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Taqsima B

L.N. 79 of 2016

PRODUCT SAFETY ACT
(CAP. 427)
Lifts Regulations, 2016

IN exercise of the powers conferred by articles 38 and 39 of the Product Safety Act, the Minister for Social Dialogue, Consumer Affairs and Civil Liberties, on the advice of the Malta Competition and Consumer Affairs Authority, has made the following regulations:-

Title, commencement and scope.

1. (1) The title of these regulations is Lifts Regulations, 2016.

(2) These regulations transpose Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (recast).

(3) These regulations shall come into force on the 20th April, 2016.

Interpretation.

2. In these regulations, unless the context otherwise requires:

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

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from an installer or a manufacturer to act on his behalf in relation to specified tasks;

"carrier" means a part of the lift by which persons and, or goods are supported in order to be lifted or lowered;

"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 as set out in Annex III of the Directive, which is set out in Schedule III;

"conformity assessment" means the process demonstrating whether the essential health and safety requirements of these regulations relating to a lift or a safety component for lifts have been fulfilled;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

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"the Directive" means European Parliament and Council Directive 2014/33/EU on the approximation of the laws of the Member States relating to lifts;

"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;

"economic operators" means the installer, the manufacturer, the authorised representative, the importer and the distributor;

"harmonised standard" means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

"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;

"installer" means the natural or legal person who takes responsibility for the design, manufacture, installation and placing on the market of the lift;

"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;

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

"manufacturer" means any natural or legal person who manufactures a safety component for lifts or has a safety component for lifts designed or manufactured, and markets it under his name or trade mark;

"model lift" means a representative lift whose technical documentation shows the way in which the essential health and safety requirements set out in Schedule I will be met for lifts which conform to the model lift defined by objective parameters and which uses identical safety components for lifts;

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

"notified body" means a body which has been appointed by a

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Member State and notified to the European Commission and the other Member States, pursuant to Article 21 of the Lifts Directive, to carry out one or more of the conformity assessment procedures mentioned and referred to in regulations 16 and 17;

"placing on the market" means:

- the first making available on the market of a safety component for lifts, or

- the supply of a lift for use on the European Union market in the course of a commercial activity, whether in return for payment or free of charge;

"recall" in relation to a lift means any measure aimed at achieving the dismantling and safe disposal of a lift, and in relation to a safety component for lifts means any measure aimed at achieving the return of a safety component for lifts that has already been made available to the installer or to the end-user;

"safe" in relation to a lift or safety component, means that the lift or, in the case of a safety component, the lift in which it is to be installed, when properly installed and maintained and used for its intended purpose conforms to all the relevant essential health and safety requirements and is not liable to endanger the health or safety of persons or, where appropriate, the safety of property, and cognate expressions shall be construed accordingly;

"technical specification" means a document that prescribes technical requirements to be fulfilled by a lift or a safety component for lifts;

"Union harmonisation legislation" means any Union legislation harmonising the conditions for the marketing of products;

"withdrawal" means any measure aimed at preventing a safety component for lifts in the supply chain from being made available on the market.

Transitional provisions.

S.L. 427.37.

2. The putting into service of lifts or the making available on the market of safety components for lifts regulated by the Lifts Regulations and which were placed on the market before 20th April, 2016, shall not in any way be impeded.

S.L. 427.37.

(3) Certificates and decisions by notified bodies under the Lifts Regulations shall also be valid under these regulations.

Applicability.

3. (1) These regulations shall apply to lifts permanently

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serving buildings and constructions and intended for the transport of:

(a) persons;

(b) persons and goods;

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

(2) These regulations shall also apply to the safety components for lifts listed in Schedule III for use in the lifts referred to in the sub-regulation (1).

(3) These regulations 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; and

(k) escalators and mechanical walkways.

(4) Where, for lifts or safety components for lifts, the risks referred to in these regulations are wholly or partly covered by specific European Union law, these regulations shall not apply or shall cease to apply in the case of such lifts or safety components for

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lifts and such risks as from the application of that specific European Union law.

Free movement.

4. (1) The making available on the market of lifts shall not be prohibited, restricted or impeded or putting into service of lifts or the making available on the market of safety components for lifts on their territory which comply with these regulations.

(2) At trade fairs, exhibitions or demonstrations, the showing of lifts or safety components for lifts which are not in conformity with these regulations, provided that a visible sign clearly indicates that they are not in conformity and will not be placed or made available on the market until they have been brought into conformity. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

(3) The provisions of these regulations shall not prevent from adopting provisions in conformity with the European Union law that are deemed 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 these regulations.

Placing on the market, making available on the market and putting into service.

5. (1) All appropriate measures must be taken to ensure that the lifts covered by these regulations may be placed on the market and put into service only if they comply with these regulations, when properly installed and maintained and used for their intended purpose.

(2) All appropriate measures must be taken to ensure that safety components for lifts covered by these regulations may be made available on the market and put into service only if they comply with these regulations when properly incorporated and maintained and used for their intended purpose.

Essential health and safety requirements.

6. (1) Lifts covered by these regulations shall satisfy the essential health and safety requirements set out in Schedule I.

(2) Safety components for lifts covered by these regulations shall satisfy the essential health and safety requirements set out in Schedule I and enable the lifts in which they are incorporated to satisfy those requirements.

Buildings or constructions in which lifts are installed.

7. (1) All appropriate measures to ensure that the person responsible for work on the building or construction and the installer both provide each other with the necessary information and take the appropriate steps in order to ensure the proper operation and safe use of the lift.

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(2) 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.

Obligations of the installers.

8. (1) When placing a lift on the market, installers shall ensure that it has been designed, manufactured, installed and tested in accordance with the essential health and safety requirements set out in Schedule I.

(2) Installers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in regulation 17 or have it carried out.

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

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

(5) When deemed appropriate with regard to the risks presented by a lift, installers shall, to protect the health and safety of consumers, investigate, and, if necessary, keep a register of complaints, and of non-conforming lifts.

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

(7) Installers shall indicate, on the lift, their name, registered trade name or registered trade mark and the postal address at which they can be contacted. The address shall indicate a single point at which the installer can be contacted. The contact details shall be in at least the Maltese or English language.

