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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 making available on
the market of lifts and safety components for lifts**

(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 95/16/EC is an example of that Union harmonisation legislation, ensuring the free movement of lifts and safety components for lifts. It sets out essential health and safety requirements that lifts and safety components for lifts must comply with in order to be made available on the EU market. Manufacturers must demonstrate that a lift and a safety component for lifts have 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
- 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 95/16/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.

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.

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

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

Consultation of interested parties

The alignment of Directive 95/16/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, standardisation bodies, representatives for the lifts sector as well as in bilateral meetings with associations representing lift installers, lifts components manufacturers and small and medium size enterprises in the lifts industry, trade unions and associations of property owners.

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, including studies concerning lifts: (2004)² and (2007)³.

² *Evaluation of the Application of the Lift Directive (95/16/EC)*. Final Report to the European Commission (DG ENTR) of 21 June 2004. [The study examined the functioning of the Directive

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.

95/16/EC in 7 Member States: Belgium, Finland, Germany, Italy, Portugal, Spain and the United Kingdom.]

³ Study on the *Technical Assessment of Means of Preventing the Crushing Risk on Lifts subject to Directive 95/16/EC*, Report Number ME/07/07 (2007). [The study aim was the examination whether the solutions available, other than free space or refuges, to prevent the crushing risk can provide an equivalent level of safety.]

3.2. Obligations of economic operators and traceability requirements

The proposal clarifies the obligations of installers, 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 safety components for lifts are correctly marked and accompanied by the required documents. 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 lift and safety component for lifts bear 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 safety components for lifts.

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

3.3. Harmonised standards

Compliance with harmonised standards provides a presumption of conformity with the essential health and safety requirements. On 1 June 2011 the Commission adopted a proposal for a Regulation on European Standardisation⁴ 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 95/16/EC which cover the same aspects have been deleted in this proposal for reasons of legal certainty.

The provision conferring presumption of conformity to harmonised standards has been modified to clarify the extent of the presumption of conformity when standards only partially cover the essential health and safety requirements.

⁴ Proposal for a Regulation of the European Parliament and of the Council 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 Council. COM(2011) 315 final

3.4. Conformity assessment and CE marking

Directive 95/16/EC has selected the appropriate conformity assessment procedures which installers have to apply in order to demonstrate that lifts they install 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. It also introduces a model for the EU Declaration of conformity.

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 to lifts and safety components for lifts 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 authorities concerned, when a non-compliant lift or safety component for lifts 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 lift or a safety component for lifts. 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 Treaty on the Functioning of the EU has introduced a clear distinction between delegated acts (Article 290) and implementing acts (Article 291) and clarified the role of committees.

Directive 95/16/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, this provision has been deleted in the proposal.

The Commission will set up an expert working group in accordance with the Commission Communication - Framework for Commission expert groups: horizontal rules and public

register⁵, that will carry out the tasks of the Standing Committee provided for in Directive 95/16/EC, to examine any question relating to the application of the Directive.

The proposal introduces the power for the Commission to adopt delegated acts in order to adapt the list of safety components for lifts set out in Annex III to technical progress and new scientific evidence.

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 95/16/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-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

⁵ C(2010) 7649 final

The alignment to the NLF Decision requires a number of substantive amendments to the provisions of Directive 95/16/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 acts⁶.

The changes made to the provisions of Directive 95/16/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 95/16/EC and the essential health and safety requirements.

5. BUDGETARY IMPLICATIONS

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

6. ADDITIONAL INFORMATION

Repeal of existing legislation

The adoption of the proposal will lead to repeal of Directive 95/16/EC.

European Economic Area

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

⁶ OJ C 77, 28.3.2002, p. 1–3

↓ 95/16/EC (adapted)

2011/0354 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**on the ~~☒~~ harmonisation ~~☒~~ approximation of the laws of the Member States relating to
☒ making available on the market of ~~☒~~ lifts ~~☒~~ and safety components for lifts ~~☒~~**

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty ~~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 Committee⁷,

Acting in accordance with the ordinary legislative procedure,

Whereas:

↓ 95/16/EC recital 1

~~Whereas Member States are responsible within their territory for the health and safety of people;~~

↓ 95/16/EC recital 2 (adapted)

~~Whereas paragraphs 65 and 68 of the White Paper on the completion of the internal market, approved by the European Council in June 1985, provide for a new approach to the approximation of laws;~~

⁷

OJ C [...].

↓ 95/16/EC recital 3 (adapted)

~~Whereas Council Directive 84/529/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to electrically, hydraulically or oil-electrically operated lifts⁸ does not ensure freedom of movement for all types of lift; whereas disparities between the binding provisions of the various national systems for types of lift not covered by Directive 84/529/EEC constitute barriers to trade within the Community; whereas the national rules on lifts should therefore be harmonized;~~

↓ 95/16/EC recital 4 (adapted)

~~Whereas Council Directive 84/528/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for lifting and mechanical handling appliances⁹ serves as a framework Directive for two specific Directives, namely Directive 84/529/EEC and Council Directive 86/663/EEC of 22 December 1986 on the approximation of the laws of the Member States relating to self-propelled industrial trucks¹⁰, repealed by Council Directive 91/368/EEC of 20 June 1991 amending Directive 89/392/EEC on the approximation of the laws of the Member States relating to machinery¹¹;~~

↓ new

- (1) Directive 95/16/EC of the European Parliament and the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts¹² has been substantially amended several times. 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 339/93¹³ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking. In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of lifts and safety components for lifts entering the Union market provided for in Regulation (EC) No 765/2008 apply to lifts and safety components for lifts covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (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

⁸ ~~OJ No L 300, 19. 11. 1984, p. 86. Directive as last amended by Directive 90/486/EEC (OJ No L 270, 2. 10. 1990, p. 21).~~

⁹ ~~OJ No L 300, 19. 11. 1984, p. 72. Directive as last amended by Directive 88/665/EEC (OJ No L 382, 31. 12. 1988, p. 42).~~

¹⁰ ~~OJ No L 384, 31. 12. 1986, p. 12.~~

¹¹ ~~OJ No L 198, 22. 7. 1991, p. 16.~~

¹² OJ No L 213, 7. 9. 1995, p. 1.

¹³ OJ L 218, 13.8.2008, p. 30.

Decision 93/465/EEC¹⁴ 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 95/16/EC should therefore be adapted to that Decision.

↓ 95/16/EC recital 5 (adapted)

- (4) ~~Whereas~~ On 8 June 1995 the Commission adopted recommendation No 95/216/EC¹⁵ to the Member States concerning improvement of safety of existing lifts.

↓ 95/16/EC recital 6 (adapted)

~~Whereas the essential requirements of this Directive will guarantee the intended level of safety only if appropriate conformity assessment procedures, chosen from among the provisions of Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives¹⁶ ensure compliance therewith.~~

↓ 95/16/EC recital 7 (adapted)

~~Whereas the CE marking must be visibly affixed to lifts or to certain safety components of lifts which meet the essential health and safety requirements of this Directive to enable them to be placed on the market;~~

↓ 95/16/EC recital 8 (adapted)

~~Whereas this Directive defines only general essential health and safety requirements; whereas, in order to help manufacturers prove conformity with these essential requirements, it is desirable to have standards harmonized at European level concerning the prevention of risks arising from the design and installation of lifts, and also in order to enable conformity with the essential requirements to be verified; whereas such standards are drawn up at European level by private law bodies and must retain their non-binding status; whereas, for this purpose, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for adopting harmonized standards in accordance with the general guidelines for cooperation between the Commission and CEN and Cenelec signed on 13 November 1984; whereas a harmonized standard within the meaning of this Directive is a technical specification adopted by CEN and/or Cenelec on the basis of a mandate from the Commission in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations¹⁷ and pursuant to the abovementioned general guidelines;~~

¹⁴ OJ L 218, 13.8.2008, p. 82.

¹⁵ OJ No L 134, 20. 6. 1995, p. 37.

¹⁶ OJ No L 220, 30. 8. 1993, p. 23.

¹⁷ OJ No L 109, 26. 4. 1983, p. 8. Directive as last amended by European Parliament and Council Directive 94/10/EC (OJ No L 100, 19. 4. 1994, p. 30).

↓ 95/16/EC recital 10 (adapted)

~~Whereas this Directive is designed to cover all risks caused by lifts and run by their users and by the occupants of the construction; whereas this Directive should therefore be regarded as a Directive within the meaning of Article 2(3) of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products¹⁸;~~

↓ 95/16/EC recital 11(adapted)

~~Whereas an agreement on a *modus vivendi* between the European Parliament, the Council and the Commission concerning the implementing measures for acts adopted in accordance with the procedure laid down in Article 189b of the EC Treaty was reached on 20 December 1994;~~

↓ new

- (5) Economic operators should be responsible for the compliance of lifts and safety components for lifts, 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 consumers and to guarantee fair competition on the Union market.
- (6) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market lifts and safety components for lifts which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each operator in the supply and distribution process.
- (7) The manufacturer and installer, having the detailed knowledge of the design and production process, are best placed to carry out the complete conformity assessment procedure. Conformity assessment should therefore remain the obligation of the installer or manufacturer alone.
- (8) It is necessary to ensure that safety components for lifts from third countries entering the Union market comply with the requirements of this Directive, and in particular that the appropriate assessment procedures have been carried out by the manufacturer with regard to those safety components for lifts. Provision should therefore be made for importers to make sure that the safety components for lifts they place on the market comply with the requirements of this Directive and that they do not place on the market safety components for lifts which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that safety component for lifts marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (9) The distributor makes a safety component for lifts available on the market after it has been placed on the market by the manufacturer or the importer and should act with due

¹⁸ OJ No L 40, 11. 2. 1989, p. 12.

care to ensure that its handling of the safety component for lifts does not adversely affect the compliance of the safety component for lifts.

- (10) When placing a safety component for lifts on the market, every importer should indicate on the safety component for lifts 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 safety component for lifts does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the safety component for lifts.
- (11) Any economic operator that either places a lift or safety component for lifts on the market under his own name or trademark or modifies a lift or safety component for lifts in such a way that compliance with the requirements of this Directive may be affected should be considered to be the installer or manufacturer and should assume the obligations of the installer or manufacturer.
- (12) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the safety components for lifts concerned.
- (13) Ensuring traceability of lifts or safety components for lifts throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant lifts or safety components for lifts available on the market.
- (14) This Directive should be limited to the expression of the essential health and safety requirements. In order to facilitate conformity assessment for lifts and safety components for lifts with those requirements it is necessary to provide for presumption of conformity for lifts and safety components for lifts which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No [...] 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 Council¹⁹ for the purpose of expressing detailed technical specifications of those requirements. The essential health and safety requirements of this Directive will guarantee the intended level of safety only if appropriate conformity assessment procedures ensure compliance therewith.
- (15) 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.
- (16) In order to enable economic operators to demonstrate and the competent authorities to ensure that lifts or safety components for lifts made available on the market conform to the essential health and safety requirements it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent,

¹⁹ OJ C [...], [Date], p. [...].

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.

- (17) The installer or the manufacturer should draw up an EU declaration of conformity to provide detailed information on the conformity of a lift or safety components for lifts with the requirements of the relevant Union harmonisation legislation.
- (18) The CE marking, indicating the conformity of a lift or safety components for lifts, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (19) 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.
- (20) Experience has shown that the criteria set out in Directive 95/16/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (21) In order to ensure a consistent level of conformity assessment quality it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (22) 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.
- (23) 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.
- (24) 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.
- (25) 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.

- (26) 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.
- (27) 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.
- (28) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (29) Directive 95/16/EC already provides for a safeguard procedure which applies only in the event of disagreement between Member States over measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (30) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to lifts or safety components for lifts presenting a risk to the health 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 lifts and safety components for lifts.
- (31) 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.
- (32) In order to keep the list of safety components for lifts up to date, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of adaptations of Annex III to this Directive to technical progress and new scientific evidence. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.
- (33) The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

- (34) In order to monitor and ensure the efficiency in the application of this Directive, Member States should be required to send a report on the application of the Directive to the Commission. The Commission should then draw up and publish a summary of the reports.
- (35) 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.
- (36) Since the objective of this Directive, namely to ensure that lifts and safety components for lifts 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.
-

↓ 95/16/EC recital 9 (adapted)
⇒ new

- (37) ~~Whereas provisions should be made~~ ☒ It is necessary to provide ☒ for transitional arrangements ~~to enable installers to place on the market lifts manufactured before the date of implementation of this Directive;~~ ⇒ that allow making available on the market and putting into service of lifts that have already been placed on the market in accordance with Directive 95/16/EC. ⇐
-

↓ new

- (38) It is necessary to provide for transitional arrangements that allow making available on the market of safety components for lifts that have already been placed on the market in accordance with Directive 95/16/EC.

(39) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive change as compared with the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(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 Directives set out in Annex XIII, Part B.

↓ 95/16/EC (adapted)

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

~~SCOPE, PLACING ON THE MARKET AND FREE MOVEMENT~~

⊠ GENERAL PROVISIONS ⊠

Article 1

⊠ Scope ⊠

1. This Directive shall apply to lifts permanently serving buildings and constructions ~~It shall also apply to the safety components for use in such lifts listed in Annex IV.~~

↓ 2006/42/EC Art. 24.1 (adapted)

~~2. For the purposes of this Directive, 'lift' shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, and intended for the transport of:~~

↓ 2006/42/EC Art. 24.1

(a) ~~persons;~~

(b) ~~persons and goods;~~

(c) ~~goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.~~

↓ 95/16/EC (adapted)

⊠ This Directive shall also apply to the safety components for lifts for use in such lifts listed in Annex III. ⊠

↓ 2006/42/EC Art. 24.1 (adapted)

~~Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive.~~

↓ 2006/42/EC Art. 24.1

~~3.2.~~ This Directive shall not apply to:

- (a) = lifting appliances whose speed is not greater than 0,15 m/s;
 - (b) = construction site hoists;
 - (c) = cableways, including funicular railways;
 - (d) = lifts specially designed and constructed for military or police purposes;
 - (e) = lifting appliances from which work can be carried out;
 - (f) = mine winding gear;
 - (g) = lifting appliances intended for lifting performers during artistic performances;
 - (h) = lifting appliances fitted in means of transport;
 - (i) = lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery;
 - (j) = rack and pinion trains;
 - (k) = escalators and mechanical walkways.
-

↓ 95/16/EC (adapted)

~~5.3.~~ Where, for lifts ☒ or safety components for lifts ☒, the risks referred to in this Directive are wholly or partly covered by specific Directives ☒ Union legislation, and in particular Directive 2006/42/EC²⁰ and Directive 2004/108/EC²¹, ☒ this Directive shall not apply or shall cease to apply in the case of such lifts ☒ or safety components for lifts ☒ and such risks as from application of these ☒ that ☒ specific Directives ☒ Union legislation. ☒

Article 2 [Article R1 of Decision No 768/2008/EC]

☒ Definitions ☒

~~4.~~ For the purposes of this Directive ☒ the following definitions apply ☒ :

²⁰ OJ L 157, 9.06.2006, p. 24.

²¹ OJ No L 390, 31.12.2004, p. 24.

↓ 2006/42/EC Art. 24.1 (adapted)

⊗ (1) 'lift' means a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, or a lifting appliance moving along a fixed course even where it does not move along rigid guides;
⊗

(2) ~~A~~ 'carrier' means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered~~;~~

↓ 95/16/EC (adapted)

~~(3) a 'model lift' shall mean~~ ⊗ means ⊗ a representative lift whose technical ~~dossier~~
⊗ file ⊗ shows the way in which the essential ⊗ health and ⊗ safety requirements ⊗ set
out in Annex I ⊗ will be met for lifts which conform to the model lift defined by objective
parameters and which uses identical safety components ⊗ for lifts ⊗~~;~~

~~(4) the 'installer of a lift' shall mean~~ ⊗ means ⊗ the natural or legal person who takes
responsibility for the design, manufacture, installation and placing on the market of the lift
~~and who affixes the CE marking and draws up the EC declaration of conformity;~~

~~«placing on the market of the lift» shall occur when the installer first makes the lift
available to the user;~~

~~«safety component» shall mean a component as listed in Annex IV;~~

~~the «manufacturer of the safety components» shall mean the natural or legal person
who takes responsibility for the design and manufacture of the safety components
and who affixes the CE marking and draws up the EC declaration of conformity;~~

↓ new

(5) 'making available on the market' means any supply of a safety component for lifts for
distribution or use on the Union market or any supply of a lift for use on the Union market in
the course of a commercial activity, whether in return for payment or free of charge;

(6) 'placing on the market' means the first making available of a lift or a safety component for
lifts on the Union market;

(7) 'manufacturer' means any natural or legal person who manufactures a safety component
for lifts or has a safety component for lifts designed or manufactured and markets it under his
name or trademark;

(8) '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
specific tasks;

(9) 'importer' means any natural or legal person established within the Union who places a
safety component for lifts from a third country on the Union market;

(10) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a safety component for lifts available on the market;

(11) ‘economic operators’ means the manufacturer or his authorised representative, the importer or the distributor of a safety component for lifts or the installer;

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

(13) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a lift or a safety component for lifts;

(14) ‘conformity assessment’ means the process demonstrating whether the essential health and safety requirements set out in Annex I relating to a lift or a safety component for lifts, process and system have been fulfilled;

(15) ‘conformity assessment body’ means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(16) ‘recall’ means any measure aimed at achieving the return of a safety component for lifts that has already been made available to the installer;

(17) ‘withdrawal’ means any measure aimed at preventing a lift from being placed on the market or a safety component for lifts from being made available on the market;

(18) ‘CE marking’ means a marking by which the installer or the manufacturer indicates that the lift or safety component for lifts are in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

(19) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products.

