Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 17,324, 6 ta' Diċembru, 2002
Taqsima B

L.N. 370 of 2002

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Lifts Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations :-

Citation and commencement

1.1. The title of these regulations is the Lifts Regulations, 2002.

1.2. These regulations shall become operative on such date as notified by the Authority in the Gazette.

1.2.1. Subject to regulation 1.2.2, these regulations shall not apply to a lift or safety component placed on the market and put into service on or before 30th June 2002, and which complies with any health and safety provisions with which it would have been required to comply for it to be placed on the market and put into service in Malta on this date.

1.2.2. The exclusion provided in regulation 1.2.1 does not apply in the case of a lift or a safety component which –

(a) unless required to bear the CE marking pursuant to any other regulations, bears the CE marking or an inscription liable to be confused with it; or

(b) bears or is accompanied by any other indication, howsoever expressed, that it complies with the Lifts Directive 95/16/EC.

1.2.3. The requirements of these regulations shall not apply to a lift insofar as and to the extent that the relevant essential health and safety requirements relate to risks wholly or partly covered by other regulations applicable to that lift.

Scope.

2.1. These regulations shall apply to lifts permanently serving buildings and constructions. It shall also apply to the safety components for use in such lifts listed in Annex IV of the Directive, which is set out in Schedule IV to these regulations.

2.2. These regulations shall not apply to:

- cableways, including funicular railways, for the public or private transportation of persons,
- lifts specially designed and constructed for military or police purposes,
- mine winding gear,
- theatre elevators,
- lifts fitted in means of transport, ·
- lifts connected to machinery and intended exclusively for access to the workplace,
- rack and pinion trains,
- construction-site hoists intended for lifting persons or persons and goods.

Definitions

3.1. For the purposes of these regulations, the following definitions shall apply:

3.1.1. "the Directive" means European Parliament and Council Directive 95/16/EC[1] on the approximation of the laws of the Member States relating to lifts.

3.1.2. "lift" means an appliance serving specific levels, having a car moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal and intended for the transport of:

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

3.1.2.1. Lifts moving along a fixed course even where they do not move along guides which are rigid shall fall within the scope of these regulations (for example, scissor lifts).

3.1.3. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC[2] of the European Parliament and of the Council laying down a

[1] OJ No. L213, 07-09-95, P.01.
[2] OJ No. L204, 21-07-98, P.37.

procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC[3] of the European Parliament and of the Council.

3.1.4. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.5. "Community" means the European Community.

3.1.6. "OJ" means the Official Journal of the European Communities.

3.1.7. "CE marking" means marking as set out in Annex III of the Directive which is set out in Schedule III to these regulations.

3.1.8. "installer of a lift" means the natural or legal person who takes responsibility for the design, manufacture, installation and placing on the market of the lift and who affixes the CE marking and draws up the EC declaration of conformity.

3.1.9. "placing on the market of the lift" shall occur when the installer first makes the lift available to the user.

3.1.10. "safety component" means a component as listed in Annex IV of the Directive, which is set out in Schedule IV to these regulations.

3.1.11. "manufacturer of the safety components" means the natural or legal person who takes responsibility for the design and manufacture of the safety components and who affixes the CE marking and draws up the EC declaration of conformity.

3.1.12. "authorized representative" means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.13. "model lift" means a representative lift whose technical dossier shows the way in which the essential safety requirements will be met for lifts which conform to the model lift defined by objective parameters and which uses identical safety components.

[3] OJ No. L217, 05-08-98, P.18.

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

3.1.13.2. 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 safety requirements.

3.1.14. "notified body" means a body which has been appointed by a Member State and notified to the Commission and the other Member States, pursuant to Article 9 (1) of the Lifts Directive, to carry out one or more of the conformity assessment procedures mentioned and referred to in regulation 6 of these regulations.

3.1.15. "responsible person" means:

(a) in the case of a lift, the installer of the lift;

(b) in the case of a safety component, the manufacturer of the safety component or his authorized representative; or

(c) where neither the installer of the lift nor the manufacturer of the safety component nor the latter's authorized representative, as the case may be, have fulfilled the requirements of these regulations applicable to the lift or safety component, the person who places the lift or the safety component on the local market.