(8) Installers shall ensure that the lift is accompanied by the instructions referred to in point 6.2 of Schedule I, in at least the Maltese or English language. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

(9) Installers who consider or have reason to believe that a lift which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that lift into conformity. Furthermore, where the lift presents a risk, installers shall immediately inform the Technical Regulations Division to that effect, giving details, in particular, of the non-

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conformity and of any corrective measures taken.

(10) Installers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the lift with these regulations, in either Maltese or English language. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by lifts which they have placed on the market.

Obligations of the manufacturer.

9. (1) When placing their safety components for lifts on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with regulation 6(2).

(2) Manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in regulation 16 or have it carried out.

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

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

(5) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a safety component for lifts is declared shall be adequately taken into account.

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

(7) Manufacturers shall ensure that safety components for lifts which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the

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size or nature of the safety component for lifts does not allow it, that the required information is provided on the label referred to in regulation 19(2).

(8) Manufacturers shall indicate on the safety component for lifts their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the label referred to in regulation 19(2). The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be either in Maltese or English language.

(9) Manufacturers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1 of Schedule I, in at least the Maltese or English language. Such instructions, as well as any labelling, shall be clear, understandable and intelligible.

(10) 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 these regulations shall immediately take the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the safety component for lifts presents a risk, manufacturers shall immediately inform the Technical Regulations Division to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

(11) Manufacturers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the safety components for lifts with these regulations, in at least the Maltese or English language.

(12) They shall cooperate with the Technical Regulations Divisions, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have placed on the market.

Authorised representatives.

10. (1) A manufacturer or an installer may, by a written mandate, appoint an authorised representative. The obligations laid down in regulation 8(1) or in regulation 9(1) and the obligation to draw up technical documentation referred to in regulation 8(2) or in regulation 9(2) shall not form part of the authorised representative's mandate.

(2) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer or the

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installer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and, where applicable, the approval decision(s) relating to the manufacturer's or the installer's quality system, and the technical documentation at the disposal of the Technical Regulations Division for 10 years after the safety component for lifts or the lift has been placed on the market;

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

(c) cooperate with the Technical Regulations Division, at their request, on any action taken to eliminate the risks posed by the safety component for lifts or the lift covered by the authorised representative's mandate.

Obligations of importers.

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

(2) Before placing a safety component for lifts on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 16 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the safety component for lifts bears the CE marking and is accompanied by the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in regulation 9(7) and (8).

(3) Where an importer considers or has reason to believe that a safety component for lifts is not in conformity with regulation 6(2), he shall not place the safety component for lifts on the market until it has been brought into conformity. Furthermore, where the safety component for lifts presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(4) Importers shall indicate on the safety component for lifts their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the safety component for lifts. The contact details shall be in either Maltese or English language.

(5) Importers shall ensure that the safety component for lifts is accompanied by the instructions referred to in point 6.1 of Schedule I

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in at least the Maltese and English language.

(6) Importers shall ensure that, while a safety component for lifts is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements referred to in regulation 6(2).

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

(8) 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 these regulations shall immediately take the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the safety component for lifts presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the safety component for lifts available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

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

(10) Importers shall, further to a reasoned request from a Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a safety component for lifts in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by safety components for lifts which they have placed on the market.

Obligations of distributors.

12. (1) When making a safety component for lifts available on the market distributors shall act with due care in relation to the requirements of these regulations.

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(2) Before making a safety component for lifts available on the market, distributors shall verify that the safety component for lifts bears the CE marking, that it is accompanied by the EU declaration of conformity, by the required documents and by the instructions referred to in point 6.1 of Schedule I, in either the Maltese or English language and that the manufacturer and the importer have complied with the requirements set out in regulation 9(7) and (8) and regulation 11(4), respectively.

(3) Where a distributor considers or has reason to believe that a safety component for lifts is not in conformity with regulation 6(2), he shall not make the safety component for lifts available on the market until it has been brought into conformity. Furthermore, where the safety component for lifts presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

(4) Distributors shall ensure that, while a safety component for lifts is under their responsibility, its storage or transport conditions do not jeopardise its compliance with regulation 6(2).

(5) 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 these regulations shall make sure that the corrective measures necessary to bring that safety component for lifts into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the safety component for lifts presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the safety component for lifts available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) Distributors shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a safety component for lifts. They shall cooperate with the Technical Regulations Division, 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.

Cases in which obligations of manufacturers apply to importers and distributors.

13. An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 9, where he places a safety component for lifts 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

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these regulations may be affected.

Identification of economic operators.

14. (1) Economic operators shall, on request, identify the following to the Technical Regulations Division:

(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;

(2) Economic operators shall be able to present the information referred to in sub-regulation (1) 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.

Presumption of conformity of lifts and safety components for lifts.

15. 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 safety requirements set out in Schedule I covered by those standards or parts thereof.

Conformity assessment procedures for safety components for lifts.

16. Safety components for lifts shall be subject to one of the following conformity assessment procedures:

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

(b) the model of the safety component for lifts shall be submitted for EU type examination set out in Schedule IV, Part A and be subject to conformity to type based on product quality assurance in accordance with Schedule VI;

(c) conformity based on full quality assurance set out in Schedule VII.

Conformity assessment procedures for lifts.

17. (1) Lifts shall be subject to one of the following conformity assessment procedures:

(a) if they are designed and manufactured in accordance with a model lift that has undergone an EU-type examination set out in Schedule IV, Part B:

(i) final inspection for lifts set out in Schedule V;

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(ii) conformity to type based on product quality assurance for lifts set out in Schedule X;

(iii) conformity to type based on production quality assurance for lifts set out in Schedule XII;

(b) if they are designed and manufactured under a quality system approved in accordance with Schedule XI:

(i) final inspection for lifts set out in Schedule V;

(ii) conformity to type based on product quality assurance for lifts set out in Schedule X;

(iii) conformity to type based on production quality assurance for lifts set out in Schedule XII;

(c) conformity based on unit verification for lifts set out in Schedule VIII;

(d) conformity based on full quality assurance plus design examination for lifts set out in Schedule XI.

(2) In the cases referred to in paragraphs (a) and (b) of sub-regulation (1), where the person responsible for the design and manufacture of the lift and the person responsible for the installation and testing of the lift are not the same, the former shall supply to the latter all the necessary documents and information to enable the latter to ensure correct and safe installation and testing of the lift.