↓ 95/16/EC (adapted)
⇒ new

Article 43

⊠ Freedom of movement ⊠

1. Member States may not prohibit, restrict or impede the placing ⇒ making available ⇐ on the market or putting into service on their territory of lifts and/or ⇒ the making available on the market of ⇐ safety components ⊠ for lifts on their territory ⊠ which comply with this Directive.

2. Member States may not prohibit, restrict or impede the placing on the market of components ⇒ not covered by Annex III ⇐ which, on the basis of a declaration by the manufacturer or his authorised representative established in the Community ⊠ Union ⊠, are intended to be incorporated into a lift covered by this Directive.

~~3.5.~~ At trade fairs, exhibitions or demonstrations ~~in particular,~~ Member States shall not prevent the showing of lifts or safety components ~~which do not conform to the Community provisions in force~~ ~~are not in conformity with this Directive~~, provided that a visible sign clearly indicates that ~~they~~ ~~such lifts or safety components~~ are not in conformity and ~~will not be made available~~ ~~are not for sale~~ until they have been brought into conformity ~~by the installer of the lift, the manufacturer of the safety components or the latter's authorized representative established in the Community.~~ During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

~~4. Without prejudice to paragraphs 1, 2 and 3, the provisions of~~ This Directive shall not affect Member States' entitlement to lay down in conformity with the ~~Treaty~~ ~~such requirements as they may deem necessary to ensure that persons are protected when the lifts in question are put into service or used, provided that this does not mean that the lifts are modified in a way not specified in~~ ~~the~~ this Directive.

Article 42

Making available on the market

1. Member States shall take all appropriate measures to ensure that the lifts covered by this Directive may be placed on the market and put into service only if they ~~are not liable to~~ ~~do not~~ endanger the health or safety of persons or, where appropriate, the safety of property, when properly installed and maintained and used for their intended purpose.

2. Member States shall take all appropriate measures to ensure that safety components for lifts covered by this Directive may be ~~placed~~ ~~made available~~ on the market and put into service only if the lifts in which they are to be installed ~~are not liable to~~ ~~do not~~ endanger the health or safety of persons or, where appropriate, the safety of property when properly installed and maintained and used for their intended purpose.

Article 52

Essential health and safety requirements

↓ 95/16/EC

1. Lifts covered by this Directive must satisfy the essential health and safety requirements set out in Annex I.

↓ 95/16/EC (adapted)

2. ~~The~~ Safety components for lifts covered by this Directive must satisfy the essential health and safety requirements set out in Annex I or enable the lifts in which they are installed to satisfy ~~those~~ ~~the said essential~~ requirements.

Article 6

✕ Buildings or constructions in which lifts are installed ✕

1. 2. Member States shall take all appropriate measures to ensure that the person responsible for work on the building or construction and the installer ~~of the lift, on the one hand, keep~~ ✕ both provide ✕ each other ✕ with the necessary information ~~✕ informed of the facts necessary for, and, on the other hand,~~ take the appropriate steps ✕ in order ✕ to ensure the proper operation and safe use of the lift.

↓ 95/16/EC

2. 3. Member States shall take all necessary measures to ensure that shafts intended for lifts do not contain any piping or wiring or fittings other than that necessary for the operation and safety of the lift.

↓ new

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 7 [Article R2 of Decision No 768/2008/EC]

Obligations of installers

1. When placing a lift on the market or putting a lift into service, installers shall ensure that it has been designed, manufactured, installed and tested in accordance with the essential health and safety requirements set out in Annex I.

2. Installers shall draw up the technical file and carry out the applicable conformity assessment procedure referred to in Article 16 or have it carried out.

Where the compliance of the lift with the applicable requirements has been demonstrated by that procedure, the installer shall draw up an EU declaration of conformity, ensure that it accompanies the lift, and affix the CE marking.

3. The installer shall keep the required technical file and the EU declaration of conformity and, where applicable, the approval decision(s) for 10 years after the lift has been placed on the market.

4. When deemed appropriate with regard to the risks presented by a lift, installers shall, to protect the health and safety of consumers investigate, and, if necessary, keep a register of complaints, of non-conforming lifts and shall keep distributors informed of any such monitoring.

5. Installers shall ensure that lifts bear a type, batch, serial number or other element allowing their identification.

6. Installers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted. The address must indicate a single point at which the installer of lifts can be contacted.

7. Installers shall ensure that the lift is accompanied by the instruction for use referred to in point 6.2 of Annex I, in a language which can easily be understood by end-users, as determined by the Member State in which the lift is installed.

8. Installers who consider or have reason to believe that a lift which they have installed is not in conformity with this Directive shall immediately take the necessary corrective measures to bring that lift into conformity. Furthermore, where the lift presents a risk, installers shall immediately inform the competent national authorities of the Member States in which they installed the lift to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

9. Installers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the lift, in a language which can be easily understood by that authority.

They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by lifts which they have installed.

Article 8 [Article R2 of Decision No 768/2008/EC]

Obligations of manufacturers

1. When placing safety components for lifts 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 I.

2. Manufacturers shall draw up the required technical file and carry out the conformity assessment procedure referred to in Article 15 or have it carried out

Where compliance of the safety component for lifts with the applicable essential health and safety requirements has been demonstrated by that procedure, the manufacturer shall draw up an EU declaration of conformity, ensure that it accompanies the safety component for lifts and affix the CE marking.

3. The manufacturer shall keep the technical file and the EU declaration of conformity and, where applicable, the approval decision(s) for 10 years after the safety component for lifts has been placed on the market.

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

5. Manufacturers shall ensure that their safety components for lifts bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the

safety component for lifts does not allow it, that the required information is provided on the packaging or in a document accompanying the safety component for lifts.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the safety component for lifts or, where that is not possible, a label inseparably attached to the safety component for lifts. The address must indicate a single point at which the manufacturers can be contacted.

7. Manufacturers shall ensure that the safety component for lifts is accompanied by the instruction manual referred to in Point 6.1 of Annex I, in a language which can easily be understood by end-users, as determined by the Member State concerned.

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

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the safety components for lifts, in a language which can be easily understood by that authority.

They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have placed on the market.

Article 9 [Article R3 of Decision No 768/2008/EC]

Authorised representatives

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

2. The obligations laid down in Article 8(1) and the drawing up of the technical file referred to in Article 8(2) shall not form part of the authorised representative's mandate.

3. 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, where applicable, the approval decision(s) relating to the manufacturer's quality assurance system, and the technical file at the disposal of the national surveillance authorities for a period of 10 years after the safety component for lifts has been placed on the market;

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

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

Article 10 [Article R4 of Decision No 768/2008/EC]

Obligations of importers of safety components for lifts

1. Importers shall place only compliant safety components for lifts on the market.

2. Before placing a safety component for lifts on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical file, that the safety component for lifts bears the CE marking and is accompanied by the EU declaration of conformity and the instruction manual and that the manufacturer has complied with the requirements set out in Article 8(5) and 8(6).

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

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the safety component for lifts or, where that is not possible, on its packaging or in a document accompanying the safety component.

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

5. Importers shall ensure that, while a safety component for lifts is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by a safety component for lifts, importers shall, to protect the health and safety of consumers, carry out sample testing of safety components for lifts made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming safety components for lifts and safety component for lifts recalls, and shall keep distributors and installers informed of such monitoring.

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

8. Importers shall, for a period of 10 years after the safety component for lifts has been placed on the market, keep a copy of the EU declaration of conformity and, where applicable, the approval decision(s) at the disposal of the market surveillance authorities and ensure that the technical file can be made available to those authorities, upon request.

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

Article 11 [Article R5 of Decision No 768/2008/EC]

Obligations of distributors

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

2. Before making a safety component for lifts available on the market, distributors shall verify that the safety component for lifts bears the CE marking, that it is accompanied by the EU declaration of conformity and by the instruction manual and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and 8(6), and Article 10(3).

Where a distributor considers or has reason to believe that a safety component for lifts is not in conformity with the essential health and safety requirements set out in Annex 1, he shall not make the safety component for lifts available on the market until it has been brought into conformity. Furthermore, where the safety component for lifts presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a safety component for lifts is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex I.

4. Distributors who consider or have reason to believe that a safety component for lifts which they have made available on the market is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the safety component for lifts presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the safety component for lifts available 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 safety components for lifts. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have made available on the market.

Article 12 [Article R6 of Decision No 768/2008/EC]

Cases in which the obligations of manufacturers apply to importers or distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8 where he places a safety component for lifts on the market under his name or trademark or modifies a safety component for lifts already placed on the market in such a way that compliance with the requirements of this Directive may be affected.

Article 13 [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:

- (a) any economic operator who has supplied them with a safety component for lifts;
- (b) any economic operator to whom they have supplied a safety component for lifts.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after they have been supplied with a safety component for lifts and for a period of 10 years after they have supplied a safety component for lifts.

↓ 95/16/EC (adapted)

CHAPTER III

⊠ CONFORMITY OF LIFTS AND SAFETY COMPONENTS FOR LIFTS ⊠

Article 14 [Article R8 of Decision No 768/2008/EC]

⊠ Presumption of conformity ⊠

~~1. Member States shall regard lifts and safety components bearing the CE marking and accompanied by the EC declaration of conformity referred to in Annex II as conforming to all the provisions of this Directive, including the conformity assessment procedures laid down in Chapter II.~~

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

↓ 95/16/EC

~~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:~~

~~— lifts constructed in accordance with that standard shall be presumed to comply with the relevant essential requirements;~~

~~or~~

~~— safety components constructed in accordance with that standard shall be presumed suitable to enable a lift on which they are correctly installed to comply with the relevant essential requirements.~~

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

↓ 95/16/EC (adapted)

~~3. Member States shall ensure that appropriate measures are taken to enable both sides of industry to have an influence at national level on the process of preparing and monitoring the harmonized standards.~~

↓ new

1. Lifts and safety components for lifts which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements covered by those standards or parts thereof set out in Annex I.

[2. Where a harmonised standard satisfies the requirements which it covers and which are set out in Annex I or Article 24, the Commission shall publish the references of this standard in the Official Journal of the European Union.]

↓ 95/16/EC (adapted)

Article ~~8~~ 15

~~☒~~ *Conformity assessment procedure for safety components for lifts* ~~☒~~

~~1. Before placing safety components listed in Annex IV on the market, the manufacturer of a safety component or his authorized representative established in the Community must:~~

~~☒~~ Safety components for lifts shall be subject to any of the following conformity assessment procedures: ~~☒~~

~~(a)~~

~~(i) either submit the model of the safety component for EC type examination in accordance with Annex V and for production checks by a notified body in accordance with Annex XI;~~

~~(ii) or submit the model of the safety component for EC type examination in accordance with Annex V and operate a quality assurance system in accordance with Annex VIII for checking production;~~

~~(iii) or operate a full quality assurance system in accordance with Annex IX;~~

☒ (a) the model of the safety component for lifts shall be submitted for EU type examination set out in Annex IV Part A and the conformity to type shall be ensured with random checking of the safety component for lifts set out in Annex IX; ☒

☒ (b) the model of the safety component for lifts shall be submitted for EU type examination set out in Annex IV Part A and be subject to a product quality assurance system in accordance with Annex VI; ☒

☒ (c) full quality assurance system set out in Annex VII. ☒

~~(b) affix the CE marking on each safety component and draw up a declaration of conformity containing the information listed in Annex II, taking account of the specifications given in the Annex used (Annex VIII, IX or XI as the case may be);~~

~~(c) keep a copy of the declaration of conformity for 10 years from the date on which the safety component was last manufactured.~~

↓ 95/16/EC (adapted)

Article 16

☒ Conformity assessment procedure for lifts ☒

~~1.2. Before being placed~~ ☒ Lifts shall be subject to ☒ ~~on the market, a lift must have undergone~~ one of the following ☒ conformity assessment ☒ procedures:

~~(i) either, if it was designed in accordance with a lift having undergone an EC type examination as referred to in Annex V, it shall be constructed, installed and tested by implementing:~~

- ~~– the final inspection referred to in Annex VI, or~~
- ~~– the quality assurance system referred to in Annex XII, or~~
- ~~– the quality assurance system referred to in Annex XIV.~~

~~The procedures for the design and construction stages, on the one hand, and the installation and testing stages, on the other, may be carried out on the same lift;~~

~~(ii) or, if it was designed in accordance with a model lift having undergone an EC type-examination as referred to in Annex V, it shall be constructed, installed and tested by implementing:~~

- ~~– the final inspection referred to in Annex VI, or~~
- ~~– the quality assurance system referred to in Annex XII, or~~
- ~~– the quality assurance system referred to in Annex XIV;~~

~~(iii) or, if it was designed in accordance with a lift for which a quality assurance system pursuant to Annex XIII was implemented, supplemented by an examination of the design if the latter is not wholly in accordance with the harmonized standards, it shall be installed and constructed and tested by implementing, in addition:~~

- ~~– the final inspection referred to in Annex VI, or~~
- ~~– the quality assurance system in accordance with Annex XII, or~~
- ~~– the quality assurance system in accordance with Annex XIV;~~

~~(iv) or, having undergone the unit verification procedure, referred to in Annex X, by a notified body;~~

~~(v) or, having been subject to the quality assurance system in accordance with Annex XIII, supplemented by an examination of the design if the latter is not wholly in accordance with the harmonized standards.~~

~~In the cases referred to in (i), (ii) and (iii) above, the person responsible for the design must supply to the person responsible for the construction, installation and testing all necessary documents and information for the latter to be able to operate in absolute security.~~

↓ 95/16/EC (adapted)

☒ (a) if they are designed and manufactured in accordance with a model lift that has undergone an EU type-examination referred to in Annex IV Part B, they shall be installed and tested by carrying out any of the following procedures: ☒

- ☒ (i) the final inspection referred to in Annex V; ☒
- ☒ (ii) the product quality assurance system referred to in Annex X; ☒
- ☒ (iii) the production quality assurance system referred to in Annex XII; ☒

☒ (b) if they are designed and manufactured in accordance with a model lift for which a full quality assurance system pursuant to Annex XI has been carried out, supplemented by a design examination if the design is not wholly in accordance with the harmonized standards, they shall be installed and tested by carrying out any of the following procedures: ☒

- ☒ (i) the final inspection referred to in Annex V; ☒
 - ☒ (ii) the product quality assurance system in accordance with Annex X; ☒
 - ☒ (iii) the production quality assurance system in accordance with Annex XII; ☒
- ☒ (c) the unit verification procedure, referred to in Annex VIII; ☒

☒ (d) the full quality assurance system referred to in Annex XI, supplemented by a design examination if the design is not wholly in accordance with the harmonized standards. ☒

☒ 2. In the cases referred to in point (a) and (b) of paragraph 1, the person responsible for the design and manufacture of the lift must supply to the person responsible for the installation and testing of the lift all the necessary documents and information to enable the latter to ensure correct and safe installation and testing of the lift. ☒

↓ 95/16/EC

~~3. In all the cases referred to in paragraph 2:~~

~~the installer shall affix the CE marking on the lift and draw up a declaration of conformity containing the information listed in Annex II, taking account of the specifications given in the Annex used (Annex VI, X, XII, XIII or XIV, as the case may be);~~

~~the installer must keep a copy of the declaration of conformity for 10 years from the date on which the lift was placed on the market;~~

~~the Commission, the Member States and the other notified bodies may, on request, obtain from the installer a copy of the declaration of conformity and reports of the tests involved in the final inspection.~~

~~4. (a) Where the lifts or safety components are subject to other Directives concerning other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the lift or safety component is also presumed to conform to the provisions of those other Directives.~~

~~(b) However, where one or more of these Directives allows the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the installer of the lift or the manufacturer of the safety components. In this case, particulars of the Directives applied, 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 lift or safety component.~~

~~5. Where neither the installer of the lift nor the manufacturer of the safety component nor his authorized representative established in the Community has complied with the obligations of the preceding paragraphs, those obligations shall devolve upon whomsoever places the lift or the safety component on the market in the Community. The same obligations shall apply to whomsoever manufactures the lift or safety component for his own use.~~

↓ 95/16/EC (adapted)

3. All permitted variations between the model lift and the lifts forming part of the lifts derived from the model lift must be clearly specified (with maximum and minimum values) in the technical ~~dossier~~ ☒ file ☒.

4. By calculation and/or on the basis of design plans it is permitted to demonstrate the similarity of a range of equipment to satisfy the essential ☒ health and ☒ safety requirements ☒ set out in Annex I ☒.

Article 17 [Article R10 of Decision No 768/2008/EC]

✕ EU declaration of conformity ✕

↓ new

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

2. The EU declaration of conformity shall have the model structure set out in Annex II, shall contain the elements specified in the relevant modules set out in Annex V, VIII, X, XI or XII, and shall be continuously updated. It shall be translated into the language or the languages required by the Member State on which market the lift or the safety component for lifts is placed or made available.

3. Where a lift or the safety component for lifts is subject to more than one Union act requiring 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 responsibility for the compliance of the safety component for lifts and the installer shall assume responsibility for the compliance of the lift.