3.1.15.1. Where a person-

(a) being the manufacturer of a lift or a safety component for his own use puts that lift or safety component, as the case may be, into service; or

(b) having imported a lift or a safety component from a country or territory outside the Community puts that lift or safety component, as the case may be, into service,for the purpose of these regulations, that person shall be deemed to have placed that lift or safety component on the market.

3.1.16. "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.

3.1.17. "relevant essential health and safety requirements" in relation to a lift or safety component means those provisions of the essential health and safety requirements referred to in Annex I of the Directive, which is set out in Schedule I to these regulations which are applicable to that particular lift or safety component, as the case may be.

Applicability.

4.1. The provisions of these regulations are applicable to all imported and locally manufactured:

(a) lifts permanently serving buildings or constructions; and
(b) safety components for use in such lifts.

4.1.1. No person may manufacture, import, place on the market or put into service any lift or safety component which do not comply with the provisions of these regulations.

4.1.2. Regulations 4.1 and 4.1.1 above shall not prohibit any person from possessing for supply at any time before it is supplied, offered for supply or exposed for supply in Malta for the first time, or before it is agreed for the first time to supply it in Malta, any lift or safety component referred to in regulation 2.1 of these regulations which has been manufactured or imported in Malta and which does not comply with the requirements of these regulations.

4.2. Nothing in these regulations shall preclude the placing on the market of any component, other than a safety component, -

(a) which is intended to be incorporated into a lift to which these regulations apply; and
(b) in respect of which a declaration is made by the manufacturer of that component or his authorized representative that the component is intended for such incorporation.

4.3. Nothing in these regulations with regard to the installation of a lift shall affect the application of the Construction Products Regulations, 2001.

4.4. For the purposes of regulations 5.1 to 5.7 of these regulations, a lift or a safety component shall not be regarded as being placed on the market or supplied by the exhibition at trade fairs and exhibitions of that lift or safety component, in respect of which the provisions of these regulations are not satisfied, if –

(a) a notice is displayed in relation to the lift or safety component in question to the effect –

(i) that it does not satisfy those provisions; and

(ii) that it may not be placed on the market or supplied until those provisions are satisfied, in the case of a lift, by the installer of the lift and, in the case of a safety component, by the manufacturer of the safety component or his authorized representative; and

(b) adequate safety measures are taken to ensure the safety of persons.

General Requirements

5.1. Subject to regulation 4.4 of these regulations, no person who is responsible shall place on the market and put into service any lift unless the requirements of regulation 5.2 of these regulations have been complied with in relation to it.

5.2. The requirements in respect of any lift are that –

(a) it satisfies the relevant essential health and safety requirements and for the purpose of satisfying those requirements–

1. where a transposed harmonised standard covers one or more of the relevant essential health and safety requirements, any lift constructed in accordance with that transposed harmonised standard shall be presumed to comply with that or, as the case may be, those essential health and safety requirements; and

2. by calculation or on the basis of design plans, it is permitted to demonstrate the similarity of a range of equipment to satisfy the essential safety requirements;

(b) the appropriate conformity assessment procedure in respect of the lift has been carried out in accordance with regulation 6.1 of these regulations;

(c) the CE marking has been affixed to it by the installer of the lift in accordance with Annex III of the Directive, which is set out in Schedule III to these regulations;

(d) a declaration of conformity has been drawn up in respect of it by the installer of the lift containing the information listed in Part B of Annex II of the Directive, which is set out in Schedule II to these regulations, taking account of the specifications given in the Schedule used for the conformity assessment procedure; and

(e) it is in fact safe.

5.3. Any technical documentation or other information in relation to a lift required to be retained under the conformity assessment procedure used shall be retained by the person specified in that respect in that conformity assessment procedure for any period specified in that procedure.

5.4. Subject to regulation 4.4 of these regulations, no person who is a responsible person shall place on the market and put into service any safety component unless the requirements of regulation 5.5 of these regulations have been complied with in relation to it.