(3) All permitted variations between the model lift and the lifts forming part of the lifts derived from the model lift shall be clearly specified (with maximum and minimum values) in the technical documentation.

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

EU declaration of conformity.

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

(2) The EU declaration of conformity shall have the model structure set out in Schedule II, shall contain the elements specified in the relevant Schedule V to XII and, shall be continuously updated. It shall be translated into the language or languages required by the

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Member State in which the lift or safety component for lifts is placed or made available on the market. For a lift or safety component for lifts made available on the Maltese market, the EU declaration of conformity shall be in at least the Maltese or English language.

(3) Where a lift or a safety component for lifts is subjected to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the safety component for lifts and the installer shall assume responsibility for the compliance of the lift with the requirements laid down in these regulations.

CE marking.

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

(2) The CE marking shall be affixed visibly, legibly and indelibly to each lift car and to each safety component for lifts or, where that is not possible, on a label inseparably attached to the safety component for lifts.

(3) The CE marking shall be affixed before the lift or the safety component for lifts is placed on the market.

(4) The CE marking on lifts shall be followed by the identification number of the notified body involved in any of the following conformity assessment procedures:

(a) the final inspection referred to in Schedule V;

(b) unit verification, referred to in Schedule VIII;

(c) quality assurance referred to in Schedules X, XI or XII.

(5) The CE marking on safety components for lifts shall be followed by the identification number of the notified body involved in any of the following conformity assessment procedures:

(a) product quality assurance referred to in Schedule VI;

(b) full quality assurance referred to in Schedule VII;

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(c) conformity to type with random checking for safety components for lifts referred to in Schedule IX.

(6) The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative or by the installer or his authorised representative. The CE marking and the identification number of the notified body may be followed by any other mark indicating a special risk or use.

(7) The Technical Regulations Division shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notification of conformity assessment bodies.

20. (1) The Technical Regulations Division shall notify the European Commission and the other Member States of bodies authorised to carry out third-party conformity assessment under these regulations.

(2) The Technical Regulations Division 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 Regulation 21.

(3) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(4) The Technical Regulations Division shall take full responsibility for the tasks performed by National Accreditation Board (Malta) referred to in sub-regulation (3).

(5) The Technical Regulations Division shall inform the European Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Requirements for notified bodies.

21. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (16) and in the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427.45.

(2) A conformity assessment body shall be established under Maltese law and have legal personality.

(3) A conformity assessment body shall be a third-party body

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independent of the organisation or the lift or the safety component 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) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of lifts or safety components for lifts which they assess nor representative of any of those parties. This shall not preclude the use of assessed lifts or safety components for lifts that are necessary for the operations of the conformity assessment body or the use of 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.

(b) 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.

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

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

(6) (a) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by

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Schedule IV to XII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

(b) 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:

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

(ii) 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;

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

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

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

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

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

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

(d) the ability to draw up certificates, records and reports

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demonstrating that assessments have been carried out.

(8) The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

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

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

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

(12) 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 these regulations insofar as the applicable harmonised standards cover those requirements.

(13) 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 these regulations, and shall inform the Technical Regulations Division accordingly.

(14) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

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

(16) Notified bodies shall keep at the disposal of the Technical Regulations Division the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Schedules IV to XII.

Notification procedures.

22. (1) A conformity assessment body established in Malta shall submit an application for notification under these regulations to the Technical Regulations Division.

(2) The application referred to in the preceding sub-regulation shall be accompanied by a description of the conformity assessment activities, the conformity assessment procedure or procedures and the lifts or safety components for lifts for which that body claims to be competent, as well as by an accreditation certificate, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulation 21 and the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427.45.

(3) The Technical Regulations Division may only notify conformity assessment bodies which have satisfied the requirements laid down in regulation 21 and the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427.45.

(4) The Technical Regulations Division shall notify conformity assessment bodies to the European Commission and the other Member States using the electronic notification tool developed and managed by the European Commission.

(5) The notification shall include full details of the conformity assessment activities, the conformity assessment procedure or procedures and the lifts or the safety component for lifts concerned and the relevant attestation of competence.

(6) The body concerned may perform the activities of a notified body only where no objections are raised by the European Commission or the other Member States within two weeks of a notification. Only such a body shall be considered a notified body for the purposes of these regulations.

(7) The Technical Regulations Division shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

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(8) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 21 or the Method for Designating Conformity Assessment Bodies Regulations, or that it is failing to fulfil its obligations, the Technical Regulations Division 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 European Commission and the other Member States accordingly.

S.L. 427.45.

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

(10) The Technical Regulations Division 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.

Operational obligations for notified bodies.

23. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in regulations 16 and 17.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the lift or safety component for the lift in question and the mass or serial nature of the production process. In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the lift or safety component for the lift with these regulations.

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

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a lift or a safety component for lifts no longer complies; it shall require the

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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.

(6) Notified bodies shall inform the Technical Regulations Division of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(7) Notified bodies shall provide the other bodies notified these regulations carrying out similar conformity assessment activities covering the same lifts or safety components for lifts with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(8) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European Commission.

Market surveillance.

24. (1) The Technical Regulations Division shall take appropriate measures to ensure that lifts and safety components of lifts may only be placed on the market if they satisfy the essential health and safety requirements set out in Schedule I.

(2) Article 15(3) and Article 17 to 22 of Regulation (EC) No 765/2008 shall apply to lifts and safety components for lifts.

(3) Where the Technical Regulations Division have sufficient reasons to believe that a lifts or a safety component for lifts covered by these regulations presents a risk to the health or safety of persons

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or, where appropriate to the safety of property, they shall carry out an evaluation in relation to the lift or safety component for lifts concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

(4) Where, in the course of the evaluation referred to in sub-regulation (3), the Technical Regulations Division find that a lift does not comply with the requirements laid down in these regulations, they shall without delay require the installer to take all appropriate corrective actions to bring the lift or safety component for lifts into compliance with those requirements, to withdraw the safety component for lifts from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe. They shall also inform the notified body accordingly.

(5) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in sub-regulation (4).

