- 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 authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities 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.

ANNEX V

~~MODULE: PRODUCT VERIFICATION~~

~~1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type examination certificate and satisfy the relevant requirements of the Directive.~~

~~2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type examination certificate and with the requirements of the Directive which apply to them. The manufacturer or his authorized representative established in the Community shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.~~

~~3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device referred to in Article 1 (2), with the relevant requirements of the Directive, by examining and testing every product as specified in Section 4.~~

~~The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured.~~

~~4. VERIFICATION BY EXAMINATION AND TESTING OF EACH PIECE OF EQUIPMENT.~~

~~4.1. All equipment shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify their conformity with the type as described in the EC-type examination certificate and the relevant requirements of the Directive.~~

~~4.2. The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the tests carried out.~~

~~4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.~~

MODULE: 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 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 technical specifications, or equivalent tests, 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. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity markings 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 product 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 declaration of conformity for each product model and keep it at the disposal of the national authorities, for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the 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 products.

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.

ANNEX VI

MODULE: CONFORMITY TO TYPE

~~1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the equipment in question is in conformity with the type as described in the EC type examination certificate and satisfies the requirements of the Directive applicable to it. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.~~

~~2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment with the type as described in the EC type examination certificate and with the relevant requirements of the Directive.~~

~~3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the Community market.~~

~~For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out by the manufacturer or on his behalf. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.~~

~~On the responsibility of the notified body, the manufacturer shall affix the former's identification number during the manufacturing process.~~

MODULE: 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. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity markings set out in this Directive to each individual product 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 declaration of conformity for a product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the 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.

ANNEX VII

MODULE: PRODUCT QUALITY ASSURANCE

~~1. This module describes the procedure whereby the manufacturer who satisfies the obligations of Section 2 ensures and declares that the equipment is in conformity with the type as described in the EC type examination certificate. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.~~

~~2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in Section 3 below and shall be subject to surveillance as specified in Section 4 below.~~

3. QUALITY SYSTEM

~~3.1. The manufacturer shall lodge an application for assessment of his quality system for the equipment, with a notified body of his choice.~~

~~The application shall include:~~

~~— all relevant information for the product category envisaged;~~

~~— documentation on the quality system;~~

~~— technical documentation on the approved type and a copy of the EC type examination certificate.~~

~~3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records.~~

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

~~— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;~~

~~— the examinations and tests which will be carried out after manufacture;~~

~~— the means to monitor the effective operation of the quality system;~~

~~— 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 Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard.~~

~~The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.~~

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

~~3.4. The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.~~

~~The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.~~

~~The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.~~

~~It shall notify its decision to the manufacturer. 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 ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.~~

~~4.2. The manufacturer shall for inspection purposes allow the notified body access to the inspection, testing and storage premises and shall provide it with all necessary information, in particular:~~

~~quality system documentation;~~

~~technical documentation;~~

~~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 manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.~~

~~4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or arrange for tests to be carried out in order to check the proper functioning of the quality system, where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.~~

~~5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:~~

~~the documentation referred to in the third indent of Section 3.1;~~

~~the updating referred to in the second paragraph of Section 3.4;~~

~~the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.~~

~~6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.~~

↓ new

MODULE: 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:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- all relevant information for the product category envisaged,
- the documentation concerning the quality system, and
- 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:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
- the examinations and tests that will be carried out after manufacture,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,
- 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 national standard that implements the relevant harmonised standard and/or technical specification.

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, fifth indent, 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:

- the quality system documentation,
- 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. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity markings 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 product 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 declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

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

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- the documentation referred to in point 3.1,
- the change referred to in point 3.5, as approved,
- 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 authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities 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.

ANNEX VIII

MODUL: INTERNAL CONTROL OF PRODUCTION

~~1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in Section 2, ensures and declares that the equipment satisfies the requirements of the Directive applicable to it. The manufacturer or his authorized representative established within the Community shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.~~

~~2. The manufacturer shall establish the technical documentation described in Section 3 and he or his authorized representative established within the Community shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.~~

~~Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community market.~~

~~3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the Directive to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:~~

~~— a general description of the equipment,~~

~~— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,~~

~~— descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment,~~

~~— a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the Directive where the standards have not been applied,~~

~~— results of design calculations made, examinations carried out, etc.,~~

~~— test reports.~~

~~4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.~~

~~5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in Section 2 and with the requirements of the Directive applicable to such equipment.~~

MODULE: 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 general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- 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. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the required conformity markings set out in this Directive to each individual product that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national

authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the 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.