↓ 95/16/EC (adapted)

~~CHAPTER III~~

~~CE MARKING~~

Article 18 [Article R11 of Decision No 768/2008/EC]

✕ General principles of the CE marking ✕

↓ new

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

↓ 95/16/EC (adapted)

Article 19 [Article R12 of Decision No 768/2008/EC]

✕ Rules and conditions for affixing the CE marking and other markings ✕

~~1. The CE marking shall consist of the initials CE. Annex III sets out the model to be used.~~

~~1.2. The CE marking shall be affixed ☒ visibly, legibly and indelibly ☒ to every ☒ each ☒ lift car distinctly and visibly in accordance with Section 5 of Annex I and shall be affixed on each of the safety components ☒ for lifts ☒ listed in Annex III IV or, where that is not possible, on a label inseparably attached to the safety component.~~

~~3. The affixing on the lifts or safety components of markings which are likely to mislead third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the lifts or safety components, provided that the visibility and legibility of the CE marking are not thereby reduced.~~

~~4. Without prejudice to Article 7:~~

~~(a) where a Member State establishes that the CE marking has been affixed irregularly, the installer of the lift, the manufacturer of the safety component or the authorized representative of the latter established within the Community shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Member State;~~

~~(b) should non conformity persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the safety component in question or to ensure that it is withdrawn from the market and prohibit the lift from being used and inform the other Member States in accordance with the procedures laid down in Article 7 (4).~~

↓ new

2. The CE marking shall be affixed before the lifts or the safety components for lifts are placed on the market.

↓ 95/16/EC (adapted)

☒ 3. The CE marking on lifts shall be followed by the identification number of the notified body involved in the following conformity assessment procedures: ☒

☒ (a) the final inspection referred to in Annex V or approval of the quality assurance system (referred to in Annex X, XI or XII); ☒

☒ (b) the unit verification procedure, referred to in Annex VIII; ☒

☒ (c) the approval of the full quality assurance system referred to in Annex XI. ☒

☒ 4. The CE marking on safety components for lifts shall be followed by the identification number of the notified body involved in the following conformity assessment procedures: ☒

☒ (a) the approval of the product quality assurance system referred to in Annex VI; ☒

☒ (b) the approval of the full quality assurance system referred to in Annex VII. ☒

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

The CE marking and, where applicable, the identification number referred to in paragraph 3 and 4 may be followed by a pictogram or any other mark indicating a special risk or use.

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 and examination procedures which these bodies have been appointed to carry out and the identification numbers assigned to them beforehand by the Commission.~~

~~The Commission shall publish for information in the Official Journal of the European Communities a list of the notified bodies and 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 VII in assessing the notified bodies. Bodies meeting the assessment criteria laid down in the relevant harmonized standards shall be presumed to fulfil the criteria laid down in Annex VII.~~

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

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20 [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 21 [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 Article 26.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 22. In addition it shall have arrangements to cover liabilities arising out of its activities.
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22 [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 23 [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 24 [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 lifts or safety components for lifts it assesses.

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

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, user or maintainer of safety components for lifts which they assess, nor the authorised representative of any of those parties.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of lifts which they assess.

This shall not preclude the use of assessed lifts or safety components for lifts that are necessary for the operations of the conformity assessment body or the use of such lifts or safety components for lifts for personal purposes.

This does not preclude the possibility of exchange of technical information between the manufacturer or the installer and the body.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those lifts or safety components for lifts, or represent the parties engaged in those activities.

They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

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

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Article 15 and 16 and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

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

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of lift or safety component for lifts 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 for which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of its relevant national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment body, its management and the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

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

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

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks according to Article 15 and 16 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.

The body shall participate in or be represented in the activities of the Coordination Group of Notified Bodies for Lifts established under Article 36 and apply as general guidance the recommendations for use produced as a result of the work of that group.

Article 25 [Article R18 of Decision No 768/2008/EC]

Presumption of conformity of a notified body

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26 [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 24 and shall inform the notifying authority accordingly.

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

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

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 15 and 16.

Article 27 [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 procedures for lifts or for safety components for lifts for which the body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28 [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 24.

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

3. The notification shall include full details of the conformity assessment procedures for lifts or for safety components for lifts concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification

where an accreditation certificate is used or within two months of a notification where accreditation is not used.

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

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

Article 29 [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 30 [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 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

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

Article 31 [Article R26 of Decision No 768/2008/EC]

Challenge to the competence of notified bodies

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

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

Article 32 [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 Article 15 and 16.

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

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the conformity of the lifts or the safety components for lifts with the provisions of this Directive.

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

4. Where, in the course of the monitoring of conformity following the issue of a certificate or an approval decision, as appropriate, a notified body finds that a lift or a safety component for lifts no longer complies, it shall require the installer or the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

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

Article 33 [Article 4(7) of Decision No 768/2008/EC]

Appeal against decisions of notified bodies

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

Article 34 [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 or approval decision;
- (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 for lifts or safety components for lifts with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35 [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 36 [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 Coordination Group of Notified Bodies for Lifts.

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

CHAPTER V

UNION MARKET SURVEILLANCE AND CONTROL OF LIFTS OR SAFETY COMPONENTS FOR LIFTS ENTERING THE UNION MARKET AND SAFEGUARD PROCEDURES

Article 37

Union market surveillance and control of lifts or safety components for lifts entering the Union market

Article 15(3) and Articles 16-29 of Regulation (EC) No 765/2008 shall apply to lifts and safety components for lifts.

Article 38 [Article R31 of Decision No 768/2008/EC]

Procedure for dealing with lifts or safety components for lifts presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a lift or a safety component for lifts covered by this Directive presents a risk to the health or safety of persons or, where appropriate, to the safety of property, they shall carry out an evaluation in relation to the lift or the safety component for lifts concerned covering all 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 the evaluation referred to in the first subparagraph, the market surveillance authorities find that a lift does not comply with the requirements laid down in this Directive, they shall, without delay, require the installer to take all appropriate corrective action to bring the lift into compliance with those requirements within a reasonable period commensurate with the nature of the risk, as they may prescribe.

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

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

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

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

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

4. Where the installer does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to restrict the placing on their national market or the putting into service.

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

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

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant lift or safety component for lifts, their origin, the nature of the alleged non-conformity and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operators. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

(a) failure of the lift or the safety component for lifts to meet the essential health and safety requirements set out in Annex I;

(b) shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the lift or the safety component for lifts concerned and, in the event of disagreement with the 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, without delay, in respect of the lift or the safety component for lifts concerned.

Article 39 [Article R32 of Decision No 768/2008/EC]

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(3) and 38(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 relating to a lift is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant lift is restricted to be placed on their national market or put into service.

If the national measure relating to a safety component for lifts is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant safety component for lifts is withdrawn from their market.

The Member States shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3. Where the national measure is considered justified and the non-compliance of the lift or the safety component for lifts is attributed to shortcomings in the harmonised standards referred to in Article 38(5)(b) of this Directive, the Commission shall apply the procedure provided for in Article 8 of Regulation (EU) No [.../...] [on European Standardisation].

Article 40 [Article R33 of Decision No 768/2008/EC]

Compliant lift or safety component for lifts which present a risk to health and safety

1. Where, having performed an evaluation under Article 38(1), a Member State finds that although a lift or safety components for lifts 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, it shall require the relevant economic operator to take all appropriate measures to ensure that the lifts or safety component for lifts concerned, when placed on the market, no longer presents that risk, to withdraw the safety component for lifts from the market or to recall it or to restrict the placing the lift on the market or the putting it into service within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

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

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

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide 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 41 [Article R34 of Decision No 768/2008/EC]

Formal non-compliance

1. Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the installer or the manufacturer, distributor or importer of a safety component for lifts to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation Article 30 of Regulation (EC) No 765/2008 or of Article 18 and 19 of this Directive;

(b) the CE marking has not been affixed;

(c) the EU declaration of conformity has not been drawn up;

(d) the EU declaration of conformity has not been drawn up correctly;

(e) the technical file referred to in Annexes IV Part A and Part B, VII, VIII and XI 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 lifts or safety components for lifts being made available on the market or ensure that safety components for lifts are recalled or withdrawn from the market.

↓ 95/16/EC (adapted)

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 essential 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, giving the reasons therefore. 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).~~

↓ 95/16/EC

~~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.~~

↓ 1882/2003 Art. 1 and Annex I.10 (new)

~~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 1999/468/EC²² shall apply, having regard to the provisions of Article 8 thereof.~~

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

↓ 95/16/EC

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

~~Article 7~~

~~1. Where a Member State ascertains that a lift or a safety component bearing the CE marking and used in accordance with its intended purpose is liable to endanger the safety of persons and, where appropriate, of property, it shall take all appropriate measures to withdraw it from the market, to prohibit it from being placed on the market or put into service or to restrict its free movement~~

~~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) themselves.~~

~~2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:~~

²² ~~Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).~~

~~the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is based on shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 6 (1), if the Member State which has taken the decision intends to maintain it, and shall initiate the procedure referred to in Article 6 (1);~~

~~the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the installer of the lift, the manufacturer of the safety components or the latter's authorized representative established in the Community.~~

~~3. Where a lift or safety component which does not comply bears the CE marking, the competent Member State shall take appropriate action against whomsoever 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 the procedure.~~

↓ new

CHAPTER VI

DELEGATING POWER

Article 42

Delegating power

The Commission shall be empowered to adopt delegated acts in accordance with Article 43 concerning adaptations of Annex III to technical progress and new scientific evidence.

Article 43

Exercise of the delegation

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

2. The delegation of power referred to in Article 42 shall be conferred for an indeterminate period of time from the date specified in Article 49 [*entry into force of the directive*].

3. The delegation of powers referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

↓ 95/16/EC (adapted)

CHAPTER ~~IV~~ VII

⊠ TRANSITIONAL AND ⊠ FINAL PROVISIONS

Article 11

~~Any decision taken pursuant to this Directive which restricts:~~

~~the placing on the market and/or putting into service and/or use of a lift,~~

~~the placing on the market and/or putting into service of a safety component,~~

~~shall state the exact grounds on which it is based. Such a decision shall be notified as soon as possible 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.~~

↓ new

Article 44

Penalties

Member States shall lay down the 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 must 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 46(1)] and shall notify it without delay of any subsequent amendment affecting them.

↓ 95/16/EC (adapted)

~~Article 12~~

~~The Commission shall take the necessary steps to have information on all the relevant decisions relating to the implementation of this Directive made available.~~

Article 45

⌘ Transitional and final provisions ⌘

↓ new

Member States shall not impede the making available on the market or putting into service of lifts or safety components for lifts covered by Directive 95/16/EC which are in conformity with that Directive and which were placed on the market before *[the date set out in the second subparagraph of Article 46(1)]*.

Certificates of conformity issued under Directive 95/16/EC shall be valid under this Directive unless they expire before that date.

↓ 95/16/EC (adapted)

⇒ new

Article 46

⌘ Transposition ⌘

1. Member States shall adopt and publish, ⌘ by ⌘ ⇒ *[day (generally the last day of a month)/month/year = 2 years after this adoption]* ⌘ at the latest, ⌘ the laws, regulations and administrative provisions necessary to comply with ~~this Directive~~ ⌘ Articles: [Article 2(5)-2(19), Articles: 7-14, Articles: 17-18, Article 19(5), Articles: 20-45, Article 46(1), Article 47-49] and Annexes: [Annex II Part A Points: (f), (k), (l), (m), Annex II Part B Points: (d), (j), (k), (l), Annex IV Part A Points: 2(e), 3(c), 3(e), 3(g), Points: 4(b)-(e), Points: 5-9, Annex IV Part B Points: 2(e), 3(c), 3(e), 3(h), Points: 4(c)-(e), Point 5 paragraphs: 2-4, Points: 6-9, Annex V Point 3.3(b), Points: 6-7, Annex VI Points: 3.1(a)-(c), Point 3.3 paragraph 4 -5, Point 4.3, Points: 6-7, Annex VII Points: 3.1(a)-(b), 3.1(d), 3.1(f), Point 3.3, Point 4.2, Point 6, Annex VII Points: 3(c)-(d), 3(g), Annex VII Point 4, Annex IX Points: 3(a)-(d), Annex X Points: 3.1(a), 3.1(e), Point: 3.4, Points: 6-7, Annex XI Points: 3.1(a)-(c), 3.1(e), Points: 3.3.3, 3.3.4, Points: 3.4 -3.5, Point 5(b) Point 6, Annex XII Point 3.1(a), Point 3.3, Point 6]. *[The articles and annexes which have been changed as to the substance by comparison with the earlier Directive]*. ⌘ ~~by 1 January 1997~~. They shall forthwith ~~inform~~ ⌘ communicate to ⌘ the Commission ~~thereof~~ ⌘ the text of those provisions and a correlation table between those provisions and this Directive. ⌘

⇒ They shall apply those provisions from *[day (generally the first day of a month)/month/year = day after the date mentioned in first subparagraph]*. ⌘

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

~~Member States shall apply these measures with effect from 1 July 1997.~~

~~2. Until 30 June 1999 Member States shall allow:~~

~~the placing on the market and putting into service of lifts,~~

~~the placing on the market and putting into service of safety components,~~

~~which conform to the provisions in force in their territories on the date of adoption of this Directive.~~

↓ 95/16/EC (adapted)

~~3.2.~~ Member States shall communicate to the Commission the texts of the ☒ main ☒ provisions of national law which they adopt in the field covered by this Directive.

Article ~~16~~ 47

☒ Reporting ☒

↓ 95/16/EC

~~No later than 30 June 2002, the Commission shall, in consultation with the Committee referred to in Article 6 (3) and on the basis of reports provided by the Member States, re-examine the functioning of the procedures laid down in this Directive and, if necessary, submit any proposals for appropriate amendments.~~

↓ new

[By ... and every 5 years after that date] Member States shall submit to the Commission reports on the application of this Directive.

↓ 95/16/EC (adapted)

Article ~~13~~ 48

☒ Repeal ☒

~~Directive 84/528/EEC and Directive 84/529/EEC are hereby repealed with effect from 1 July 1999.~~

Article 14

~~With regard to the aspects concerning the installation of the lift, this Directive is a Directive within the meaning of Article 2 (3) of Directive 89/106/EEC.~~

↓ 95/16/EC

⇒ new

⇒ Directive 95/16/EC, as amended by the acts listed in Annex XIII, Part A, is repealed with effect from the date set out in the second subparagraph of Article 46(1) of this Directive, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex XIII, Part B. ⇐

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

↓ 95/16/EC (adapted)

Article 49

⊠ Entry into force ⊠

↓ 95/16/EC (adapted)

⇒ new

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

⊠ Articles: [Article 1, Article 2(1)-2(5), Articles: 3-6, Articles: 15-16, Article 19(1)-19(4), Article 45, Article 46(2), Article 50] and Annexes: [Annex I, Annex II Part A Points: (a), (b), (c), (d), (e), (g), (h), (i), (j), Annex II Part B Points: (a), (b), (c), (e), (f), (g), (h), (i), Annex III, Annex IV Part A Points: 1, 2(a)-(d), 3(a)-(b), 3(d), 3(f), 3(h)-(i), Annex IV Part A Point 4(a), Points 10-11, Annex IV Part B Points: 1, 2(a)-(d), 3(a)-(b), 3(d), 3(f)-(g) 3(i)-(j), Points: 4(a)-(b), Point 5 paragraph 1, Points: 10-11, Annex V Points: 1-3.2, Point 3.3(a), Points: 3.4-5, Annex VI Points: 1-2, Point 3.1(d)-(f), Point 3.2, Point 3.3 paragraphs: 1-3, Points: 3.4-4.2, Point 5, Annex VII Points 1-2, Points: 3.1(c), 3.1(e), Point 3.2, Point 3.4, Point 4.1, Points: 4.3-5, Point 7, Annex VII Points: 1-2, Points: 3(a)-(b), 3(e)-(f), 3(h), Points: 5-6, Annex IX Points: 1-2, Points: 4-7, Annex X Points: 1-2, Points: 3.1(b)-(d), Points: 3.2-3.3, Points: 4-5, Annex XI Points: 1-2, Point: 3.1(d), Point 3.2, Point 3.3.1, Point 4, Point 5(a), 5(c), 5(d), Point 7, Annex XII Points: 1-2, Points 3.1(b)-(d), Point 3.2, Point 3.4, Points: 4-5, Point 7]. [The articles and annexes which are unchanged by comparison with the earlier Directive] shall apply from [the date set out in the second subparagraph of Article 46(1)]. ⊠

Article 50~~17~~

This Directive is addressed to the Member States.

Done at [...],

For the European Parliament
The President

For the Council
The President

ANNEX I

~~ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF LIFTS AND SAFETY COMPONENTS~~

PRELIMINARY REMARKS

1. Obligations under essential health and safety requirements apply only where ☒ the corresponding risk exists for ☒ the lift or safety component ☒ for lifts ☒ ~~is subject to the hazard~~ in question when used as intended by the installer ~~of the lift~~ or the manufacturer ~~of the safety components~~.
2. The essential health and safety requirements contained in the Directive are imperatives. However, given the present state of the art, the objectives which they lay down may not be attainable. In such cases, and to the greatest extent possible, the lift or safety components ☒ for lifts ☒ must be designed and built in such a way as to approximate to those objectives.
3. The ~~safety component~~ manufacturer and the installer ~~of the lift~~ are under an obligation ☒ to carry out ☒ ~~assess the hazards~~ ☒ a risk assessment ☒ in order to identify all ~~those~~ ☒ the risks ☒ which apply to their products; they must then design and construct them taking account of the assessment.

~~4. In accordance with Article 14, the essential requirements laid down in Directive 89/106/EEC, not included in this Directive, apply to lifts.~~

1. GENERAL

1.1. Application of Directive ~~89/392/EEC~~, as amended by Directives ~~91/368/EEC~~, ~~93/44/EEC~~ and ~~93/68/EEC~~ 2006/42/EC.

Where the relevant ~~hazard~~ ☒ risk ☒ exists and is not dealt with in this Annex, the essential health and safety requirements of Annex I to Directive ~~89/392/EEC~~ 2006/42/EC²³ of the European Parliament and of the Council apply. The essential ☒ health and safety ☒ requirements of Section Point 1.1.2 of Annex I to Directive ~~89/392/EEC~~ 2006/42/EC ~~must~~ apply in any event.