(6) Where the Technical Regulations Division consider that non-compliance is not restricted to the Maltese territory, it shall inform the European Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

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

(8) Where the installer does not take adequate corrective action within the period referred to in sub-regulation (4), the Technical Regulations Division shall take all appropriate provisional measures to prohibit or restrict the placing on the Maltese market or the use of the lifts concerned, or recall it.

(9) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (4), the Technical Regulations Division shall take all appropriate provisional measures to prohibit or restrict the safety component for lifts being made available on their national market, to withdraw the safety component for lifts from that market or to recall it.

(10) The Technical Regulations Division shall inform the European Commission and the other Member States, without delay, of those measures.

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(11) The information referred to in the sub-regulation (10) shall include all available details, in particular the data necessary for the identification of the non-compliant lift or safety component for lifts, the origin, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the Technical Regulations Division shall indicate whether the non-compliance is due to either of the following:

(a) failure of the lift or the safety component for lifts to meet the essential health or safety requirement of these regulations; or

(b) shortcomings in the harmonised standards referred to in regulation 15 conferring a presumption of conformity.

(12) When the procedure under these regulations is initiated by another Member State, the Technical Regulations Division, shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the lift or the safety component for lifts concerned, and, in the event of disagreement with the adopted national measure, of their objections.

(13) Where, within three months of receipt of the information referred to in sub-regulation (10), no objection has been raised by either a Member State or the European Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

(14) In such cases, the Technical Regulations Division shall ensure that appropriate restrictive measures, such as withdrawal of the lift or the safety component for lifts from the Maltese market, are taken in respect of the lift or the safety component for lifts concerned without delay.

(15) Where on completion of the procedure set out in sub-regulations (7) and (8), objections are raised against the measures taken by Technical Regulations Division; the European Commission shall conduct an evaluation including appropriate consultations with these entities and the relevant economic operator or operators.

(16) If, on the basis of this evaluation, the national measure is considered justified, the Technical Regulations Division shall take the measures necessary to ensure that the placing on the market or use of the non-compliant lift or the safety component for lifts is withdrawn from the Maltese market and shall inform the European Commission

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accordingly. If, on the basis of this evaluation, the national measure is considered unjustified, the national measure shall be withdrawn.

(17) Where, having carried out an evaluation under sub-regulation (3), the Technical Regulations Division, finds that although a lift or the safety component for lifts is in compliance with these regulations, 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 lift or the safety component for lifts concerned, when placed on the Maltese market, no longer presents that risk, to withdraw the lift or the safety component for lifts from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(16) 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 European Union.

(17) The Technical Regulations Division, upon consultation with the Commissioner of Police, shall immediately inform the European Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the lift or the safety component for lifts concerned, the origin and the supply chain of the lifts or safety component of lifts, the nature of the risk involved and the nature and duration of the national measures taken.

(18) Without prejudice to sub-regulations (3) to (14), where the Technical Regulations Division and, or the Commissioner of Police make one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

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

(b) the CE marking has not been affixed;

(c) the identification number of the notified body has been affixed in violation of regulation 19 or has not been affixed where required by regulation 19;

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

(e) the EU declaration of conformity has not been

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drawn up correctly;

(f) technical documentation is either not available or not complete;

(g) the name, registered trade name or registered trade mark or the address of the installer, manufacturer or importer has not been indicated in compliance with regulation 8(7), regulation 9(8) or regulation 11(4);

(h) the information allowing identification of the lift or the safety component for lifts has not been indicated in compliance with regulation 8(6) or regulation 8(5);

(i) the lift or the safety component for lifts is not accompanied by the documents referred to in regulation 8(8) or regulation 9(9) or those documents are not in compliance with the applicable requirements.

(19) Where the non-compliance referred to in sub-regulation (18) persists, the Technical Regulations Division shall take all appropriate measures to restrict or prohibit the use of the lift or to recall it, or to restrict or prohibit the making available on the Maltese market of the safety component for lifts or ensure that it is recalled or withdrawn from the Maltese market.

(20) The powers of the Commissioner of Police under this regulation may be exercised by any officer or other entity as he may direct.

Penalties.

25. The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act.

Cap. 427.

Revocation and saving. S.L. 427.37.

26. (1) The Lift Regulations are being hereby being revoked, hereinafter being referred to as "the revoked regulations".

(2) Any references to the revoked regulations shall be construed as references to these regulations.

(2) Any references in existing laws, regulations and administrative provisions to Directive 2007/23/EC shall be construed as references to Directive 2013/29/EU.

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Schedule I

ESSENTIAL SAFETY REQUIREMENTS

Preliminary Remarks

1. Obligations under essential health and safety requirements apply only where the corresponding risk exists for the lift or safety component for lifts in question when used as intended by the installer or the manufacturer.

2. The essential health and safety requirements contained in these regulations are imperatives. However, given the present state of the art, the objectives which they lay down may not be attainable. In such cases, and to the greatest extent possible, the lift or safety components for lifts must be designed and constructed in such a way as to approximate to those objectives.

3. The manufacturer and the installer are under an obligation to carry out a risk assessment in order to identify all the risks which apply to their products; they must then design and construct them taking account of the assessment.

1. General

1.1. Application of Directive 2006/42/EC

Where the relevant risk exists and is not dealt with in this Schedule, the essential health and safety requirements of Schedule I to Directive 2006/42/EC of the European Parliament and of the Council (1) apply. The essential health and safety requirements of point 1.1.2 of Schedule I to Directive 2006/42/EC apply in any event.

1.2. Carrier

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

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

1.3. Means of suspension and means of support

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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 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:

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

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

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

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

2. Risks for persons outside the car

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

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

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

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

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

An interlocking device must prevent during normal operation:

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

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

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

3. Risks for persons in the car

3.1. Lift cars must be completely enclosed by full-length walls, fitted floors and ceilings included, with the exception of ventilation apertures, and

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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 sub-paragraph of point 2.3, unless the doors are closed, and comes to a halt if the doors are opened.

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

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

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

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

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

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

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

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

4. Other risks

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

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

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

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

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

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

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

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

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

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

5. Marking

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

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

6. **Instructions**

6.1. The safety components for lifts referred to in Schedule III must be accompanied by instructions, so the following can be carried out effectively and without danger:

(a) assembly;

(b) connection;

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(c) adjustment;

(d) maintenance.