5.5. The requirements in respect of any safety component are that –

(a) it satisfies the relevant essential health and safety requirements and for the purpose of satisfying those requirements where a transposed harmonised standard covers one or more of the relevant essential health and safety requirements, any safety component constructed in accordance with that transposed harmonised standard shall be presumed to be suitable to enable a lift on which it is correctly installed to comply with that or, as the case may be, those essential health and safety requirements;

(b) subject to regulation 5.6 of these regulations, the appropriate conformity assessment procedure in respect of the safety component has been carried out in accordance with regulation 6.1 of these regulations;

(c) the CE marking has been affixed to it, or on a label inseparably attached to the safety component, by the manufacturer of that safety component or his authorized representative in accordance with regulations 8.4 and 9.1 to 9.4 of these regulations and Schedule III to these regulations;

(d) a declaration of conformity has been drawn up in respect of it by the manufacturer of that safety component or his authorized representative containing the information listed in Part A of Annex II of the Directive, which is set out in Schedule II to these regulations, taking account of the specifications given in the Schedule used for the conformity assessment procedure; and

(e) it is in fact safe.

5.6. Any technical documentation or other information in relation to a safety component required to be retained under the conformity assessment procedure used shall be retained by the person specified in that respect in that conformity assessment procedure for any period specified in that procedure.

5.7. Subject to regulations 4.1.2 and 4.4 of these regulations, it shall be the duty of any person who supplies any lift or safety component but who is not a person to whom regulations 5.1 to 5.6 above apply, to ensure that the lift or safety component, as the case may be, is safe.

5.8. The person responsible for work on the building or construction where a lift is to be installed and the installer of the shaft shall –

(a) keep each other informed of the facts necessary for, and

(b) take the necessary steps to ensure,the proper operation and safe use of the lift: in particular it shall be ensured that shafts intended for lifts do not contain any piping or wiring or fittings other than that necessary for the operation and safety of that lift.

5.9. Where, in the case of a lift, for the purposes of regulation 5.2(b) the appropriate conformity assessment procedure is one of the procedures set out in regulation 6.2 (a), (b) or (c), the person responsible for the design of the lift must supply to the person responsible for the construction, installation and testing all necessary documents and information for the latter person to be able to operate in absolute security.

5.10. A copy of the declaration of conformity referred to in regulation 5.2(d) and 5.5(d) shall –

(a) in the case of a lift, be supplied to the Commission, the Member States and any other Notified Bodies, on request, by the installer of the lift together with a copy of the reports of the tests involved in the final inspection to be carried out as part of the appropriate conformity assessment procedure referred to in regulation 5.2 (b); and

(b) be retained, by the person who draws up that declaration, for a period of 10 years –

(i) in the case of a lift, from the date on which the lift was placed on the market; and

(ii) in the case of a safety component, from the date on which safety components of that type were last manufactured by that person.

Conformity assessment procedure.

6.1. For the purposes of regulations 5.2 (b) and 5.5 (b), the appropriate conformity assessment procedure shall be –

(a) in the case of a lift, one of the procedures set out in regulation 6.2 of these regulations; and

(b) in the case of a safety component, one of the procedures set out in regulation 6.3 of these regulations.

6.2. The procedures referred to in regulation 6.1 of these regulations are as follows:

(a) if the lift was designed in accordance with a lift having undergone an EC type-examination as referred to in Annex V of the Directive, which is set out in Schedule V to these regulations, it shall be constructed, installed and tested by implementing either –

(i) the final inspection referred to in Annex VI of the Directive, which is set out in Schedule VI to these regulations; or

(ii) the quality assurance system referred to in Annex XII of the Directive, which is set out in Schedule XII to these regulations; or

(iii) the quality assurance system referred to in Annex XIV of the Directive, which is set out in Schedule XIV to these regulations;

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

(b) if the lift was designed in accordance with a model lift having undergone an EC type-examination as referred to in Annex V of the Directive, which is set out in Schedule V to these regulations, it shall be constructed, installed and tested by implementing either –

(i) the final inspection referred to in Annex VI of the Directive, which is set out in Schedule VI to these regulations; or

(ii) the quality assurance system referred to in Annex XII of the Directive, which is set out in Schedule XII to these regulations; or

(iii) the quality assurance system referred to in Annex XIV of the Directive, which is set out in Schedule XIV to these regulations,

and all permitted variations between a model lift and the lifts forming part of the lifts derived from that model lift must be clearly specified (with maximum and minimum values) in the technical dossier required as part of the appropriate conformity assessment procedure;