²³ OJ L 157, 9.06.2006, p. 24.

1.2. Carrier

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.

1.3. Means of suspension and means of support

The means of suspension and/or support of the car, its attachments and any terminal parts thereof must be selected and designed so as to ensure an adequate level of overall safety and to minimize the risk of the car falling, taking into account the conditions of use, the materials used and the conditions of manufacture.

Where ropes or chains are used to suspend the car, there must be at least two independent cables or chains, each with its own anchorage system. Such ropes and chains must have no joins or splices except where necessary for fixing or forming a loop.

1.4. Control of loading (including overspeed)

1.4.1. Lifts must be so designed, constructed and installed as to prevent normal starting if the rated load is exceeded.

1.4.2. Lifts must be equipped with an overspeed governor.

These requirements do not apply to lifts in which the design of the drive system prevents overspeed.

1.4.3. Fast lifts must be equipped with a speed-monitoring and speed-limiting device.

1.4.4. Lifts driven by friction pulleys must be designed so as to ensure stability of the traction cables on the pulley.

1.5. Machinery

1.5.1. All passenger lifts must have their own individual lift machinery. This requirement does not apply to lifts in which the counterweights are replaced by a second car.

1.5.2. The installer of the lift must ensure that the lift machinery and the associated devices of a lift are not accessible except for maintenance and in emergencies.

1.6. Controls

1.6.1. The controls of lifts intended for use by unaccompanied disabled persons must be designed and located accordingly.

1.6.2. The function of the controls must be clearly indicated.

1.6.3. The call circuits of a group of lifts may be shared or interconnected.

1.6.4. Electrical equipment must be so installed and connected that:

~~(a)~~ there can be no possible confusion with circuits which do not have any direct connection with the lift₂;

~~(b)~~ the power supply can be switched while on load₂;

~~(c)~~ movements of the lift are dependent on electrical safety devices in a separate electrical safety circuit₂;

~~(d)~~ a fault in the electrical installation does not give rise to a dangerous situation.

2. ~~HAZARD TO~~ RISKS FOR PERSONS OUTSIDE THE CAR

2.1. The lift must be designed and constructed to ensure that the space in which the car travels is inaccessible except for maintenance or in emergencies. Before a person enters that space, normal use of the lift must be made impossible.

2.2. The lift must be designed and constructed to prevent the risk of crushing when the car is in one of its extreme positions.

The objective will be achieved by means of free space or refuge beyond the extreme positions.

However, in specific cases, in affording Member States the possibility of giving prior approval, particularly in existing buildings, where this solution is impossible to fulfil, other appropriate means may be provided to avoid this risk.

2.3. The landings at the entrance and exit of the car must be equipped with landing doors of adequate mechanical resistance for the conditions of use envisaged.

An interlocking device must prevent during normal operation:

~~(a)~~ starting movement of the car, whether or not deliberately activated, unless all landing doors are shut and locked₂;

~~(b)~~ the opening of a landing door when the car is still moving and outside a prescribed landing zone.

However, all landing movements with the doors open shall be allowed in specified zones on condition that the levelling speed is controlled.

3. ~~HAZARD TO~~ ⚠ RISKS FOR ⚠ PERSONS IN THE CAR

3.1. Lift cars must be completely enclosed by full-length walls, fitted floors and ceilings included, with the exception of ventilation apertures, and with full-length doors. These doors must be so designed and installed that the car cannot move, except for the landing movements referred to in the third subparagraph of Section Point 2.3, unless the doors are closed, and comes to a halt if the doors are opened.

The doors of the car must remain closed and interlocked if the lift stops between two levels where there is a risk of a fall between the car and the shaft or if there is no shaft.

3.2. In the event of a power cut or failure of components the lift must have devices to prevent free fall or uncontrolled ~~upward~~ movements of the car.

The device preventing the free fall of the car must be independent of the means of suspension of the car.

This device must be able to stop the car at its rated load and at the maximum speed anticipated by the installer of the lift. Any stop occasioned by this device must not cause deceleration harmful to the occupants whatever the load conditions.

3.3. Buffers must be installed between the bottom of the shaft and the floor of the car.

In this case, the free space referred to in Section Point 2.2 must be measured with the buffers totally compressed.

This requirement does not apply to lifts in which the car cannot enter the free space referred to in Section Point 2.2 by reason of the design of the drive system.

3.4. Lifts must be so designed and constructed as to make it impossible for them to be set in motion if the device provided for in Section Point 3.2 is not in an operational position.

4. ~~OTHER HAZARDS~~ ⚠ RISKS ⚠

4.1. The landing doors and car doors or the two doors together, where motorized, must be fitted with a device to prevent the risk of crushing when they are moving.

4.2. Landing doors, where they have to contribute to the protection of the building against fire, including those with glass parts, must be suitably resistant to fire in terms of their integrity and their properties with regard to insulation (containment of flames) and the transmission of heat (thermal radiation).

4.3. Counterweights must be so installed as to avoid any risk of colliding with or falling on to the car.

4.4. Lifts must be equipped with means enabling people trapped in the car to be released and evacuated.

4.5. Cars must be fitted with two-way means of communication allowing permanent contact with a rescue service.

4.6. Lifts must be so designed and constructed that, in the event of the temperature in the lift machine exceeding the maximum set by the installer of the lift, they can complete movements in progress but refuse new commands.

4.7. Cars must be designed and constructed to ensure sufficient ventilation for passengers, even in the event of a prolonged stoppage.

4.8. The car should be adequately lit whenever in use or whenever a door is opened; there must also be emergency lighting.

4.9. The means of communication referred to in Section Point 4.5 and the emergency lighting referred to in Section Point 4.8 must be designed and constructed so as to function even without the normal power supply. Their period of operation should be long enough to allow normal operation of the rescue procedure.

4.10. The control circuits of lifts which may be used in the event of fire must be designed and manufactured so that lifts may be prevented from stopping at certain levels and allow for priority control of the lift by rescue teams.

5. MARKING

5.1. In addition to the minimum particulars required for any machine pursuant to Section Point 1.7.3 of Annex I to Directive ~~89/392/EEC~~ 2006/42/EC, each car must bear an easily visible plate clearly showing the rated load in kilograms and the maximum number of passengers which may be carried.

5.2. If the lift is designed to allow people trapped in the car to escape without outside help, the relevant instructions must be clear and visible in the car.

↓ 95/16/EC (adapted)
⇒ new

6. INSTRUCTIONS FOR USE

6.1. The safety components $\boxtimes$ for lifts $\boxtimes$ referred to in Annex ~~IV~~ III must be accompanied by an instruction manual drawn up $\Rightarrow$ in a language which can be easily understood by consumers and other end-users, as determined by $\Leftarrow$ ~~in an official language of the Member State of the lift installer or another Community language acceptable to him~~ $\Rightarrow$ concerned $\Leftarrow$, so ~~that~~ $\boxtimes$ the following can be carried out effectively and without danger: $\boxtimes$

(a) assembly;₃

(b) connection;₃

(c) adjustment;₃ ~~and~~

(d) maintenance;₃

~~can be carried out effectively and without danger.~~

6.2. Each lift must be accompanied by ~~documentation~~ ⇒ instructions for use ⇐ drawn up in ⇒ a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. ⇐ ~~the official language(s) of the Community, which may be determined in accordance with the Treaty by the Member State in which the lift is installed. The documentation~~ ⇒ Those instructions for use ⇐ shall contain at least ☒ the following documents: ☒

↓ 95/16/EC

(a) an instruction manual containing the plans and diagrams necessary for normal use and relating to maintenance, inspection, repair, periodic checks and the rescue operations referred to in Section Point 4.4;

(b) a logbook in which repairs and, where appropriate, periodic checks can be noted.

ANNEX II

A. CONTENT OF THE ~~EU~~ ~~EC~~ DECLARATION OF CONFORMITY FOR SAFETY COMPONENTS ~~FOR LIFTS~~ ²⁴

The ~~EU~~ ~~EC~~ declaration of conformity ~~for~~ safety components for lifts shall be drafted in the same language as the instruction manual referred to in Annex I, Point 6.1, and be either typewritten or printed and ~~must~~ shall contain the following information:

(a) business ~~name and~~ full address of the manufacturer ~~of the safety components~~ ²⁵:

(b) where appropriate, business name and address of his authorized representative established in the ~~Community~~ ²⁶ Union:

(c) description of the safety component ~~for lifts~~, details of type or series and serial number (if any):

(d) safety function of the safety component ~~for lifts~~, if not obvious from the description:

(e) year of manufacture of the safety component ~~for lifts~~:

(f) all relevant provisions with which the safety component ~~for lifts~~ complies:

↓ new

(g) a statement that the safety component for lifts is in conformity with all the relevant Union harmonisation legislation;

↓ 95/16/EC (adapted)

(h) where appropriate, ~~reference~~ reference(s) to harmonized ~~standard~~ standard(s) used:

(i) where appropriate, the name, address and identification number of the notified body which carried out the ~~EU~~ ~~EC~~ type-examination in accordance with Article 15(a) and (b) ~~8 (1)(a)(i) and (ii)~~ and ~~where appropriate, the reference to~~ of the ~~EU~~ ~~EC~~ type-examination certificate issued by that notified body:

²⁴ ~~The declaration must be drafted in the same language as the instruction manual referred to in Annex I, Section 6.1, and be either typewritten or printed.~~

²⁵ ~~Business name, full address; in the case of an authorized representative, also indicate the business name and address of the manufacturer of the safety components.~~

²⁶ ~~Business name, full address; in the case of an authorized representative, also indicate the business name and address of the manufacturer of the safety components.~~

~~(j)~~ where appropriate, name, address and identification number of the notified body which carried out the ~~production checks in accordance with Article 8(1) (a) (ii)~~ ☒ conformity assessment procedure in accordance with Article 15(a) ☒;

~~(k)~~ where appropriate, name, address and identification number of the notified body which ~~checked~~ ☒ approved ☒ the ~~system of~~ quality assurance ☒ system operated ☒ implemented by the manufacturer in accordance with Article 15(b) and (c); ~~8(1) (a) (iii)~~;

~~identification of the signatory empowered to act on behalf of the manufacturer of the safety components or his authorized representative established in the Community.~~

☒ (l) the name and function of the person empowered to sign the declaration on behalf of the manufacturer or his authorized representative established in the Union; ☒

↓ new

(m) place and date of signature;

(n) signature.

↓ 95/16/EC (adapted)

B. CONTENT OF THE ~~EC~~ ☒ EU ☒ DECLARATION OF CONFORMITY FOR INSTALLED LIFTS²⁷

The ~~EC~~ ☒ EU ☒ declaration of conformity ☒ for lifts shall be drafted in the same language as the instruction manual referred to in Annex I, Point 6.2, and be either typewritten or printed and ☒ must ☒ shall ☒ contain the following information:

☒ (a) business ☒ name and ☒ full ☒ address of the installer ~~of the lift~~²⁸;

~~(b)~~ description of the lift, details of the type or series, serial number and address where the lift is ~~fitted~~ ☒ installed ☒;

↓ 95/16/EC

~~(c)~~ year of installation of the lift;

~~(d)~~ all relevant provisions to which the lift conforms;

↓ new

(e) a statement that the lift is in conformity with all the relevant Union harmonisation legislation;

²⁷ ~~This declaration must be drafted in the same language as the instruction manual referred to in Annex I, Section 6.2, and be either typewritten or printed.~~

²⁸ ~~Business name and full address.~~

~~(f)~~ where appropriate, ☐ the ☐ ~~reference~~ ☐ reference(s) ☐ to harmonized standards used;

~~(g)~~ where appropriate, ☐ the ☐ name, address and identification number of the notified body which carried out the ~~EE~~ ☐ EU ☐ type-examination ~~of the model of the lift~~ in accordance with Article ~~16(1) (a) 8 (2), (i) and (ii),~~ ☐ and the ☐ ~~= where appropriate,~~ reference of the ~~EE~~ ☐ EU ☐ type-examination certificate, ☐ issued by that notified body; ☐

~~(h)~~ where appropriate, ☐ the ☐ name, address and identification number of the notified body which carried out the ☐ unit ☐ verification ☐ procedure ☐ ~~of the lift~~ in accordance with Article ~~8 (2) (iv),~~ 16(1)(c);

~~(i)~~ where appropriate, ☐ the ☐ name, address and identification number of the notified body which carried out the final inspection of the lift in accordance with the ~~first indent of Article 8 (2), (i), (ii) and (iii),~~ 16(1)(a)(i) and 16(1)(b)(i);

~~(j)~~ where appropriate, name, address, and identification number of the notified body which ~~inspected~~ ⇒ approved ⇐ the quality assurance system ~~implemented~~ ☐ operated ☐ by the installer in accordance with the ~~second and third indents of Article (8) (2) (i), (ii), (iii) and (v)~~ 16(1)(a)(ii); 16(1)(a)(iii); 16(1)(b)(ii); 16(1)(b)(iii) and 16(1)(d);

– ~~identification of the signatory having been empowered to act on behalf of the lift installer.~~

☐ (k) the name and function of the person empowered to sign the declaration on behalf of the installer; ☐

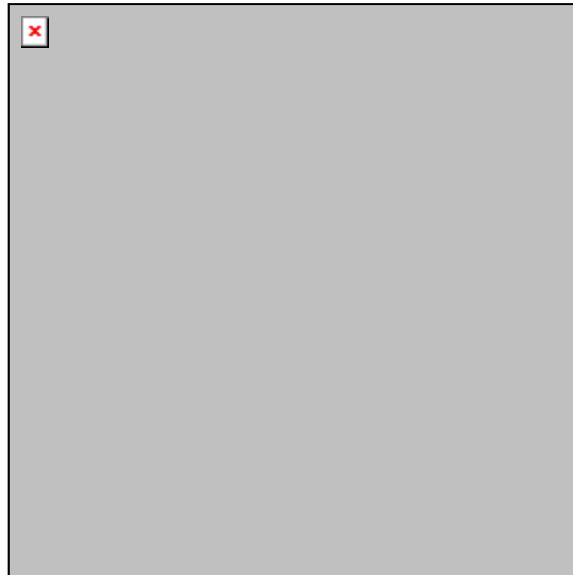
(l) place and date of signature;

(m) signature.

ANNEX III

CE CONFORMITY MARKING

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



~~If the CE marking is reduced or enlarged the proportions given in the above 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 safety components.~~

~~The CE marking shall be followed by the identification number of the notified body that deals with~~

~~the procedures referred to in Article 8 (1) (a) (ii) or (iii),~~

~~the procedures referred to in Article 8 (2).~~

ANNEX IIIIV

**LIST OF SAFETY COMPONENTS ☒ FOR LIFTS ☒ REFERRED TO IN ARTICLE
1 (1) AND ARTICLE 8(1)15**

1. Devices for locking landing doors.

↓ 95/16/EC (adapted)

2. Devices to prevent falls referred to in Section Point 3.2 of Annex I to prevent the car from falling or ~~unchecked upward~~ ☒ uncontrolled ☒ movements.

↓ 95/16/EC

3. Overspeed limitation devices.

↓ 95/16/EC (adapted)

4. (a) Energy-accumulating ~~shock absorbers~~ ☒ buffers ☒ :

(i) ~~either~~ non-linear, ☒ or ☒

(ii) ~~or~~ with damping of the return movement.

(b) Energy-dissipating ~~shock absorbers~~ ☒ buffers ☒ .

↓ 95/16/EC

5. Safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls.

↓ 95/16/EC (adapted)

6. Electric safety devices in the form of safety ~~switches~~ ☒ circuits ☒ containing electronic components.

ANNEX IV

~~EC~~ ☒ EU ☒ TYPE-EXAMINATION ☒ FOR LIFTS AND SAFETY COMPONENTS FOR LIFTS ☒

(module B)

A. ~~EC~~ ☒ EU ☒ TYPE-EXAMINATION OF SAFETY COMPONENTS ☒ FOR LIFTS ☒

1. ~~EC~~ ☒ EU ☒ type-examination is the ⇒ part of a conformity assessment ⇐ procedure whereby a notified body ascertains and certifies that a representative specimen of a safety component ☒ for lifts ☒ will permit the lift to which it is correctly fitted to satisfy the applicable requirements of the Directive.

2. The application for ☒ EU ☒ ~~EC~~ type-examination shall be lodged by the manufacturer, ~~of the safety component~~, or his authorized representative established in the ~~Community~~ ☒ Union, ☒ with a ⇒ single ⇐ notified body of his choice.

The application ~~must~~ ☒ shall ☒ include:

(a) = the name and address of the manufacturer ~~of the safety component~~ and ~~of his authorized representative, if the application is made by the latter~~, ☒ if the application is lodged by the authorized representative, his name and address as well ☒ and the place of manufacture of the safety components ☒ for lifts ☒;

↓ 95/16/EC

(b) = a written declaration that the same application has not been lodged with any other notified body;

↓ 95/16/EC (adapted)

(c) = a technical ~~dossier~~, ☒ file(s); ☒

(d) = a representative specimen of the safety component ☒ for lifts ☒ or details of the place where it can be examined. The notified body may ~~make reasoned request for~~ further specimens ☒ if needed for carrying out the test program ☒;

↓ new

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

↓ 95/16/EC (adapted)

3. The technical ~~dossier~~ ☒ file ☒ ~~must~~ ☒ shall ☒ allow an assessment of the conformity and adequacy of the safety component ☒ for lifts ☒ to enable a lift to which it is correctly fitted to conform ~~with the provisions~~ ☒ to the applicable requirements ☒ of the Directive.