6.2. Each lift must be accompanied by instructions. The instructions shall contain at least the following documents:

(a) instructions containing the plans and diagrams necessary for normal use and relating to maintenance, inspection, repair, periodic checks and the rescue operations referred to in point 4.4;

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

Schedule II

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

The EU declaration of conformity for safety components for lifts shall contain the following information:

(a) business name and address of the manufacturer;

(b) where appropriate, business name and address of the authorised representative;

(c) description of the safety component for lifts, details of type or series and serial number (if any); it may, where necessary for the identification of the safety component for lifts, include an image;

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

(e) year of manufacture of the safety component for lifts;

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

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

(i) where appropriate, the name, address and identification number of the notified body which carried out the EU-type examination

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of safety components for lifts set out in Schedule IV, Part A and Schedule VI, and the reference of the EU- type examination certificate issued by that notified body;

(j) where appropriate, the name, address and identification number of the notified body which carried out the conformity to type with random checking for safety components for lifts set out in Schedule IX;

(k) where appropriate, the name, address and identification number of the notified body which approved the quality system operated by the manufacturer in accordance with the conformity assessment procedure set out in Schedule VI or VII;

(l) the name and function of the person empowered to sign the declaration on behalf of the manufacturer or his authorised representative;

(m) place and date of signature;

(n) signature.

B. CONTENT OF THE EU DECLARATION OF CONFORMITY FOR LIFTS

The EU declaration of conformity for lifts shall be drafted in the same language as the instructions referred to in Schedule I, point 6.2 and contain the following information:

(a) business name and address of the installer;

(b) where appropriate, business name and address of the authorised representative;

(c) description of the lift, details of the type or series, serial number and address where the lift is installed;

(d) year of installation of the lift;

(e) all relevant provisions to which the lift conforms;

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

(g) where appropriate, reference(s) to harmonised standard(s) used;

(h) where appropriate, the name, address and identification number of the notified body which carried out the EU-type examination

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of lifts set out in Schedule IV, Part B and the reference of the EU-type examination certificate issued by that notified body;

(i) where appropriate, the name, address and identification number of the notified body which carried out the unit verification for lifts set out in Schedule VIII;

(j) where appropriate, the name, address and identification number of the notified body which carried out the final inspection for lifts set out in Schedule V;

(k) where appropriate, the name, address, and identification number of the notified body which approved the quality assurance system operated by the installer in accordance with the conformity assessment procedure set out in Schedule X, XI or XII;

(l) the name and function of the person empowered to sign the declaration on behalf of the installer or his authorised representative;

(m) place and date of signature;

(n) signature.

Schedule III

LIST OF SAFETY COMPONENTS FOR LIFTS

1. Devices for locking landing doors.

2. Devices to prevent falls referred to in point 3.2 of Schedule I to prevent the car from falling or uncontrolled movements.

3. Overspeed limitation devices.

4. (a) Energy-accumulating buffers:

    (i) non-linear, or

    (ii) with damping of the return movement.

    (b) Energy-dissipating buffers.

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

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

Schedule IV

EU-TYPE EXAMINATION FOR LIFTS AND SAFETY COMPONENTS FOR LIFTS

(module B)

A. EU-type examination of safety components for lifts

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a safety component for lifts and verifies and attests that the technical design of the safety component for lifts satisfies the applicable essential health and safety requirements of Schedule I and will enable a lift in which it is correctly incorporated to satisfy those requirements.

2. The application for EU-type examination shall be lodged by the manufacturer, or his authorised representative, with a single notified body of his choice.

   The application shall include:

   (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well and the place of manufacture of the safety components for lifts;

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

   (c) the technical documentation;

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

   (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents, including other relevant technical specifications, that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in

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accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

3. The technical documentation shall make it possible to assess whether the safety component for lifts meets the conditions referred to in point 1 and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the safety component for lifts.

The technical documentation shall contain, where applicable, the following:

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

(b) design and manufacturing drawings and diagrams;

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

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to enable the safety component for lifts to meet the conditions referred to in point 1, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations performed by or for the manufacturer;

(f) test reports;

(g) a copy of the instructions for the safety components for lifts;

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

4. The notified body shall:

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(a) examine the technical documentation and the supporting evidence to assess the adequacy of the technical design of the safety component for lifts;

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

(c) verify that the representative specimen(s) has (have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

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

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications enable the safety component for lifts to meet the conditions referred to in point 1.

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

5. Where the type of the safety component for lifts meets the conditions referred to in point 1, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

The EU-type examination certificate may have one or more Schedules attached.

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

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Where the type of the safety component for lifts does not satisfy the conditions referred to in point 1, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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

6. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer meet the conditions referred to in point 1 and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

7. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of any modification to the approved type that may affect the conformity of the safety component for lifts with the conditions referred to in point 1 or the conditions of validity of the EU-type examination certificate.

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

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

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

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

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10. The manufacturer shall keep with the technical documentation a copy of EU-type examination certificates, its Schedule and additions at the disposal of the national authorities for 10 years after the safety component for lifts has been placed on the market.

11. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in point 2 and fulfil the obligations set out in points 7 and 10, provided that they are specified in the mandate.

B. EU-type examination of lifts

1. EU-type examination of lifts is the part of a conformity assessment procedure in which a notified body examines the technical design of a model lift, or a lift for which there is no provision for an extension or variant, and verifies and attests that the technical design of the model lift or the lift meets the applicable essential health and safety requirements set out in Schedule I.

EU-type examination of a lift includes an examination of a representative specimen of a complete lift.

2. The application for EU-type examination shall be lodged by the installer or his authorised representative with a single notified body of his choice.

The application shall include:

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

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

(c) the technical documentation;

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

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents, including other relevant technical specifications that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in

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accordance with other relevant technical specifications by the appropriate laboratory of the installer, or by another testing laboratory on his behalf and under his responsibility.

3. The technical documentation shall make it possible to assess the conformity of the lift with the applicable essential health and safety requirements set out in Schedule I.

The technical documentation shall contain, where applicable, the following:

(a) a description of the model lift indicating clearly all the permitted variations of the model lift;

(b) design and manufacturing drawings and diagrams;

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

(d) a list of the essential health and safety requirements taken into consideration;

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

(f) a copy of the EU declarations of conformity of the safety components for lifts incorporated in the lift;

(g) results of design calculations performed by or for the installer;

(h) test reports;

(i) a copy of the instructions referred to in point 6.2 of Schedule I;

(j) steps taken at the installation stage to ensure that the series-produced lift conforms to the essential health and safety requirements set out in Schedule I.