(c) if the lift was designed in accordance with a model lift for which a quality assurance system pursuant to Annex XIII of the Directive, which is set out in Schedule XIII to these regulations was implemented, supplemented by an examination of the design if the latter is not wholly in accordance with the harmonised standards, it shall be installed and constructed and tested by implementing, in addition either –

(i) the final inspection referred to in Annex VI of the Directive, which is set out in Schedule VI to these regulations; or

(ii) the quality assurance system in accordance with Annex XII of the Directive, which is set out in Schedule XII to these regulations; or

(iii) the quality assurance system in accordance with Annex XIV of the Directive, which is set out in Schedule XIV to these regulations;

(d) the unit verification procedure, referred to in Annex X of the Directive, which is set out in Schedule X to these regulations, by a notified body; or

(e) the quality assurance system in accordance with Annex XIII of the Directive, which is set out in Schedule XIII to these regulations, supplemented by an examination of the design if the latter is not wholly in accordance with the transposed harmonised standards.

6.3. The procedures referred to in regulation 6.1 (b) of these regulations are as follows:

(a) to submit the model of the safety component for EC type-examination in accordance with Annex V of the Directive, which is set out in Schedule V to these regulations and for production checks by a notified body in accordance with Annex XI of the Directive, which is set out in Schedule XI to these regulations; or

(b) to submit the model of the safety component for EC type-examination in accordance with Annex V of the Directive, which is set out in Schedule V to these regulations and operate a quality assurance system in accordance with Annex VIII of the Directive, which is set out in Schedule VIII to these regulations for checking production; or

(c) to operate a full quality assurance system in accordance with Annex IX of the Directive, which is set out in Schedule IX to these regulations.

Withdrawal and prohibition from market.

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

7.1.1. The Director of Consumer Affairs shall immediately inform the Consumer and Industrial Goods Directorate[4] of the Malta Standards Authority of any such measure, indicating the reasons for its decision and in particular whether non-conformity is due to:

(a) failure to satisfy the essential requirements referred to in regulations 5.2 and 5.5 of these regulations;

(b) incorrect application of the standards referred to in regulations 5.2 and 5.5 of these regulations and Article 5 (2) of the Directive;

(c) shortcomings in the standards referred to in regulations 5.2 and 5.5 of these regulations and Article 5 (2) of the Directive themselves.

7.2. Any decision taken pursuant to these regulations which restricts the placing on the market and putting into service of a lift or a safety component shall state the exact grounds on which it is based.

[4] L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

7.2.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

7.3. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 7.1, 7.1.1, 7.2 and 7.2.1.

Conformity.

8.1. Subject to regulation 8.2 of these regulations, a lift or safety component which –

(a) bears the CE marking or, in the case of a safety component, the label attached to it bears that marking in accordance with regulations 5.2 (c) and 5.5 (c) of these regulations; and

(b) is accompanied by an EC declaration of conformity in accordance with regulation 5.2 (d) or 5.5 (d),

shall be taken to conform with all the provisions of these regulations, which apply to it, including the appropriate conformity assessment procedure specified in regulations 6.1 to 6.3 of these regulations, unless there are reasonable grounds for suspecting that it does not so conform.

8.2. Regulation 8.1 of these regulations does not apply in relation to the Director of Consumer Affairs where a person fails or refuses to make available to the Director of Consumer Affairs the documentation which he is required, by the conformity assessment procedure which applies to that lift or safety component, to retain.

8.3. Where in the case of a lift or a safety component, any of the requirements of regulations 5.1 to 6.3 of these regulations to be fulfilled by the installer of the lift or the manufacturer of the safety component or, in the case of the latter, his authorized representative, have not been so fulfilled such requirements may be fulfilled by the person who places that lift or safety component on the market.

8.3.1. Nothing in regulation 8.3 of these regulations shall affect the power of the Director of Consumer Affairs to take action under regulation 9.4 of these regulations in respect of the installer of the lift, the manufacturer of the safety component or, in the case of the latter, his authorized representative in respect of a contravention of or a failure to comply with any of those requirements.

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

8.4.1. However, where one or more of these Directives allows the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the installer of the lift or the manufacturer of the safety components.

8.4.2. In this case, particulars of the Directives applied, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying the lift or safety component.

CE Conformity Marking.

9.1. The CE marking shall consist of the initials CE. Annex III of the Directive, reproduced in Schedule III to these regulations sets out the model to be used.