~~In so far as is necessary for the purpose of assessing conformity, The technical dossier~~ ☒ file ☒ should include the following:

~~(a) a general~~ description of the safety component ☒ for lifts ☒, including its area of use (in particular possible limits on speed, load and power) and conditions (in particular explosive environments and exposure to the elements)~~);~~

↓ 95/16/EC

~~(b)~~ design and manufacturing drawings or diagrams~~;~~

↓ new

(c) explanations necessary for the understanding of those drawings and diagrams and the operation of the safety component for lifts;

↓ 95/16/EC (adapted)

☒ (d) a list of the essential health and safety requirements; ~~☒ essential requirement(s) taken into consideration and the means adopted to satisfy it (them) (e.g. a harmonized standard);~~

↓ new

(e) a list of the harmonised standards 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 the Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical file shall specify the parts which have been applied;

↓ 95/16/EC (adapted)

~~(f)~~ results of any tests or calculations performed ☒ by ☒ or ~~subcontracted by~~ ☒ for ☒ the manufacturer~~;~~

↓ new

(g) test reports;

↓ 95/16/EC (adapted)

~~(h)~~ a copy of the ~~assembly~~ instruction ☒ manual ☒ for the safety components ☒ for lifts ☒~~;~~

~~(i) steps taken at the manufacturing stage to ensure that series-produced safety components~~
~~☒ for lifts ☒ conform to the safety component ☒ for lifts ☒ examined.~~

4. The notified body shall:

~~examine the technical dossier to assess how far it can meet the desired aims,~~

☒ (a) examine the technical file to assess the adequacy of the technical design of the safety component for lifts; ☒

↓ new

(b) agree with the applicant on a location where the examinations and tests will be carried out;

↓ 95/16/EC (adapted)

– ~~examine the safety component to check its adequacy in terms of the technical dossier,~~

☒ (c) verify that the representative specimen(s) has(have) been manufactured in conformity with the technical file, and identify the elements which have been designed in accordance with the specifications of harmonised standards, as well as the elements which have been designed without applying the specifications of those standards; ☒

– ~~perform or have performed the appropriate checks and tests necessary to check whether the solutions adopted by the manufacturer of the safety component meet the requirements of the Directive allowing the safety component to carry out its function when correctly fitted on a lift.~~

☒ (d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the specifications of the relevant harmonised standards, these have been applied correctly; ☒

☒ (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer meet the corresponding essential health and safety requirements of the Directive. ☒

↓ new

The notified body shall draw up an evaluation report that records the examinations, verifications and tests carried out and their outcome. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

↓ 95/16/EC (adapted)

~~5. If the representative specimen of the safety component complies with the provisions of the Directive applicable to it, the notified body must issue an EC type examination certificate to the applicant. The certificate must contain the name and address of the manufacturer of the~~

~~safety component, the conclusions of the check, any conditions of validity of the certificate and the particulars necessary to identify the approved type.~~

~~The Commission, the Member States and the other notified bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical dossier and reports of examinations, calculations and tests carried out. If the notified body refuses to issue an EC type-examination certificate to the manufacturer, it must state the detailed grounds for refusal. Provision must be made for an appeal procedure.~~

☒ 5. If the representative specimen(s) of the safety component for lifts complies(comply) with the essential health and safety requirements of the Directive, the notified body shall issue an EU type-examination certificate to the applicant manufacturer. The certificate shall contain the name and address of the manufacturer of the safety component and, where appropriate, of his authorised representative, the conclusions of the type-examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type. ☒

↓ new

The certificate may have one or more annexes attached.

Where the representative specimen(s) does(do) not comply with the applicable essential health and safety requirements of the 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.

The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file and the evaluation report, for a period of 15 years from the date of issue of the certificate.

↓ 95/16/EC (adapted)

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

~~6. The manufacturer of the safety component or his authorized representative established in the Community must inform the notified body of any alterations, even of a minor nature, which he has made or plans to make to the approved safety component, including new extensions or variants not specified in the original technical dossier (see the first indent of Section 3). The notified body must examine the alterations and inform the applicant whether the EC type-examination certificate remains valid²⁹.~~

☒ 7. The manufacturer or his authorized representative shall inform the notified body of any modification to the approved type that may affect the conformity of the safety component for

²⁹ ~~If the notified body deems it necessary, it may either issue an addition to the original EC type-examination certificate or ask for a fresh application to be submitted.~~

lifts with the essential health and safety requirements of the Directive or the conditions of validity of the EU type-examination certificate. ☒

~~7. Each notified body must communicate to the Member States the relevant information concerning:~~

- ~~– EC type-examination certificates issued,~~
- ~~– EC type-examination certificates withdrawn.~~

~~Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn.~~

☒ The notified body shall examine the modification and inform the applicant whether the EU type-examination certificate remains valid or whether further examinations, verifications or tests are needed. As appropriate, the notified body shall issue an addition to the original EU type-examination certificate or ask for a new application for an EU type-examination to be submitted. ☒

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

☒ Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/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. ☒

☒ 9. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and additions thereto. On request, the Commission and the Member States may obtain a copy of the technical file and of the report on the examinations, verifications and tests carried out by the notified body. ☒

☒ 10. EU ☒ ~~8. EC~~ type-examination certificates and the ~~do~~ ☒ documents ☒ and correspondence relating to ☒ EU ☒ ~~EC~~ type-examination procedures ~~must~~ ☒ shall ☒ be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.

↓ 95/16/EC (adapted) ⇒ new

~~9. 11. The manufacturer of the safety component or his authorized representative must~~ ☒ shall ☒ keep with the technical ~~documentation~~ ☒ file ☒ copies of ☒ EU ☒ ~~EC~~ type-examination certificates ☒ , their annexes ☒ and their additions for a period of 10 years after the last safety component ☒ for lifts ☒ has been ☒ placed on the market ☒ ~~manufactured~~.

Where neither the manufacturer ~~of a safety component~~ nor his authorized representative is established in the ~~Community~~ ☒ Union, ☒ the obligation to keep the technical ~~documentation~~ ☒ file ☒ available falls to the person who places the safety component ☒ for lifts ☒ on the ~~Community~~ ☒ Union ☒ market.

↓ 95/16/EC (adapted) ⇒ new

B. ~~EU~~ ~~EC~~ TYPE-EXAMINATION OF LIFTS

1. ~~EU~~ ~~EC~~ type-examination is the ~~⇒ part of a conformity assessment ⇐~~ procedure whereby ~~in which~~ a notified body ascertains and certifies that a model lift or that a lift for which there is no provision for an extension or variant, satisfies the applicable requirements of the Directive.

2. The application for ~~EU~~ ~~EC~~ type-examination ~~must~~ shall be lodged by the installer of the lift with a single notified body of his choice.

The application ~~must~~ shall include:

(a) the name and address of the installer ~~of the lift~~;

↓ 95/16/EC

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

↓ 95/16/EC (adapted)

(c) a technical ~~dossier~~, file(s);

(d) details of the place where the model lift can be examined. The model lift submitted for examination shall include the terminal parts and be capable of serving at least three levels (top, middle and bottom);

↓ new

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the lifts manufacturer, or by another testing laboratory on his behalf and under his responsibility.

↓ 95/16/EC (adapted)

3. The technical ~~dossier~~ file ~~must~~ shall allow an assessment of the conformity of the lift with the ~~provisions~~ essential health and safety requirements of the Directive and an understanding of the design and operation of the lift.

~~In so far as is necessary for the purpose of assessing conformity, The technical dossier~~ file should include the following:

~~(a) a general description of the representative model of the lift. The technical dossier should indicate~~ ☒ indicating ☒ clearly all ☒ the permitted variations of the ☒ possible extensions to the representative model lift under examination (see Article 1 (4)), ☒ referred to in Article 2(3); ☒

↓ 95/16/EC

~~(b) design and manufacturing drawings or diagrams;~~

↓ new

(c) explanations necessary for the understanding of those drawings and diagrams and of the operation of the model lift;

↓ 95/16/EC (adapted)

☒ (d) a list of the ☒ essential ☒ health and safety ☒ requirements taken into consideration and the means adopted to satisfy them (e.g. a harmonised standard);

↓ new

(e) a list of the harmonised standards 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 the Directive where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical file shall specify the parts which have been applied;

↓ 95/16/EC (adapted)

~~(f) a copy of the ☒ EU ☒ EC declarations of conformity of the safety components ☒ for lifts ☒ used in the manufacture of the ☒ model ☒ lift;~~

~~(g) results of any tests or calculations performed or subcontracted by the manufacturer ☒ by or for the installer ☒.~~

↓ new

(h) test reports;

↓ 95/16/EC

~~(i) a copy of the lift instruction manual;~~

↓ 95/16/EC (adapted)

~~(j) steps taken at the installation stage to ensure that the series-produced lift conforms to the provisions ☒ essential health and safety requirements ☒ of the Directive.~~

4. The notified body ~~must~~ ☒ shall: ☒

~~(a) examine the technical dossier~~ ☒ file ☒ to assess ~~how far it can meet the desired aims,~~
☒ the adequacy of the technical design of the model lift; ☒

↓ new

(b) agree with the installer on a location where the examinations and tests will be carried out;

↓ 95/16/EC (adapted)

– ~~examine the representative model of the lift to check that it has been manufactured in accordance with the technical dossier,~~

↓ new

(c) examine the model lift to check that it has been manufactured in accordance with the technical file, and identify the elements which have been designed in accordance with the specifications of the relevant harmonised standards, as well as the elements which have been designed without applying the specifications of those standards;

↓ 95/16/EC (adapted)

– ~~perform or have performed the appropriate checks and tests necessary to check that the solutions adopted by the installer of the lift meet the requirements of the Directive and allow the lift to comply with them.~~

↓ new

(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the installer has chosen to apply the specifications of the relevant harmonised standards, these have been applied correctly;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards have not been applied, the solutions adopted by the installer meet the corresponding essential health and safety requirements of the Directive.

The notified body shall draw up an evaluation report that records the examinations, verifications and tests carried out undertaken and their outcome. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the lifts manufacturer

↓ 95/16/EC (adapted)

⇒ new

5. If the model lift complies with the ~~provisions of the Directive~~ ☒ essential health and safety requirements set out in Annex I ☒ applicable to it, the notified body ~~must~~ ☒ shall ☒ issue an ~~EC~~ ☒ EU ☒ type-examination certificate to the ~~applicant~~ ☒ installer ☒. The certificate ~~must~~ ☒ shall ☒ contain the name and address of the installer, the conclusions of ~~the check,~~ ☒ the EU type-examination ☒, any conditions of validity of the certificate and the particulars necessary to identify the approved ~~type~~ ☒ model lift ☒.

~~If the notified body refuses to issue an EC type-examination certificate to the manufacturer, it must state the detailed grounds for refusal. Provision must be made for an appeal procedure.~~

~~6. The installer of the lift must inform the notified body of any alterations, even of a minor nature, which he has made or plans to make to the approved lift, including new extensions or variants not specified in the original technical dossier (see the first indent of Section 3). The notified body must examine the alterations and inform the applicant whether the EC type-examination certificate remains valid³⁰.~~

~~7. Each notified body must communicate to the Member States the relevant information concerning:~~

- ~~– EC type-examination certificates issued,~~
- ~~– EC type-examination certificates withdrawn.~~

~~Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn.~~

↓ new

The certificate may have one or more annexes attached.

Where the model lift does not comply with the essential health and safety requirements set out in Annex I, the notified body shall refuse to issue an EU type-examination certificate and shall inform the installer accordingly, giving detailed reasons for its refusal.

The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file and the evaluation report for a period of 15 years from the date of issue of the certificate.

6. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the essential health and safety requirements set out in Annex I and shall determine whether such changes require further investigation. If so, the notified body shall inform the installer accordingly.

7. The installer shall inform the notified body of any modifications to the approved type, including variations not specified in the original technical file, that may affect the conformity of the lift with the essential health and safety requirements set out in Annex I or the conditions of validity of the certificate.

The notified body shall examine the modification and inform the installer whether the EU type-examination certificate remains valid or whether further examinations, verifications or tests are needed. As appropriate the notified body shall issue an addition to the original EU type-examination certificate or ask for a new application for an EU type-examination to be submitted.

³⁰

~~If the notified body deems it necessary, it may either issue an addition to the original EC type-examination certificate or ask for a fresh application to be submitted.~~

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

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

↓ 95/16/EC (adapted)

9. The Commission, the Member States and the other notified bodies may ☒, on request, ☒ obtain a copy of the ~~EC~~ ☒ EU type-examination certificates and additions thereto ☒ ~~certificate and, on a reasoned request,~~ ☒ On request, the Commission and the Member States may obtain ☒ a copy of the technical ☒ file ☒ ~~dossier~~ and ☒ of the report on the examinations, verifications and tests carried out by the notified body. ☒ ~~and reports of examinations, calculations and tests carried out~~

~~8.10.~~ ~~EC~~ ☒ EU ☒ type-examination certificates and the ~~dossiers~~ ☒ documents ☒ and correspondence relating to ~~EC~~ ☒ EU ☒ type-examination procedures ~~must~~ ☒ shall ☒ be drawn up in ~~one~~ ☒ an ☒ ~~of the official languages~~ ☒ language ☒ of the Member State where the notified body is established or in a language acceptable to it.

↓ 95/16/EC (adapted)

⇒ new

~~9.11.~~ The installer ~~of the lift must~~ ☒ shall ☒ keep with the technical ~~documentation~~ ☒ file ☒ copies of ~~EC~~ ☒ EU ☒ type-examination certificates ⇒, their annexes ⇐ and ~~their~~ additions for a period of at least 10 years after the last lift has been ~~manufactured~~ ☒ placed on the market ☒ in conformity with the ~~representative~~ model of the lift.

ANNEX VVI

FINAL INSPECTION ☒ FOR LIFTS ☒

~~1. Final inspection is the procedure whereby the installer of the lift who fulfils the obligations of Section 2 ensures and declares that the lift which is being placed on the market satisfies the requirements of the Directive. The installer of the lift shall affix the CE marking in the car of each lift and draw up an EC declaration of conformity.~~

☒ 1. Final inspection is the part of a conformity assessment procedure whereby a notified body ascertains and certifies that an installed lift subject to an EU type-examination certificate or designed and manufactured according to an approved full quality assurance system satisfies the essential health and safety requirements set out in Annex I. ☒

~~2. The installer of the lift shall take all steps necessary to ensure that the lift being placed on the market conforms with the model lift described in the EC type-examination certificate and the essential health and safety requirements applicable to it.~~

☒ 2. OBLIGATIONS OF THE INSTALLER ☒

☒ 2.1. The installer shall take all measures necessary to ensure that the lift being installed complies with the essential health and safety requirements set out in Annex I and with any of the following: ☒

☒ (a) an approved type described in an EU type-examination certificate; ☒

☒ (b) a lift designed and manufactured in accordance with a full quality assurance system pursuant to Annex XI and the EU design examination certificate if the design is not wholly in accordance with the harmonized standards. ☒

☒ 2.2. The installer shall draw up an EU declaration of conformity and affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of this Directive. ☒

☒ 3. FINAL INSPECTION. ☒

~~5. The notified body must receive the following documents:~~

☒ 3.1 The installer shall provide to the notified body the following documents: ☒

~~(a) the plan of the complete lift;~~

~~(b) the plans and diagrams necessary for final inspection, in particular control circuit diagrams;~~

~~(c)~~ a copy of the instruction ~~manual~~ ☒ for use ☒ referred to in Annex I, ~~Section~~ Point 6.2.

The notified body may not require detailed plans or precise information not necessary for verifying the conformity of the ☒ installed ☒ lift ~~about to be placed on the market with the model lift described in the EC type-examination declaration.~~

☒ 3.2 A notified body chosen by the installer shall carry out the final inspection of the installed lift about to be placed on the market in order to check the conformity of the lift with the applicable essential health and safety requirements of this Directive. ☒

☒ The appropriate examinations and tests set out in the relevant harmonised standard(s) referred to in Article 14 shall be carried out in order to ensure the conformity of the lift with the applicable essential health and safety requirements of this Directive. In the absence of such harmonised standards, the notified body concerned shall determine the appropriate equivalent tests to be carried out. ☒

~~4. A notified body chosen by the installer of the lift shall carry out or have carried out the final inspection of the lift about to be placed on the market. The appropriate tests and checks defined by the applicable standard(s) referred to in Article 5, or equivalent tests, must be carried out in order to ensure conformity of the lift with the relevant requirements of the Directive.~~

~~These checks and tests shall cover in particular:~~

~~(a) examination of the documentation to check that the lift conforms with the representative model of the lift approved in accordance with Annex V.B;~~

☒ 3.3. The examinations shall include at least any of the following: ☒

☒ (a) examination of the documents referred to in point 3.1 to check that the installed lift conforms with the model lift subject to an EU type-examination certificate pursuant to Annex IV B; ☒

↓ new

(b) examination of the documents referred in point 3.1 to check that the installed lift conforms with the lift designed and manufactured in accordance with an approved full quality assurance system pursuant to Annex XI and if the design is not wholly in accordance with the harmonized standards, with the EU design examination certificate.

↓ 95/16/EC (adapted)

☒ 3.4. The tests shall include at least any of the following: ☒

↓ 95/16/EC

~~(a)~~ operation of the lift both empty and at maximum load to ensure correct installation and operation of the safety devices (end stops, locking devices, etc.);

~~(b)~~ operation of the lift at both maximum load and empty to ensure the correct functioning of the safety devices in the event of loss of power;

↓ 95/16/EC (adapted)

~~(c)~~ static test with a load equal to 1,25 times the ~~nominal~~ ☒ rated ☒ load.