4. The notified body shall:

(a) examine the technical documentation and supporting evidence

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to assess the adequacy of the technical design of the model lift or of the lift for which there is no provision for an extension or variant;

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

(c) examine the specimen lift to check that it has been manufactured in accordance with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

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

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

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

6. Where the type meets the essential health and safety requirements set out in Schedule I applicable to the lift concerned, the notified body shall issue an EU-type examination certificate to the installer. That certificate shall contain the name and address of the installer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

The EU-type examination certificate may have one or more Schedules attached.

The EU-type examination certificate and its Schedules shall contain all the information necessary to enable the conformity of lifts with the approved type to be assessed during the final inspection.

Where the type does not comply with the essential health and safety

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requirements set out in Schedule 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 Schedules and additions, as well as the technical documentation and the evaluation report for 15 years from the date of issue of that certificate.

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

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

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

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

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

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

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11. The installer shall keep with the technical documentation a copy of the EU-type examination certificate, including its Schedule and additions, at the disposal of the national authorities for 10 years after the lift has been placed on the market.

12. Authorised representative

The installer's authorised representative may lodge the application referred to in point 2 and fulfil the obligations set out in points 8 and 11, provided that they are specified in the mandate.

Schedule V

FINAL INSPECTION FOR LIFTS

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

2. **Obligations of the installer**

The installer shall take all measures necessary to ensure that the lift being installed complies with the applicable essential health and safety requirements set out in Schedule I and with one of the following:

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

(b) a lift designed and manufactured in accordance with a quality system pursuant to Schedule XI and the EU design examination certificate if the design is not wholly in accordance with the harmonised standards.

3. **Final inspection**

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

3.1. The installer shall lodge an application for final inspection with a single notified body of his choice and shall provide to the notified body the following documents:

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(a) the plan of the complete lift;

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

(c) a copy of the instructions referred to in Schedule I, point 6.2;

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

The notified body may not require detailed plans or precise information not necessary for verifying the conformity of the lift.

The appropriate examinations and tests set out in the relevant harmonised standard(s) or equivalent tests shall be carried out in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Schedule I.

3.2. The examinations shall include at least one of the following:

(a) examination of the documents referred to in point 3.1 to check that the lift conforms with the approved type described in the EU-type examination certificate pursuant to Schedule IV, Part B;

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

3.3. The tests of the lift shall include at least the following:

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

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

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

The rated load shall be that referred to in Schedule I, point 5.

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

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

The notified body shall fill in the corresponding pages in the logbook referred to in Schedule I, point 6.2.

If the notified body refuses to issue the final inspection certificate, it shall state the detailed reasons for refusal and indicate the necessary corrective measures to be taken. Where the installer again applies for final inspection, he shall apply to the same notified body.

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

5.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of these regulations, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.

5.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity and the final inspection certificate at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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

7. **Authorised representative**

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

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Schedule VI

CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE FOR SAFETY COMPONENTS FOR LIFTS

(module E)

1. Conformity to type based on product quality assurance for safety components for lifts is the part of the conformity assessment procedure whereby a notified body assesses the quality system of a manufacturer in order to ensure that the safety components for lifts are manufactured and monitored in conformity with the type described in the EU- type examination certificate, satisfy the applicable requirements of Schedule I and will enable a lift to which they are correctly incorporated to satisfy those requirements.

2. **Obligations of the manufacturer**

The manufacturer shall operate an approved quality system for final inspection and testing of the safety components for lifts as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system for the safety components for lifts concerned with a single notified body of his choice.

The application shall include:

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

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

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

(d) all relevant information on the safety components for lifts to be manufactured;

(e) the documentation concerning the quality system;

(f) the technical documentation of the approved safety components for lifts and a copy of the EU-type examination certificate.

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3.2. Under the quality system, each safety component for lifts shall be inspected and appropriate tests as set out in the relevant harmonised standards or equivalent tests shall be carried out in order to ensure that it meets the conditions referred to in point 1. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

(a) the quality objectives;

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

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

(d) the means of monitoring the effective operation of the quality system; and

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Schedule I.

The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 3.1(f) in order to verify the manufacturer's ability to identify the relevant requirements of these regulations and to carry out the necessary examinations with a view to ensuring compliance of the safety components for lifts with those requirements.

The decision shall be notified to the manufacturer. The notification shall

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contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer or his authorised representative shall keep the notified body which has approved the quality system informed of any intended changes of the quality system.

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

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

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

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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

(a) the quality system documentation;

(b) the technical documentation;

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

4.3. The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

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

At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer, with

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a visit report and, if a test has been carried out, with a test report.

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

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.

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

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

(a) the technical documentation referred to in point 3.1(f);

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

(c) the information relating to the change referred to in point 3.5;

(d) the decisions and reports from the notified body which are referred to in the third paragraph of point 3.5 and in points 4.3 and 4.4.

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

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

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

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his

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responsibility, provided that they are specified in the mandate.

Schedule VII

CONFORMITY BASED ON FULL QUALITY ASSURANCE FOR SAFETY COMPONENTS FOR LIFTS

(module H)

1. Conformity based on full quality assurance for safety components for lifts is the conformity assessment procedure whereby a notified body assesses the quality system of a manufacturer to ensure that the safety components for lifts are designed, manufactured, inspected and tested in order to satisfy the applicable requirements of Schedule I and to enable a lift to which they are correctly incorporated to satisfy those requirements.

2. **Obligations of the manufacturer**

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

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice. The application shall include:

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

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

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

(d) the technical documentation described in point 3 of Schedule IV, Part A for one model of each category of safety component for lifts to be manufactured;

(e) the documentation on the quality system;

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

3.2. The quality system shall ensure compliance of the safety components for lifts with the conditions referred to in point 1. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;

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

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

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

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

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

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In addition to experience in quality management systems, the auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Schedule I. The audit shall include an assessment visit to the manufacturer's premises.

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

The decision shall be notified to the manufacturer and, where appropriate, to his authorised representative. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body which has approved the quality system informed of any intended change to the quality system.