ANNEX IX

MODULE: UNIT VERIFICATION

~~1. This module describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in Section 2 conforms to the requirements of the Directive which are applicable to it. The manufacturer or his authorized representative in the Community shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.~~

~~2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the Directive.~~

~~The notified body shall affix, or cause to be affixed, its identification number on the approved equipment or protective system and shall draw up a certificate of conformity concerning the tests carried out.~~

~~3. The aim of the technical documentation is to enable conformity with the requirements of the Directive to be assessed and the design, manufacture and operation of the equipment or protective system to be understood.~~

~~The documentation shall contain:~~

~~— a general description of the product;~~

~~— conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;~~

~~— descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;~~

~~— a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied;~~

~~— results of design calculations made, examinations carried out, etc.;~~

~~— test reports.~~

MODULE: 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

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 general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports.

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 technical specifications, or equivalent tests, 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 and/or technical specification 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. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity markings 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 product that satisfies the applicable requirements of this Directive.

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

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

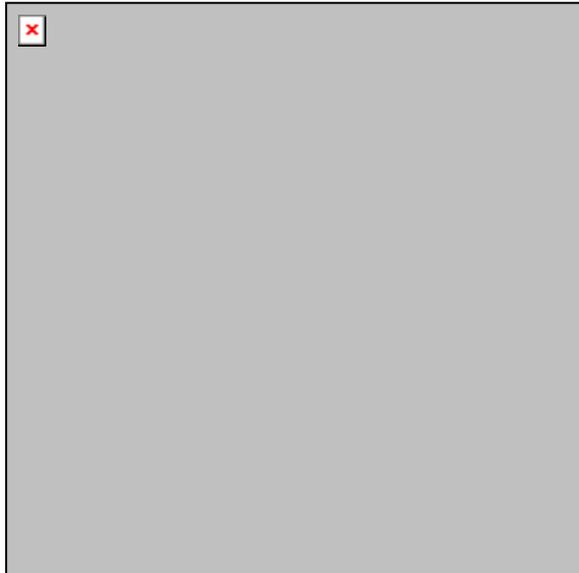
6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX X

A. CE MARKING

~~The CE conformity marking shall consist of the initials «CE» taking the following form:~~



~~If the marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.~~

~~The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.~~

~~This minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in Article 1 (2).~~

B. CONTENT OF THE EC DECLARATION OF CONFORMITY

~~The EC declaration of conformity must contain the following elements:~~

~~the name or identification mark and the address of the manufacturer or his authorized representative established within the Community;~~

~~a description of the equipment, protective system, or device referred to in Article 1 (2);~~

~~all relevant provisions fulfilled by the equipment, protective system, or device referred to in Article 1 (2);~~

~~where appropriate, the name, identification number and address of the notified body and the number of the EC type examination certificate;~~

~~where appropriate, reference to the harmonized standards;~~

~~where appropriate, the standards and technical specifications which have been used;~~

~~where appropriate, references to other Community Directives which have been applied;~~

~~identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorized representative established within the Community.~~

ANNEX XI

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

~~1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices referred to in Article 1 (2) which they inspect, nor the authorized representative of any of these parties. They shall become involved neither directly nor as authorized representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices referred to in Article 1 (2) in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.~~

~~2. The body and its inspection staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which may influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.~~

~~3. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.~~

~~4. The staff responsible for inspection shall have:~~

~~— sound technical and professional training;~~

~~— satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;~~

~~— the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.~~

~~5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.~~

~~6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the tests.~~

~~7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis à vis* the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.~~

ANNEX XI

CORRELATION TABLE

Directive 94/9/EC	This Directive
Article 1 (1)	Article 1(1)(a)
Article 1 (2)	Article 1(1)(b)
Article 1 (3), except the fourth subparagraph of the definition of " <i>Equipment groups and categories</i> "	Article 2(1) to (9)
–	Article 2(10) to (26)
Article 1 (3), fourth subparagraph of the definition of " <i>Equipment groups and categories</i> "	Article 16(6)
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) and (3)	–
–	Articles 6 to 11
–	Article 12(1)
Article 6	–
Article 7	–
Article 8 (1) to (6)	Article 13(1) to (6)
Article 8 (7)	–
–	Articles 14 and 15
–	Article 16(1) to (5)
–	Articles 17 to 39

–	Article 40(1)
Articles 9 to 13	–
Article 14(1)	–
Article 14(2) and (3)	Article 40(2) and (3)
Article 15(1)	Article 41(1)
Article 15(2)	–
–	Article 41(2)
–	Article 42
–	Article 43
Article 16	Article 44
Annexes I to IX	Annexes I to IX
Annex X	–
Annex XI	–
–	Annex X
–	Annex XI