The ~~nominal~~ ☒ rated ☒ load shall be that referred to in Annex I, ~~Section~~ Point 5.

↓ 95/16/EC

After these tests, the notified body shall check that no distortion or deterioration which could impair the use of the lift has occurred.

↓ 95/16/EC (adapted)

☒ 4. If the installed lift satisfies the essential health and safety requirements set out in Annex I, the notified body shall affix or have affixed its identification number adjacent to the CE marking in accordance with Articles 18 and 19 and shall draw up a final inspection certificate which mentions the examinations and tests carried out. ☒

~~6. If the lift satisfies the provisions of the Directive, the notified body shall affix or have affixed its identification number adjacent to the CE marking in accordance with Annex III and shall draw up a final inspection certificate which mentions the checks and tests carried out.~~

↓ 95/16/EC

The notified body shall fill in the corresponding pages in the logbook referred to in Annex I, Section Point 6.2.

↓ 95/16/EC (adapted)

If the notified body refuses to issue the final inspection certificate, it ~~must~~ ☒ shall ☒ state the detailed reasons for refusal ~~recommend means whereby acceptance may be obtained.~~ ☒ and indicate the necessary corrective measures to be taken. ☒ Where the installer again applies for final inspection, he ~~must~~ ☒ shall ☒ apply to the same notified body.

~~7. The final inspection certificate, dossiers and correspondence relating to the acceptance procedures shall be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.~~

☒ 5. The final inspection certificate, documentation and correspondence relating to the final inspection acceptance procedures shall be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it. ☒

~~6. 3-~~ The installer ~~of the lift~~ shall keep a copy of the ~~EC~~ ☒ EU ☒ declaration of conformity and the final inspection certificate ~~referred to in Section 6~~ for 10 years after ☒ the placing ☒ ~~from the date when the lift was placed on the market~~ ☒ of the lift ☒.

↓ new

7. The Commission and the Member states may obtain a copy of the final inspection certificate on request.

ANNEX VII

~~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 verification operations may not be the designer, builder, supplier or manufacturer of safety components or installer of the lifts which they inspect, nor the authorized representative of any of these parties. Similarly, the body, its director and the staff responsible for supervising the quality assurance systems referred to in Article 8 of the Directive may not be the designer, builder, supplier or manufacturer of safety components or installer of the lifts which they inspect, nor the authorized representative of any of these parties. They may not become involved either directly or as authorized representatives in the design, construction, marketing or maintenance of the safety components or in the installation of lifts. This does not preclude the possibility of exchanges of technical information between the manufacturer of the safety components or the installer of the lift and the body.~~
- ~~2. The body and its staff must carry out the inspection or supervision operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of inspection or supervision.~~
- ~~3. The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with inspection or supervision; it must also have access to the equipment required for special verification.~~
- ~~4. The staff responsible for inspection must have:~~

~~sound technical and professional training, satisfactory knowledge of the requirements for the tests 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 the inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.~~
- ~~6. The body must 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 must 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 ~~VI~~ ~~VIII~~

PRODUCT QUALITY ASSURANCE ~~☒~~ FOR SAFETY COMPONENTS FOR LIFTS ~~☒~~

(module E)

~~Product quality assurance is the procedure whereby the manufacturer of the safety component who satisfies Section 2 ensures and declares that the safety components are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them and ensures and declares that the safety component will enable a lift to which it is correctly fitted to satisfy the provisions of the Directive.~~

~~The manufacturer of the safety component or his authorized representative established in the Community must affix the CE marking to each safety component and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.~~

~~2. The manufacturer must apply an approved quality assurance system for final inspection of the safety component and testing as specified in Section 3, and must be subject to surveillance as specified in Section 4.~~

☒ 1. Product quality assurance for safety components for lifts is the part of the conformity assessment procedure whereby a notified body assesses the product quality assurance system of a manufacturer in order to ensure that the safety components for lifts are manufactured and monitored in conformity with the type described in the EU type-examination certificate and satisfy the essential health and safety requirements set out in Annex I and will enable a lift to which they are correctly fitted to satisfy those requirements. ☒

☒ 2. OBLIGATIONS OF THE MANUFACTURER ☒

☒ 2.1. The manufacturer shall apply an approved product quality assurance system for final inspection and testing of the safety component for lifts as specified in Point 3, and shall be subject to surveillance as specified in Point 4. ☒

☒ 2.2. The manufacturer or his authorized representative established in the Union shall affix the CE marking to each safety component for lifts and draw up an EU declaration of conformity. ☒

3. ☒ PRODUCT ~~☒~~ ~~Q~~ QUALITY ASSURANCE SYSTEM

3.1. The manufacturer ~~of the safety components~~ ☒ or his authorised representative ☒ ~~must~~ ☒ shall ☒ lodge an application for assessment of ~~his~~ ☒ the product ☒ quality assurance system for the safety components ~~concerned~~ ☒ for lifts ☒ with a ~~single~~ ☒ notified body of his choice.

The application must include:

↓ new

(a) the name and address of the manufacturer and, if the application is lodged by his authorised representative, his name and address as well;

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

(c) the premises where final inspection and testing of the safety components for lifts are carried out;

↓ 95/16/EC (adapted)

~~(d)~~ all relevant information ~~for~~ ☒ on ☒ the safety components ~~envisaged~~ ☒ for lifts to be manufactured ☒.

~~(e)~~ the documentation on the ☒ product ☒ quality assurance system;

~~(f)~~ the technical ~~documentation~~ ☒ file(s) ☒ of the ~~approved~~ safety components ☒ for lifts to be manufactured ☒ and a copy of the ~~EC~~ ☒ EU ☒ type-examination ~~certificates~~ ☒ certificate(s). ☒

3.2. Under the ☒ product ☒ quality assurance system, each safety component ☒ for lifts shall ☒ ~~must~~ be ~~examined~~ ☒ inspected ☒ and appropriate tests as set out in the relevant standards referred to in Article 5~~14~~ or equivalent tests ☒ shall ☒ ~~must~~ be carried out in order to ensure its conformity to the relevant ~~requirements of the Directive~~ ☒ essential health and safety requirements set out in Annex I. ☒

All the elements, requirements and provisions adopted by the manufacturer ~~of the safety components must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality assurance system documentation ~~must~~ ☒ shall ☒ ensure a common understanding of the quality programmes, plans, manuals and records.

↓ 95/16/EC

It must contain in particular an adequate description of:

(a) the quality objectives;

↓ 95/16/EC (adapted)

(b) the organizational structure, responsibilities and powers of the management with regard to quality of the safety component ☒ for lifts ☒.

(c) the ~~examinations~~ ☒ inspections ☒ and tests that will be carried out after manufacture;

(d) the means to verify the effective operation of the ☒ product ☒ quality assurance system;

↓ 95/16/EC

- (e) quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
-

↓ 95/16/EC (adapted)

3.3. The notified body must assess the ☒ product ☒ quality assurance system to determine whether it satisfies the requirements referred to in Section Point 3.2. It ☒ shall ☒ ~~must~~ presume conformity with these requirements in respect of ☒ product ☒ quality assurance systems that implement the relevant harmonized standard³¹.

The auditing team must have at least one member with experience of assessment in the lift technology concerned ☒ and knowledge of the essential health and safety requirements set out in Annex I. ☒

The assessment procedure ~~must~~ ☒ shall ☒ include a visit to the premises ~~of the safety component manufacturer~~ ☒ where final inspection and testing of safety components for lifts are carried out ☒.

↓ 95/16/EC (adapted)

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

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

↓ new

Under the responsibility of the notified body, the manufacturer shall affix the identification number of the notified body adjacent to the CE marking in accordance with Articles 18 and 19 to the safety components for lifts during the manufacturing process.

↓ 95/16/EC (adapted)

3.4. The manufacturer ~~of the safety components must~~ ☒ shall ☒ undertake to discharge the obligations arising from the ☒ product ☒ quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The manufacturer ~~of the safety components~~ or his authorized representative established ~~in the Community~~ ☒ Union ☒ ~~must~~ ☒ shall ☒ keep the notified body which has approved the ☒ product ☒ quality assurance system informed of any intended updating of the ~~quality assurance~~ system.

³¹ ~~This harmonized standard will be EN 29003, supplemented where necessary to take account of the specific features of safety components.~~

The notified body ~~must~~ ☒ shall ☒ assess the modifications proposed and decide whether the modified ☒ product ☒ quality assurance system still satisfies the requirements referred to in Section Point 3.2 or whether a reassessment is required.

It ~~must~~ ☒ shall ☒ notify its decision to the manufacturer. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the examination and the reasoned assessment ☒ report ☒ decision.

4. SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

4.1. The purpose of surveillance is to make sure that the manufacturer ~~of the safety component~~ duly fulfils the obligations arising out of the approved ☒ product ☒ quality assurance system.

4.2. The manufacturer ~~must~~ ☒ shall ☒ allow the notified body access for inspection purposes to the ☒ premises where final ☒ inspection, testing and storage ~~locations~~ ☒ are carried out ☒ and provide it with all necessary information, in particular:

(a) ~~the~~ ☒ product ☒ quality assurance system documentation;

(b) ~~the technical~~ ☒ file(s); ☒ ~~documentation~~;

↓ 95/16/EC

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

↓ 95/16/EC (adapted)
⇒ new

4.3. The notified body ~~must~~ ☒ shall ☒ periodically carry out audits to ensure that the manufacturer ~~of the safety components~~ maintains and applies the ☒ product ☒ quality assurance system and ~~must~~ ☒ shall ☒ provide an audit report to the manufacturer ~~of the safety components~~, ⇒ and, where appropriate, to his authorised representative. ⇐

4.4. Additionally, the notified body may pay unexpected visits to the ~~manufacturer of the safety component~~ ☒ premises where final inspection and testing of safety components for lifts are carried out ☒.

At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the ☒ product ☒ quality assurance system where necessary; ~~it must~~ ☒ It shall ☒ provide the manufacturer ~~of the safety components~~ ⇒ and, where appropriate, to his authorised representative, ⇐ with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer ~~must~~ ☒ shall ☒ for a period ending 10 years after the last safety component ☒ for lifts ☒ has been ~~manufactured~~ ⇒ placed on the market ⇐, keep at the disposal of the national authorities:

↓ 95/16/EC (adapted)

~~(a) the documentation~~ ☒ technical file(s) ☒ referred to in ~~the third indent of the second paragraph of Section Point 3.1(f);~~

↓ new

(b) the documentation referred to in Point 3.1(e);

↓ 95/16/EC (adapted)

~~(c) the updating referred to in the second paragraph of Section Point 3.4;~~

~~(d) the decisions and reports from the notified body which are referred to in the final paragraph of Section Point 3.4 and in Sections Points 4.3 and 4.4.~~

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

↓ new

6. Each notified body shall inform its notifying authorities of product quality assurance system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of approval decisions, issued, refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of product quality assurance system approval decision(s) which it has refused, suspended or withdrawn and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of product quality assurance system approval decision(s) issued.

7. The documents and correspondence relating to the product quality assurance system shall be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.

ANNEX VII

FULL QUALITY ASSURANCE ☒ FOR SAFETY COMPONENTS FOR LIFTS ☒

(module H)

~~1. Full quality assurance is the procedure whereby the manufacturer of the safety component who satisfies the obligations of Section 2 ensures and declares that the safety components satisfy the requirements of the Directive that apply to them and that the safety component will enable a lift to which it is correctly fitted to satisfy the requirements of the Directive.~~

~~The manufacturer or his authorized representative established in the Community must affix the CE marking to each safety component and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the surveillance as specified in Section 4.~~

~~2. The manufacturer must operate an approved quality assurance system for design, manufacture and final inspection of the safety components and testing as specified in Section 3 and must be subject to surveillance as specified in Section 4.~~

☒ 1. Full quality assurance for safety components for lifts is the conformity assessment procedure whereby a notified body assesses the full quality assurance system of a manufacturer to ensure that the safety components for lifts are designed, manufactured, inspected and tested in order to satisfy the essential health and safety requirements set out in Annex I and to enable a lift to which they are correctly fitted to satisfy those requirements. ☒

☒ 2.1. The manufacturer shall operate an approved full quality assurance system for the design, manufacture, final inspection and testing of safety components for lifts as specified in Point 3 and shall be subject to surveillance as specified in Point 4. ☒

☒ 2.2. The manufacturer or his authorized representative established in the Union shall affix the CE marking to each safety component for lifts and draw up an EU declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for the surveillance as specified in Point 4. ☒

3. ☒ FULL ☒ QUALITY ASSURANCE SYSTEM

3.1. The manufacturer ~~must~~ ☒ or his authorised representative shall ☒ lodge an application for assessment of his ☒ full ☒ quality assurance system with a ☒ single ☒ notified body ☒ of his choice ☒. The application ~~must~~ ☒ shall ☒ include:

(a) the name and address of the manufacturer and, if the application is lodged by his authorised representative, his name and address as well;

(b) the premises where the safety components for lifts are designed, manufactured, inspected and tested;

↓ 95/16/EC (adapted)

~~(c)~~ all relevant information on safety components ☒ for lifts to be manufactured ☒;

↓ new

(d) a technical file according to Annex IVA Point 3 for one model of each category of safety component for lifts according to Annex III to be manufactured;

↓ 95/16/EC (adapted)

~~(e)~~ the documentation on the ☒ full ☒ quality assurance system;

↓ new

(f) a written declaration that the same application has not been lodged with any other notified body.

↓ 95/16/EC (adapted)

~~3.2. The quality assurance system must ensure compliance of the safety components with the requirements of the Directive that apply to them and enable lifts to which they have been correctly fitted to satisfy those requirements.~~

3.2. All the elements, requirements and provisions adopted by the manufacturer ~~must~~ ☒ shall ☒ be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This ☒ full ☒ quality assurance system documentation ~~must~~ ☒ shall ☒ ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It ~~must~~ ☒ shall ☒ contain in particular an adequate description of:

~~(a)~~ the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and quality of the safety components ☒ for lifts ☒;

~~(b)~~ the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 514 ☒ are not ☒ will not be applied ☒ or not applied ☒ in full, the means that will be used to ensure that the essential ☒ health and safety ☒ requirements ~~of the Directive that apply to the safety components~~ ☒ set out in Annex I ☒ will be met;

~~(c)~~ the design control and design verification techniques, processes and systematic actions that will be used when designing the safety components ☒ for lifts ☒;

↓ 95/16/EC

~~(d)~~ the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

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

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

~~(g)~~ the means of monitoring the achievement of the required design and product quality and the effective operation of the quality assurance system.

↓ 95/16/EC (adapted)
⇒ new

3.3. The notified body ~~must~~ shall assess the full quality assurance system to determine whether it satisfies the requirements referred to in ~~Section~~ Point 3.2. It ~~must~~ shall presume compliance with these requirements in respect of quality assurance systems that implement the relevant harmonized standard³².

The auditing team ~~must~~ shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Annex I. The assessment procedure must include a visit to the manufacturer's premises.

↓ new

The auditing team shall review the technical file(s) referred to in Point 3.1 to verify the manufacturer's ability to identify the essential health and safety requirements set out in Annex I and to carry out the necessary examinations with a view to ensuring compliance of the safety components for lifts with those requirements.

↓ 95/16/EC (adapted)
⇒ new

The decision ~~must~~ shall be notified to the manufacturer ~~of the safety components~~ and, where appropriate, to his authorised representative. The notification ~~must~~ shall contain the conclusions of the assessment ~~examination~~ and the reasoned ~~assessment~~ approval decision.

³² This harmonized standard will be EN 29001, supplemented where necessary to take account of the specific features of safety components.

↓ new

Under the responsibility of the notified body, the manufacturer shall affix the identification number of the notified body adjacent to the CE marking in accordance with Articles 18 and 19 to the safety components for lifts during the manufacturing process.

↓ 95/16/EC (adapted)

3.4. The manufacturer ~~of the safety components must undertake~~ ☒ shall undertake ☒ to discharge the obligations arising from the ☒ full ☒ quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The manufacturer or his authorized representative ~~established in the Community must~~ ☒ shall ☒ keep the notified body which has approved the ☒ full ☒ quality assurance system informed of any intended updating of the ~~quality assurance~~ system.

The notified body ~~must~~ ☒ shall ☒ assess the modifications proposed and decide whether the modified ☒ full ☒ quality assurance system will still satisfy the requirements referred to in Section Point 3.2 or whether a reassessment is required.

It ~~must~~ ☒ shall ☒ notify its decision to the manufacturer. The notification ~~must~~ ☒ shall ☒ contain the conclusions of the ☒ assessment ☒ ~~examination~~ and the reasoned ~~assessment~~ ☒ approval ☒ decision.

4. SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

4.1. The purpose of surveillance is to make sure that the manufacturer ~~of the safety components~~ duly fulfils the obligations arising out of the approved ☒ full ☒ quality assurance system.