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

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

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

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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

(a) the quality system documentation;

(b) the quality records provided for in the design part of the quality system such as results of analyses, calculations, tests;

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

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

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

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

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

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.

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

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

(a) the documentation referred to in point 3.1(e);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the change referred to in the first paragraph of point 3.5;

(d) the decisions and reports from the notified body referred to in the third paragraph of point 3.5. and in points 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system

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approval decision(s) issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of approval decisions refused, suspended or otherwise restricted.

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

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

The notified body shall keep a copy of the approval decision issued, schedules and additions, as well as the technical documentation for 15 years from the date of their issue.

8. **Authorised representative**

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

Schedule VIII

CONFORMITY BASED ON UNIT VERIFICATION FOR LIFTS

(module G)

1. Conformity based on unit verification is the conformity assessment procedure whereby a notified body assesses whether a lift complies with the applicable essential health and safety requirements set out in Schedule I.

2. **Obligations of the installer**

2.1. The installer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the lift with the applicable essential health and safety requirements set out in Schedule I.

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

The application shall contain:

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

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well;

(b) the location where the lift is installed;

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

(d) the technical documentation.

3. The technical documentation shall allow an assessment of the conformity of the lift with the applicable essential health and safety requirements set out in Schedule I.

The technical documentation shall contain at least the following elements:

(a) a description of the lift;

(b) design and manufacturing drawings and diagrams;

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

(d) a list of the essential health and safety requirements taken into consideration;

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

(f) a copy of the EU-type examination certificates of the safety components for lifts incorporated in the lift;

(g) results of design calculations performed by or for the installer;

(h) test reports;

(i) a copy of the instructions referred to in point 6.2 of Schedule I.

4. **Verification**

The notified body chosen by the installer shall examine the technical

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documentation and the lift and carry out the appropriate tests as set out in the relevant harmonised standard(s), or equivalent tests, to check its conformity with the applicable essential health and safety requirements set out in Schedule I. The tests shall include at least the tests referred to in point 3.3 of Schedule V.

If the lift meets the essential health and safety requirements set out in Schedule I the notified body shall issue a certificate of conformity relating to the tests carried out.

The notified body shall fill in the corresponding pages of the logbook referred to in point 6.2 of Schedule I.

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

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

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

5.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of these regulations, and, under the responsibility of the notified body referred to in point 2.2, the latter's identification number adjacent to the CE marking in the car of each lift.

5.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The installer shall keep with the technical documentation a copy of the certificate of conformity at the disposal of the national authorities for 10 years from the date on which the lift is placed on the market.

7. **Authorised representative**

The installer's obligations set out in points 2.2 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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Schedule IX

CONFORMITY TO TYPE WITH RANDOM CHECKING FOR SAFETY COMPONENTS FOR LIFTS

(module C 2)

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

2. **Manufacturing**

   The manufacturer shall take all measures necessary to ensure that the manufacturing process and its monitoring ensure that the manufactured safety components for lifts meet the conditions referred to in point 1.

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

   The application shall include:

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

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

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

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

4. The notified body shall carry out or have carried out checks on safety components for lifts at random intervals. An adequate sample of the final safety components for lifts, taken on site by the notified body, shall be examined and appropriate tests set out in the relevant harmonised standards, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check whether the safety components for lifts meets the conditions referred to in point 1. In cases where one or more of the safety components for lifts checked do not conform, the notified body shall take appropriate measures.

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

The notified body shall issue a certificate of conformity to type with respect to the examinations and tests carried out.

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

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

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual safety component for lifts that meets the conditions referred to in point 1.

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

6. **Authorised representative**

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

Schedule X

CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE FOR LIFTS

(module E)

1. Conformity to type based on product quality assurance is the part of the conformity assessment procedure whereby a notified body assesses the product quality system of an installer to ensure that the lifts are in conformity with the approved type as described in the EU-type examination certificate or with a lift designed and manufactured under a full quality system approved in accordance with Schedule XI, and satisfy the applicable essential health and safety requirements set out in

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Schedule I.

2. **Obligations of the installer**

The installer shall operate an approved quality system for final inspection and testing of the lift as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The installer shall lodge an application for assessment of his quality system for the lifts concerned with a single notified body of his choice.

The application shall include:

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

(b) all relevant information on the lifts to be installed;

(c) the documentation on the quality system;

(d) the technical documentation of the lifts to be installed;

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

3.2. Under the quality system, each lift shall be examined and appropriate tests as set out in the relevant harmonised standards or equivalent tests shall be carried out in order to ensure its conformity with the applicable essential health and safety requirements set out in Schedule I.

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

It shall contain in particular an adequate description of:

(a) the quality objectives;

(b) the organisational structure, responsibilities and powers of the management with regard to product quality;

(c) the examinations and tests that will be carried out before placing on the market, including at least the tests laid down in point 3.3

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of Schedule V;

(d) the means of monitoring the effective operation of the quality system;

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Schedule I. The audit shall include an assessment visit to the premises of the installer and a visit to the installation site.

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

3.4. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.4.1. The installer shall keep the notified body which has approved the quality system informed of any intended change to the system.

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

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Regulation 19.

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

4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.

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4.2. The installer shall, for assessment purposes, allow the notified body access to the installation, inspection and testing locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation;

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

4.3. The notified body shall periodically carry out audits to ensure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

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

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

5. The installer shall, for 10 years after the last lift has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in point 3.4.1;

(d) the decisions and reports from the notified body which are referred to in the second paragraph of point 3.4.2 and in points 4.3 and 4.4.

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

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

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

7. **CE marking and EU declaration of conformity**

7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of these regulations, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.

7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. **Authorised representative**

The installer's obligations set out in points 3.1, 3.4.1, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Schedule XI

CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION FOR LIFTS

(module H1)

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

2. **Obligations of the installer**

The installer shall operate an approved quality system for the design, manufacture, assembly, installation, final inspection and testing of the lifts as specified in point 3, and shall be subject to surveillance as specified in point 4. The adequacy of the technical design of the lifts shall have been examined in accordance with point 3.3.