4.2. The manufacturer ~~of the safety components must~~ ☒ shall ☒ allow the notified body access for inspection purposes to the design, manufacture, inspection and testing, and storage locations, and ~~must~~ ☒ shall ☒ provide it with all necessary information, in particular:

(a) ~~the~~ ☒ full ☒ quality assurance system documentation;

(b) ~~the~~ the quality records provided for in the design part of the ☒ full ☒ quality ☒ assurance ☒ system, such as results of analyses, calculations, tests, etc.;

↓ new

(c) the technical files for the safety components for lifts manufactured;

↓ 95/16/EC (adapted)

⇒ new

(d) ~~the~~ the quality records provided for in the manufacturing part of the ☒ full ☒ quality assurance system, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body ~~must~~ ☒ shall ☒ periodically carry out audits to make sure that the manufacturer ~~of the safety components~~ maintains and applies the ☒ the approved full ☒ quality assurance system and ~~must~~ ☒ shall ☒ provide an audit report to the manufacturer ~~of the safety components~~.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer ~~of the safety components~~. At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the ☒ full ☒ quality assurance system ~~where necessary~~; ~~it must~~ ☒ It shall ☒ provide the manufacturer ~~of the safety components~~ with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer ~~of the safety components~~ or his authorized representative ~~must~~ ☒ shall ☒ for a period of 10 years after the last safety component ☒ for lifts ☒ has been ~~manufactured~~ ⇒ placed on the market, ⇐ keep at the disposal of the national authorities:

↓ 95/16/EC (adapted)

~~(a)~~ the documentation referred to in ~~the second indent of the second paragraph of Section Point 3.1(e)~~;

↓ new

(b) the technical file referred to in Point 3.1(d);

↓ 95/16/EC

~~(c)~~ the updating referred to in the second paragraph of ~~Section Point 3.4~~;

↓ 95/16/EC (adapted)

~~(d)~~ the decisions and reports from the notified body ~~which are~~ referred to in the final paragraph of ~~Section Point 3.4~~ and in ~~Sections Points 4.3 and 4.4~~.

Where, neither the manufacturer of the safety components ☒ for lifts ☒ nor his authorized representative is established in the ☒ Union ☒ ~~Community~~, the obligation to keep the technical documentation available falls to the person who places the safety component ☒ for lifts ☒ on the ☒ Union ☒ ~~Community~~ market.

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

↓ new

6. Each notified body shall inform its notifying authorities of full quality assurance system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of approval decisions issued, refused, suspended or otherwise restricted.

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

On request, the notified body shall provide the Commission and the Member States with a copy of full quality system approval decision(s) issued.

The notified body shall keep a copy of the approval decision(s) issued, its annexes and additions, as well as the technical file for a period of 15 years from the date of their issue.

↓ 95/16/EC (adapted)

7. The ~~dossiers~~ ☒ documents ☒ and correspondence relating to the full quality assurance procedures ~~must~~ ☒ shall ☒ be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.

↓ 95/16/EC (adapted)
⇒ new

ANNEX VIII X

UNIT VERIFICATION ☒ FOR LIFTS ☒

(module G)

~~1. Unit verification is the procedure whereby the installer of a lift ensures and declares that a lift which is being placed on the market and which has obtained the certificate of conformity referred to in Section 4 complies with the requirements of the Directive. The installer of the lift must affix the CE marking in the car of the lift and draw up an EC declaration of conformity.~~

☒ 1. Unit verification is the conformity assessment procedure whereby a notified body assesses whether an installed lift complies with the essential health and safety requirements set out in Annex I. ☒

☒ 2. OBLIGATIONS OF THE INSTALLER ☒

☒ 2.1. The installer shall affix the CE marking in the car of the lift and draw up an EU declaration of conformity. ☒

~~2.2.~~ The ~~lift~~ installer shall apply to a ⇒ single ⇐ notified body of his choice for unit verification.

↓ 95/16/EC

The application shall contain:

↓ 95/16/EC (adapted)

~~(a)~~ the name and address of the installer, ~~of the lift,~~

~~(b)~~ and the location where the lift is installed;

↓ 95/16/EC

~~(c)~~ a written declaration to the effect that a similar application has not been lodged with another notified body;

↓ 95/16/EC (adapted)

~~(d)~~ a technical ☒ file ☒ ~~dossier.~~

~~3. The purpose of the technical dossier is to enable the conformity of the lift with the requirements of the Directive to be assessed and the design, installation and operation of the~~

~~lift to be understood.~~ ☒ The technical file shall allow an assessment of the conformity of the lift with the essential health and safety requirements set out in Annex I ☒.

↓ 95/16/EC (adapted)

~~So far as relevant for conformity assessment,~~ The technical ☒ file ☒ ~~dossier~~ shall contain ☒ at least ☒ the following ☒ elements ☒ :

~~(a) a general~~ description of the lift;

~~(b) design and manufacturing drawings and diagrams;~~

– ~~the essential requirements in question and the solution adopted to meet them (e.g. harmonized standard);~~

↓ new

(c) explanations necessary for the understanding of those drawings and diagrams and of the operation of the lift;

(d) a list of the harmonised standards 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 set out in Annex I where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical file shall specify the parts which have been applied;

↓ 95/16/EC (adapted)

~~(e) a copy of the~~ ☒ EU ☒ ~~EC~~ type-examination certificates of the safety components ☒ for lifts ☒ used ☒ in the lift ☒;

~~(f) results of any tests or calculations~~ ☒ performed by or for the installer; ~~☒ carried out or subcontracted by the installer of the lift;~~

↓ new

(g) test reports;

↓ 95/16/EC (adapted)

~~(h) a copy of the instructions for use of the lift~~ ☒ referred to in point 6.2 of Annex I ☒ .

4. The notified body ~~must~~ ☒ shall ☒ examine the technical ~~dossier~~ ☒ file ☒ and the lift and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article ~~514~~ of the Directive, or equivalent tests, to ensure its conformity with the ~~relevant~~ ☒ essential health and safety ☒ requirements ~~of this Directive~~ ☒ set out in Annex I. The tests shall include at least the tests referred to in Point 3.4 (e) of Annex V. ☒

~~If the lift meets the requirements of this Directive, the notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Annex III and shall draw up a certificate of conformity relating to the tests carried out.~~

☒ If the lift meets the essential health and safety requirements set out in Annex I the notified body shall draw up a certificate of conformity relating to the tests carried out. The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 21. ☒

The notified body shall fill in the corresponding pages of the logbook referred to in Section Point 6.2 of Annex I.

If the notified body refuses to issue the certificate of conformity, it ~~must~~ ☒ shall ☒ state in detail its reasons for ~~refusing~~ ☒ refusal ☒ and indicate ☒ the necessary corrective measures to be taken ☒ ~~how conformity can be achieved~~. When the installer ~~of the lift~~ reapplies for ☒ unit ☒ verification he ~~must~~ ☒ shall ☒ apply to the same notified body.

↓ new

On request, the notified body shall provide the Commission and the Member states with a copy of the certificate of conformity.

↓ 95/16/EC (adapted)

5. The certificate of conformity and the ~~dossiers~~ ☒ documents ☒ and correspondence relating to unit verification procedures ~~must~~ ☒ shall ☒ be drawn up in an official language of the Member State where the notified body is established or in a language acceptable to it.

6. The installer ~~of the lift~~ shall keep with the technical ☒ file ☒ ~~dossier~~ a copy of the certificate of conformity for a period of 10 years from the date on which the lift is placed on the market.

ANNEX IX ~~XI~~

CONFORMITY TO TYPE WITH RANDOM CHECKING

☒ FOR SAFETY COMPONENTS FOR LIFTS ☒

(module ☒ F ☒ €)

~~1. Conformity to type is the procedure whereby the manufacturer of the safety components or his authorized representative established in the Community ensures and declares that the safety components are in conformity with the type as described in the EC type certificate and satisfy the requirements of the Directive that apply to them and enable any lift to which they are correctly fitted to satisfy the essential health and safety requirements of the Directive.~~

☒ 1. Conformity to type with random checking is the part of the conformity assessment procedure whereby a notified body carries out checks on safety components for lifts to ensure that they are in conformity with the type as described in the EU type certificate and satisfy the applicable essential health and safety requirements of the Directive and enable a lift to which they are correctly fitted to satisfy those requirements. ☒

~~The manufacturer of the safety components, or his authorized representative established in the Community, must affix the CE marking to each safety component and draw up an EC declaration of conformity.~~

~~2. The manufacturer of the safety components must take all measures necessary to ensure that the manufacturing process assures conformity of the manufactured safety components with the type as described in the EC type examination certificate and with the requirements of the Directive that apply to them.~~

☒ 2. OBLIGATIONS OF THE MANUFACTURER ☒

☒ 2.1. The manufacturer shall take all measures necessary to ensure that the manufacturing process ensures conformity of the manufactured safety components for lifts with the type as described in the EU type examination certificate and with the essential health and safety requirements set out in Annex I. ☒

☒ 2.2. The manufacturer or his authorized representative established in the Union must affix the CE marking to each safety component for lifts and draw up an EU declaration of conformity. ☒

☒ 3. The manufacturer or his authorised representative shall lodge an application for random checking with a single notified body of his choice.

The application shall include: ☒

↓ new

(a) the name and address of the manufacturer and, if the application is lodged by his authorised representative, his name and address as well;

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

(c) all relevant information on the safety components for lifts manufactured;

(d) the premises where the sample of the safety components for lifts can be taken.

↓ 95/16/EC (adapted)

4. ~~A~~ ☒ The ☒ notified body ~~chosen by the manufacturer must~~ ☒ shall ☒ carry out or have carried out checks on safety components ☒ for lifts ☒ at random intervals. An adequate sample of the finished safety components, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 514, or equivalent tests, ~~must~~ ☒ shall ☒ be carried out to check the conformity of production to the ~~relevant requirements of the Directive~~ ☒ essential health and safety requirements set out in Annex I ☒. In ~~those~~ cases where one or more of the safety components ☒ for lifts ☒ checked do not conform, the notified body ~~must~~ ☒ shall ☒ take appropriate measures.

The points to be taken into account when checking the safety components ☒ for lifts ☒ will be defined by joint agreement between all the notified bodies responsible for this procedure, taking into consideration the essential characteristics of the safety components ☒ for lifts ☒ referred to in Annex III ~~IV~~.

☒ On request, the notified body shall provide the Commission and the Member states with a copy of the certificate of conformity. ☒

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

☒ 6. Under the responsibility of the notified body, the manufacturer shall affix the identification number of the notified body adjacent to the CE marking in accordance with Articles 18 and 19 to the safety components for lifts during the manufacturing process. ☒

~~3. The manufacturer of the safety components or his authorized representative must keep a copy of the EC declaration of conformity for a period of 10 years after the last safety component has been manufactured.~~

☒ The manufacturer or his authorized representative must keep a copy of the EU declaration of conformity for a period of 10 years after the last safety component has been manufactured. ☒

Where neither the manufacturer ~~of the safety components~~ nor his authorized representative are established in the ~~Community~~ ☒ Union ☒, the obligation to keep the technical documentation available falls to the person who places the safety components ☒ for lifts ☒ on the ☒ Union ☒ market.

5.7. The ~~the~~ documents ~~the dossiers~~ and correspondence relating to the random checking procedures referred to in Section Point 4 ~~the~~ shall ~~the must~~ be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.

ANNEX X~~XI~~

PRODUCT QUALITY ASSURANCE FOR LIFTS

(module E)

~~1. Product quality assurance is the procedure whereby the installer of a lift who satisfies Section 2 ensures and declares that the lifts installed are in conformity with the type as described in the EC type examination certificate and satisfy the requirements of the Directive that apply to them.~~

~~The installer of a lift must affix the CE marking to each lift and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.~~

~~2. The installer of a lift must apply an approved quality assurance system for final inspection of the lift and testing as specified in Section 3, and must be subject to surveillance as specified in Section 4.~~

⊗ 1. Product quality assurance is the part of the conformity assessment procedure whereby a notified body assesses the product quality assurance system of an installer to ensure that the lifts installed are in conformity with the type as described in the EU type-examination certificate or with a lift designed and manufactured by an installer who operates a full quality assurance system in accordance with Annex XI, and satisfy the essential health and safety requirements set out in Annex I. ⊗

⊗ 2. OBLIGATIONS OF THE INSTALLER ⊗

⊗ 2.1. The installer shall apply an approved product quality assurance system for final inspection and testing of the lift as specified in Point 3, and shall be subject to surveillance as specified in Point 4. ⊗

⊗ 2.2. The installer shall affix the CE marking to each lift and draw up an EU declaration of conformity. ⊗

3. ⊗ PRODUCT ⊗ QUALITY ASSURANCE SYSTEM

3.1. The installer ~~of a lift~~ ⊗ shall ⊗ ~~must~~ lodge an application for assessment of his ⊗ product ⊗ quality assurance system for the lifts concerned with a ⇒ single ⇐ notified body of his choice.

The application ⊗ shall ⊗ ~~must~~ include:

(a) the name and address of the installer;

↓ 95/16/EC (adapted)

~~(b)~~ all relevant information ☒ on the lifts to be installed ~~☒ for the lifts envisaged;~~

~~(c)~~ the documentation on the ☒ product ☒ quality assurance system;

~~(d)~~ the technical ~~documentation~~ ☒ file ☒ ~~on the approved lifts and a copy of the EC type-examination certificates,~~ ☒ of the lifts to be installed; ☒

↓ new

(e) a written declaration that the same application has not been lodged with any other notified body.

↓ 95/16/EC (adapted)

3.2. Under the ☒ product ☒ quality assurance system, each lift ☒ shall ☒ ~~must~~ be examined and appropriate tests as set out in the relevant standards referred to in Article 514 or equivalent tests ☒ shall ☒ ~~must~~ be carried out in order to ensure its conformity ~~to the relevant requirements of the Directive~~ ☒ to the essential health and safety requirements set out in Annex I ☒ .

All the elements, requirements and provisions adopted by the installer ~~of a lift~~ ☒ shall ☒ ~~must~~ be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This ☒ product ☒ quality assurance system documentation ☒ shall ☒ ~~must~~ ensure a common understanding of the quality programmes, plans, manuals and quality records.

It ☒ shall ☒ ~~must~~ contain in particular an adequate description of:

~~(a)~~ the quality objectives;

~~(b)~~ the organizational structure, responsibilities and powers of the management with regard to lift quality;

~~(c)~~ the examinations and tests that will be carried out before placing on the market, including at ~~the very~~ least the tests laid down in Point 3.3.(b) of Annex VI, 4(b);

~~(d)~~ the means to verify the effective operation of the ☒ product ☒ quality assurance system;

↓ 95/16/EC

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

↓ 95/16/EC (adapted) ⇒ new

3.3. The notified body ~~must~~ ☒ shall ☒ ~~must~~ assess the ☒ product ☒ quality assurance system to determine whether it satisfies the requirements referred to in Section Point 3.2. It ~~must~~ ☒ shall ☒ presume conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard³³.

The auditing team ~~must~~ ☒ shall ☒ have at least one member with experience of assessment in the lift technology concerned ⇒ and knowledge of the essential health and safety requirements set out in Annex I. ⇐ The assessment procedure ~~must~~ ☒ shall ☒ include a visit to the premises of the ~~lift~~ installer and a visit to the installation site.

The decision ~~must~~ ☒ shall ☒ be notified to the lift installer. The notification must contain the conclusions of the examination and the reasoned ~~assessment~~ ☒ approval ☒ decision.

3.4. The installer ~~of a lift must~~ ☒ shall ☒ undertake to discharge the obligations arising from the ☒ product ☒ quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The installer ~~of a lift~~ must keep the notified body which has approved the quality ☒ product ☒ assurance system informed of any intended updating of the ~~quality assurance~~ system.

The notified body ~~must~~ ☒ shall ☒ assess the modifications proposed and decide whether the modified ☒ product ☒ quality assurance system still satisfies the requirements referred to in Section Point 3.2 or whether a reassessment is required.

It ~~must~~ ☒ shall ☒ notify its decision to the ~~lift~~ installer. The notification must contain the conclusions of the ~~examination~~ ☒ assessment ☒ and the reasoned assessment decision.

↓ new

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 21.

↓ 95/16/EC (adapted)

4. SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

4.1. The purpose of surveillance is to make sure that the installer ~~of a lift~~ duly fulfils the obligations arising out of the approved ☒ product ☒ quality assurance system.

4.2. The installer ~~of a lift must~~ ☒ shall ☒ allow the notified body access for inspection purposes to the inspection and testing locations and provide it with all necessary information, in particular:

³³ ~~This harmonized standard will be EN 29003, supplemented where necessary to take account of the specific features of the lifts.~~

~~(a)=~~ the ☒ product ☒ quality assurance system documentation~~;~~

~~(b)=~~ the technical ☒ file(s) ☒ documentation~~;~~

↓ 95/16/EC

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

↓ 95/16/EC (adapted)

4.3. The notified body ~~must~~ ☒ shall ☒ periodically carry out audits to ensure that the installer ~~of a lift~~ maintains and applies the quality assurance system and ~~must~~ ☒ shall ☒ provide an audit report to the ~~lift~~ installer.

↓ 95/16/EC

4.4. Additionally, the notified body may pay unexpected visits to the lift installation sites.

↓ 95/16/EC (adapted)

At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the ☒ product ☒ quality assurance system ~~where necessary~~ and of the lift~~;~~ ~~it must~~ ☒ It shall ☒ provide the ~~lift~~ installer with a visit report and, if a test has been carried out, with a test report.

5. The installer ~~of a lift~~, ~~must~~ ☒ shall ☒ for a period of 10 years after the last lift has been ☒ installed ☒ ~~manufactured~~, keep at the disposal of the national authorities:

↓ 95/16/EC (adapted)

~~(a)=~~ the documentation referred to in ~~the third indent of the second paragraph of~~ Section Point 3.1(c)~~;~~

↓ new

~~(b)~~ the technical file referred to in Point 3.1(d);

↓ 95/16/EC (adapted)

~~(c)=~~ the updating referred to in the second paragraph of Section Point 3.4~~;~~

~~(d)=~~ the decisions and reports from the notified body which are referred to in the final paragraph of Section Point 3.4 and in Sections Points 4.3 and 4.4.

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

6. Each notified body shall inform its notifying authorities of product quality assurance system approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of approval decisions, issued, refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of product quality assurance system approval decision(s) which it has refused, suspended or withdrawn and, upon request, of approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of product quality assurance system approval decision(s) issued.

7. The documents and correspondence relating to the product quality assurance procedures shall be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.

ANNEX XI ~~XIII~~

FULL QUALITY ASSURANCE ☒ PLUS DESIGN EXAMINATION ☒ FOR LIFTS

(module H)

~~1. Full quality assurance is the procedure whereby the installer of a lift who satisfies the obligations of Section 2 ensures and declares that lifts satisfy the requirements of the Directive that apply to them.~~

~~The installer of a lift must affix the CE marking on each lift and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the surveillance as specified in Section 4.~~

~~2. The installer of a lift must operate an approved quality assurance system for design, manufacture, assembly, installation and final inspection of the lifts and testing as specified in Section 3 and must be subject to surveillance as specified in Section 4.~~

☒ 1. Full quality assurance plus design examination for lifts is the conformity assessment procedure whereby a notified body assesses the full quality assurance system of an installer and, where appropriate, the design of the lifts, to ensure that the lifts installed satisfy the essential health and safety requirements set out in Annex I. ☒

☒ 2. OBLIGATIONS OF THE INSTALLER ☒

☒ 2.1. The installer shall operate an approved full quality assurance system for the design, manufacture, assembly, installation, final inspection and testing of lifts as specified in Point 3 and shall be subject to surveillance as specified in Point 4. ☒

☒ 2.2. The installer must affix the CE marking on each lift and draw up an EU declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for the surveillance as specified in Point 4. ☒

3. ☒ FULL ☒ QUALITY ASSURANCE SYSTEM

3.1. The installer ~~of a lift must~~ ☒ shall ☒ lodge an application for assessment of his ☒ full ☒ quality assurance system with a ⇒ single ⇐ notified body ⇒ of his choice ⇐ .

The application ~~must~~ ☒ shall ☒ include:

↓ new

(a) the name and address of the installer;

↓ 95/16/EC (adapted)

~~(b)~~ all relevant information on the lifts ~~to~~ to be installed ~~in~~ , in particular information which makes for an understanding of the relationship between the design and operation of the lift ~~and enables conformity with the requirements of the Directive to be assessed~~;

↓ 95/16/EC

~~(c)~~ the documentation on the quality assurance system;

↓ new

(d) a technical file according to Annex IV B for one model of lift;

(e) a written declaration that the same application has not been lodged with any other notified body.

↓ 95/16/EC (adapted)

3.2. ~~The quality assurance system must ensure conformity of the lifts with the requirements of the Directive that apply to them.~~

All the elements, requirements and provisions adopted by the lift installer ~~must~~ shall be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality assurance system documentation ~~must~~ shall ensure a common understanding of the procedures such as programmes, plans, manuals and quality records.

It shall contain in particular an adequate description of:

↓ 95/16/EC

~~(a)~~ the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and quality of the lifts;

↓ 95/16/EC (adapted)

~~(b)~~ the technical design specifications, including standards that will be applied and, where the standards referred to in Article 514 of the Directive ~~will~~ are not be applied or not applied in full, the means that will be used to ensure that the applicable essential health and safety requirements of the Directive ~~that apply to the lifts~~ will be met;

↓ 95/16/EC (adapted)

~~(c)~~ the design control and design verification techniques, processes and systematic actions that will be used when designing the lifts;

~~(d)~~ the examinations and tests that will be carried out on acceptance of the supplies of materials, components and sub-assemblies;

(e) the corresponding assembly, installation and quality control techniques, processes and systematic actions that will be used;

(f) the examinations and tests that will be carried out before (inspection of installation conditions: shaft, housing of machinery, etc.), during and after installation (including at the very least the tests laid down in Point 3.4 (e) of Annex V ~~Annex VI, Section 4 (b))~~;

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

(h) the means of monitoring the achievement of the required design and installation quality and the effective operation of the quality assurance system.

↓ 95/16/EC (adapted)

3.3. Design inspection

3.3.1. When the design is not entirely in accordance with harmonized standards, the notified body must ascertain whether the design conforms to the ~~provisions~~ ☒ essential health and safety requirements set out in Annex I ☒ ~~of the Directive~~ and, if it does, issue an ~~EC~~ ☒ EU ☒ design examination certificate² to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.

↓ new

3.3.2. Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue a design examination certificate and shall inform the installer accordingly, giving detailed reasons for its refusal.

The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the essential health and safety requirements set out in Annex I, and shall determine whether such changes require further investigation. If so, the notified body shall inform the installer accordingly.

The installer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential health and safety requirements set out in Annex I or the conditions for validity of the certificate. Such modifications shall require additional approval — from the notified body that issued the EU design examination certificate — in the form of an addition to the original EU design examination certificate.

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

Each notified body shall inform the other notified bodies of the EU design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or

otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical files and of the results of the examinations carried out by the notified body.

3.3.4. The installer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical file at the disposal of the national authorities for 10 years after the lift has been placed on the market.

↓ 95/16/EC (adapted)

⇒ new

3.4. Assessment of the ☒ full ☒ quality assurance system

The notified body must assess the ☒ full ☒ quality assurance system to determine whether it satisfies the requirements referred to in Section Point 3.2. It ☒ shall ☒ ~~must~~ presume compliance with these requirements in respect of ☒ full ☒ quality assurance systems that implement the relevant harmonized standard³⁴.

The auditing team ☒ shall ☒ ~~must~~ have at least one member with experience of assessment in the lift technology concerned ☒ and knowledge of the essential health and safety requirements set out in Annex I. ☒ The assessment procedure ☒ shall ☒ ~~must~~ include a visit to the ~~lift~~ installer's premises and a visit to an installation site.

↓ new

The auditing team shall review the technical file referred to in point 3.1, to verify the installer's ability to identify the essential health and safety requirements of set out in Annex I and to carry out the necessary examinations with a view to ensuring compliance of the lift with those requirements.

↓ 95/16/EC (adapted)

The decision ☒ shall ☒ ~~must~~ be notified to the ~~lift~~ installer. The notification must contain the conclusions of the ~~examination~~ ☒ assessment ☒ and the reasoned assessment ☒ report ☒ ~~decision~~.

3.5. The ~~lift~~ installer ☒ shall ☒ ~~must~~ undertake to discharge the obligations arising from the ☒ full ☒ quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The ~~lift~~ installer ☒ shall ☒ ~~must~~ keep the notified body that has approved the ☒ full ☒ quality assurance system informed of any intended updating of the ~~quality assurance~~ system.

³⁴ ~~This harmonized standard will be EN 29001, supplemented where necessary to take account of the specific features of the lifts.~~

The notified body ☒ shall ☒ ~~must~~ assess the modifications proposed and decide whether the modified ☒ full ☒ quality assurance system will still satisfy the requirements referred to in ~~Section~~ Point 3.2 or whether a reassessment is required.

It ☒ shall ☒ ~~must~~ notify its decision to the ~~lift~~ installer. The notification must contain the conclusions of the ~~examination~~ ☒ assessment ☒ and the reasoned ~~assessment~~ ☒ approval ☒ decision.

↓ new

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Articles 18 and 21.

↓ 95/16/EC (adapted)

4. SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

4.1. The purpose of surveillance is to make sure that the installer ~~of a lift~~ duly fulfils the obligations arising out of the approved ☒ full ☒ quality assurance system.

4.2. The ~~lift~~ installer ☒ shall ☒ ~~must~~ allow the notified body access for inspection purposes to the design, manufacture, assembly, installation, inspection and testing and storage locations, and ☒ shall ☒ ~~must~~ provide it with all necessary information, in particular:

~~(a)~~ the ☒ full ☒ quality assurance system documentation~~;~~

↓ 95/16/EC

~~(b)~~ the quality records provided for in the design part of the quality assurance system, such as results of analyses, calculations, tests, etc.~~;~~

~~(c)~~ the quality records provided for in the part of the quality assurance system concerning acceptance of supplies and installation, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the installer of a lift maintains and applies the quality assurance system and must provide the installer with an audit report.

↓ 95/16/EC (adapted)

4.4. Additionally, the notified body may pay unexpected visits to the premises of a lift installer or to the assembly site of a lift. At the time of such visits, the notified body may, ☒ where necessary, ☒ carry out tests or have them carried out in order to check the proper functioning of the ☒ full ☒ quality assurance system, ~~where necessary, it must~~ ☒ It shall ☒ provide the ~~lift~~ installer with a visit report and, if a test has been carried out, with a test report.

5. The installer ☒ shall ☒ ~~of a lift must~~, for a period of 10 years after the lift has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in ~~the second indent of the second paragraph of Section Point 3.1(c)~~;

↓ new

(b) a technical file referred to in Point 3.1(d);

↓ 95/16/EC (adapted)

(c) the ☒ updates ~~☒ updating~~ referred to in the second paragraph of ~~Section Point 3.5~~;

↓ 95/16/EC

(d) the decisions and reports from the notified body which are referred to in the final paragraph of ~~Section Point 3.5~~ and in ~~Sections Points 4.3 and 4.4~~.

↓ 95/16/EC (adapted)

Where the installer is not established in the ☒ Union ~~☒ Community~~, this obligation falls to the notified body.

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

↓ new

6. Each notified body shall inform its notifying authorities of full quality assurance system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of full quality assurance system approval decision(s) issued, refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of full quality assurance system approval decision(s) which it has refused, suspended or withdrawn, and, upon request, of full quality assurance system approval decision(s) which it has issued.

The notified body shall keep a copy of the approval decision(s) issued, its annexes and additions, as well as the technical file for a period of 15 years from the date of their issue.

On request, the notified body shall provide the Commission and the Member States with a copy of full quality assurance system approval decision(s) issued.

↓ 95/16/EC (adapted)

7. The ~~dossiers~~ ☒ documents ~~☒~~ and correspondence relating to the full quality assurance procedures must be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.

ANNEX XII XIV

PRODUCTION QUALITY ASSURANCE ☒ FOR LIFTS ☒

(module D)

~~1. Production quality assurance is the procedure whereby the installer of a lift who satisfies the obligations of Section 2 ensures and declares that the lifts satisfy the requirements of the Directive that apply to them. The installer of the lift must affix the CE marking to each lift and draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in Section 4.~~

~~2. The installer of the lift must operate an approved quality assurance system for production, installation, final lift inspection and testing as specified in Section 3 and is subject to surveillance as specified in Section 4.~~

☒ 1. Production quality assurance for lifts is the part of the conformity assessment procedure whereby a notified body assesses the production quality assurance system of a installer to ensure that the lifts installed are in conformity with the type as described in the EU type-examination certificate or with a lift designed and manufactured by an installer who operates a full quality assurance system in accordance with Annex XI, and satisfy the essential health and safety requirements set out in Annex I. ☒

☒ 2. OBLIGATIONS OF THE INSTALLER ☒

☒ 2.1. The installer shall operate an approved production quality assurance system for manufacture, assembly, installation, final inspection and testing of lifts as specified in Point 3 and is subject to surveillance as specified in Point 4. ☒

☒ 2.2. The installer shall affix the CE marking to each lift and draw up a written declaration of conformity. ☒

3. ☒ PRODUCTION ☒ QUALITY ASSURANCE SYSTEM

3.1. The installer ~~must~~ ☒ shall ☒ lodge an application for assessment of his ☒ production ☒ quality assurance system with a notified body of his choice.

The application ~~must~~ ☒ shall ☒ include:

↓ new

(a) the name and address of the installer;

↓ 95/16/EC (adapted)

(b) ~~all~~ relevant information for the lifts ☒ to be installed ☒.

~~(c)~~ the documentation concerning ☒ on the production ☒ the quality assurance system;

~~(d)~~ the technical documentation ☒ file ☒ of ☒ the lifts to be installed ☒ the approved type and a copy of the EC type examination certificate;

↓ new

(e) a written declaration that the same application has not been lodged with any other notified body.

↓ 95/16/EC

3.2. The quality assurance system must ensure compliance of the lifts with the requirements of the Directive that apply to them.

↓ 95/16/EC (adapted)

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

It ☒ shall ☒ ~~must~~ contain in particular an adequate description of:

~~(a)~~ the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the lifts;

~~(b)~~ the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

~~(c)~~ the examinations and tests that will be carried out before, during and after installation³⁵;

~~(d)~~ the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

~~(e)~~ the means to monitor the achievement of the required lift quality and the effective operation of the ☒ production ☒ quality assurance system.

3.3. The notified body ☒ shall ☒ ~~must~~ assess the ☒ production ☒ quality assurance system to determine whether it satisfies the requirements referred to in Section Point 3.2. It presumes conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard³⁶.

The auditing team ~~must~~ ☒ shall ☒ have at least one member with experience of assessment in the lift technology concerned ☒ and knowledge of the requirements set out in Annex I. ☒

³⁵ These tests include at least the tests provided for in Annex V Point 3.4 VI, Section 4 (b).

³⁶ This harmonized standard will be EN 29002, supplemented where necessary to take account of the specific nature of the lifts.

The assessment procedure ~~must~~ shall include an inspection visit to the installer's premises and a visit to an installation site.

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

3.4. The installer shall ~~must~~ undertake to discharge the obligations arising from the production quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The installer shall keep the notified body that has approved the production quality assurance system informed of any intended updating of the ~~quality assurance~~ system.

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

It shall ~~must~~ notify its decision to the installer. The notification must contain the conclusions of the ~~examination~~ assessment and the reasoned assessment report ~~decision~~.

4. SURVEILLANCE UNDER THE RESPONSIBILITY OF THE NOTIFIED BODY

4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved production quality assurance system.

4.2. The installer shall ~~must~~ allow the notified body access for inspection purposes to the manufacture, inspection, assembly, installation, testing and storage locations and must provide it with all necessary information, in particular:

~~(a)~~ the production quality assurance system documentation;

(b) the technical file(s);

↓ 95/16/EC

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

↓ 95/16/EC (adapted)

4.3. The notified body shall ~~must~~ periodically carry out audits to make sure that the installer maintains and applies the quality production assurance system and shall ~~must~~ provide an audit report to the installer.

4.4. Additionally the notified body may pay unexpected visits to the installer. During such visits the notified body may, where necessary carry out, or cause to be carried out, tests to verify that the production quality assurance system is functioning correctly, ~~if necessary~~. The notified body shall ~~must~~ provide the installer with a visit report and, if a test has taken place, with a test report.

5. The installer ☒ shall ☒ ~~must~~, for a period of 10 years after the last lift has been manufactured, keep at the disposal of the national authorities:

↓ 95/16/EC (adapted)

~~(a) the documentation referred to in the second indent of Section Point 3.1(c);~~

↓ new

(b) the technical file referred to in Point 3.1(d);

↓ 95/16/EC

~~(c) the updating referred to in the second paragraph of Section Point 3.4;~~

~~(d) the decisions and reports from the notified body which are referred to in the final paragraph of Section Points 3.4, Section 4.3 and 4.4.~~

↓ new

6. Each notified body shall inform its notifying authorities of production quality assurance system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of production quality assurance system approval decision(s) issued, refused, suspended or otherwise restricted.

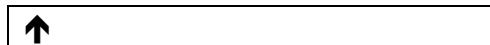
Each notified body shall inform the other notified bodies of production quality assurance system approval decision(s) which it has refused, suspended or withdrawn, and, upon request, of production quality assurance system approval decision(s) which it has issued.

On request, the notified body shall provide the Commission and the Member States with a copy of production quality assurance system approval decision(s) issued.

↓ 95/16/EC (adapted)

~~6. Each notified body must give the other notified bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.~~

7. ☒ The documentation ☒ ~~Documents~~ and correspondence relating to the production quality assurance procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to it.



ANNEX XIII

Part A

Repealed Directive with list of its successive amendments

European Parliament and Council Directive 95/16/EC (OJ L 213, 7.9.1995, p. 1)	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p.1)	Only Pt. 10) of Annex I
Directive 2006/42/EC of the European Parliament and the Council (OJ L 157, 9.6.2006, p.24)	Only Article 24

Part B

List of time-limits for transposition into national law [and application]

<i>Directive</i>	<i>Time-limit for transposition</i>	<i>Date of application</i>
95/16/EC	1 January 1997	1 July 1997 ³⁷
2006/42/EC Art.24	29 June 2008	29 December 2009

ANNEX XIV

CORRELATION TABLE

Directive 95/16/EC	This Directive
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³⁷ Until 30 June 1999 Member States shall allow: — the placing on the market and putting into service of lifts, — the placing on the market and putting into service of safety components, which conform to the provisions in force in their territories on the date of adoption of this Directive. See Article 15(2) of Directive 95/16/EC.

Article 1(1)	Article 1(1) first subparagraph
—	Article 1(1), second subparagraph
Article 1(2) first subparagraph	—
Article 1(2), second subparagraph	—
Article 1(2), third subparagraph	Article 2(2)
Article 1(3)	Article 1(2)
Article 1(4) first indent of first subparagraph	Article 2(4)
Article 1(4) second, third and fourth indents of first subparagraph	—
Article 1(4) fifth indent of first subparagraph	Article 2(3)
Article 1(4) second subparagraph	Article 16(3)
Article 1(4) third subparagraph	Article 16(4)
Article 1(5)	Article 1(3)
—	Article 2(1)
Article 2(1) first indent	Article 4(1)
Article 2(1) second indent	Article 4(2)
Article 2(2)	Article 6(1)
Article 2(3)	Article 6(2)
Article 2(4)	Article 3(4)
Article 2(5)	Article 3(3)
Article 3, first paragraph	Article 5(1)
Article 3, second paragraph	Article 5(2)
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—	Articles 47 to 49
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