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3. **Quality system**

3.1. The installer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

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

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

(c) the documentation on the quality system;

(d) the technical documentation described in point 3 of Schedule IV, Part B;

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

3.2. The quality system shall ensure compliance of the lifts with the applicable essential health and safety requirements set out in Schedule I. All the elements, requirements and provisions adopted by the installer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and quality records.

It shall contain in particular an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards will not be applied in full, the means, including other relevant technical specifications that will be used to ensure that the applicable essential health and safety requirements set out in Schedule I will be met;

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

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

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

(f) the examinations and tests that will be carried out before (inspection of installation conditions: shaft, housing of machinery, etc.), during and after installation (including at least the tests laid down in point 3.3 of Schedule V);

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

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

3.3. Design examination

3.3.1. When the design is not entirely in accordance with harmonised standards, the notified body shall ascertain whether the design conforms to the essential health and safety requirements set out in Schedule I and, if it does, issue an EU design examination certificate to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.

3.3.2. Where the design does not satisfy the applicable essential health and safety requirements set out in Schedule I, the notified body shall refuse to issue an EU design examination certificate and shall inform the installer accordingly, giving detailed reasons for its refusal.

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

3.3.3. The installer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential health and safety requirements set out in Schedule 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

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the form of an addition to the original EU design examination certificate.

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

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

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

3.3.5. The installer shall keep a copy of the EU design examination certificate, its Schedules and additions together with the technical documentation at the disposal of the national authorities for 10 years after the lift has been placed on the market.

3.4. **Assessment of the quality system**

The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard.

The auditing team shall have at least one member with experience of assessment in the lift technology concerned and knowledge of the essential health and safety requirements set out in Schedule I. The audit shall include an assessment visit to the installer’s premises and a visit to an installation site.

The auditing team shall review the technical documentation referred to in point 3.1(d), to verify the installer’s ability to identify the applicable essential health and safety requirements set out in Schedule I and to carry out the necessary examinations with a view to ensuring compliance of the lift with those requirements.

The decision shall be notified to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

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3.5. The installer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

The installer shall keep the notified body that has approved the quality system informed of any intended change to the system.

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

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Regulation 19.

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

4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.

4.2. The installer shall, for assessment purposes, allow the notified body access to the design, manufacture, assembly, installation, inspection, testing and storage locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests;

(c) the quality records provided for in the part of the quality system concerning acceptance of supplies and installation, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

4.4. Additionally, the notified body may pay unexpected visits to the premises of the installer or to the installation site of a lift. At the time of such visits, the notified body may, where necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the installer with a visit report and, if

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tests have been carried out, with a test report.

5. The installer shall, keep at the disposal of the national authorities for a period ending 10 years after the lift has been placed on the market:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in the second paragraph of point 3.5;

(d) the decisions and reports from the notified body which are referred to in the fourth paragraph of point 3.5 and in points 4.3 and 4.4.

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

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

The notified body shall keep a copy of the approval decision issued, its Schedule and additions, as well as the technical documentation for 15 years from the date of their issue.

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

7. **CE marking and EU declaration of conformity**

7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of these regulations, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.

7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

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8. **Authorised representative**

The installer's obligations set out in points 3.1, 3.3.3, 3.3.5, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Schedule XII

CONFORMITY TO TYPE BASED ON PRODUCTION QUALITY ASSURANCE FOR LIFTS

(module D)

1. Conformity to type based on production quality assurance for lifts is the part of the conformity assessment procedure whereby a notified body assesses the production quality system of an installer to ensure that the lifts installed are in conformity with the approved type as described in the EU-type examination certificate or with a lift designed and manufactured under a quality system approved in accordance with Schedule XI, and satisfy the applicable essential health and safety requirements set out in Schedule I.

2. **Obligations of the installer**

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

3. **Quality system**

3.1. The installer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

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

(b) all relevant information for the lifts to be installed;

(c) the documentation on the quality system;

(d) the technical documentation of the lifts to be installed;

(e) a written declaration that the same application has not been

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lodged with any other notified body.

3.2. The quality system shall ensure compliance of the lifts with the applicable essential health and safety requirements set out in Schedule I.

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

It shall contain in particular an adequate description of:

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

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

(c) the examinations and tests that will be carried out before, during and after installation;

(d) the quality records, such as inspection reports and test data, calibration data, reports on the qualification of the personnel concerned;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

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

The audit shall include an assessment visit to the installer’s premises and a visit to an installation site.

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

3.4. The installer shall undertake to fulfil the obligations arising from the

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quality system as approved and to maintain it so that it remains adequate and efficient.

3.4.1. The installer shall keep the notified body that has approved the quality system informed of any intended change to the system.

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

It shall notify its decision to the installer or, where appropriate, to his authorised representative. The notification shall contain the conclusions of the assessment and the reasoned assessment decision.

The notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in accordance with Regulation 19.

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

4.1. The purpose of surveillance is to make sure that the installer duly fulfils the obligations arising out of the approved quality system.

4.2. The installer shall, for assessment purposes, allow the notified body access to the manufacture, assembly, installation, inspection, testing and storage locations, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation;

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

4.3. The notified body shall carry out periodic audits to make sure that the installer maintains and applies the quality system and shall provide the installer with an audit report.

4.4. Additionally, the notified body may pay unexpected visits to the installer. During such visits the notified body may, where necessary carry out tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the installer with a visit report and, if tests have been carried out, with a test report.

5. The installer shall, keep at the disposal of the national authorities for a

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period ending 10 years after the lift has been placed on the market:

(a) the documentation referred to in point 3.1(c);

(b) the technical documentation referred to in point 3.1(d);

(c) the information relating to the changes referred to in point 3.4.1;

(d) the decisions and reports from the notified body which are referred to in the second paragraph of point 3.4.2, and in points 4.3 and 4.4.

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

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

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

7. **CE marking and EU declaration of conformity**

7.1. The installer shall affix the CE marking in the car of each lift which satisfies the essential health and safety requirements of these regulations, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number adjacent to the CE marking in the car of each lift.

7.2. The installer shall draw up a written EU declaration of conformity for each lift and keep a copy of the EU declaration of conformity at the disposal of the national authorities for 10 years after the placing on the market of the lift. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. **Authorised representative**

The installer's obligations set out in points 3.1, 3.4.1, 5 and 7 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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STATEMENT OF THE EUROPEAN PARLIAMENT

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

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