9.2. The CE marking shall be affixed to every lift car distinctly and visibly in accordance with Section 5 of Annex I of the Directive, which is set out in Schedule I to these regulations and shall be affixed on each of the safety components listed in Annex IV of the Directive, which is set out in Schedule IV to these regulations or, where that is not possible, on a label inseparably attached to the safety component.

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

9.4. Without prejudice to regulation 7.1 of these regulations:

(a) where it is established that the CE marking has been affixed irregularly, the installer of the lift, the manufacturer of the safety component or the authorized representative of the latter shall be obliged by the Director of Consumer Affairs to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Director of Consumer Affairs;

(b) should non-conformity persist, the Director of Consumer Affairs must take all appropriate measures to restrict or prohibit the placing on the market of the safety component in question or to ensure that it is withdrawn from the market and prohibit the lift from being used and inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority, which in turn shall inform the Commission accordingly.

Revokes L.N. 249 of 2001.

10.1 The Lifts Regulations, 2001 are hereby being revoked.

Schedule I

Based on Annex I of the Directive

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

PRELIMINARY REMARKS

1. Obligations under essential health and safety requirements apply only where the lift or safety component is subject to the hazard in question when used as intended by the installer of the lift or the manufacturer of the safety components.

2. The essential health and safety requirements contained in 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 must be designed and built in such a way as to approximate to those objectives.

3. The safety-component manufacturer and the installer of the lift are under an obligation to assess the hazards in order to identify all those which apply to their products; they must then design and construct them taking account of the assessment.

4. In accordance with Article 14 of the Directive, the essential requirements laid down in Directive 89/106/EEC[5], not included in this Directive, apply to lifts.

1. GENERAL

1.1. Application of Directive 98/37/EC[6], as amended by Directives 98/79/EC.

Where the relevant hazard exists and is not dealt with in this Schedule, the essential health and safety requirements of Annex I to Directive 98/37/EC apply. The essential requirement of Section 1.1.2 of Annex I to Directive 98/37/EC must apply in any event.

1.2. Car

The 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.

In the case of lifts 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

[5] Adopted through LN 270 of 2001: Construction Products Regulations, 2001.
[6] Adopted through LN 250 of 2001: Machinery Regulations, 2001.

do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.

1.3. **Means of suspension and means of support**

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

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

1.4. **Control of loading (including overspeed)**

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

1.4.2. Lifts must be equipped with an overspeed governor.

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

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

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

1.5. **Machinery**

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

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

1.6. **Controls**

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

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

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

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

- there can be no possible confusion with circuits which do not have any direct connection with the lift,
- the power supply can be switched while on load,
- movements of the lift are dependent on electrical safety devices in a separate electrical safety circuit,
- a fault in the electrical installation does not give rise to a dangerous situation.

2. HAZARDS TO 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, 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:

- starting movement of the car, whether or not deliberately activated, unless all landing doors are shut and locked,
- 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. HAZARDS TO PERSONS IN THE CAR

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

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

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

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

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

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

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

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

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

4. OTHER HAZARDS

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

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

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

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

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

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

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

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

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

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

5. MARKING

5.1. In addition to the minimum particulars required for any machine pursuant to Section 1.7.3 of Annex I to Directive 98/37/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 FOR USE

6.1. The safety components referred to in Annex IV of the Directive, which is set out in Schedule IV to these regulations must be accompanied by an instruction manual drawn up in Maltese or in any other language of the Community acceptable to the installer of the lift, so that:

- assembly,
- connection,
- adjustment, and
- maintenance,

can be carried out effectively and without danger.

6.2. Each lift must be accompanied by documentation drawn up in Maltese or in any other language of the Community acceptable to the Maltese authorities. The documentation shall contain at least:

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

- a logbook in which repairs and, where appropriate, periodic checks can be noted.

Schedule II

Based on Annex II of the Directive

A. Content of the EC declaration of conformity for safety components[7]

The EC declaration of conformity must contain the following information:

- name and address of the manufacturer of the safety components[8].
- where appropriate, name and address of his authorized representative[8].
- description of the safety component, details of type or series and serial number (if any),
- safety function of the safety component, if not obvious from the description,
- year of manufacture of the safety component,
- all relevant provisions with which the safety component complies,
- where appropriate, reference to harmonized standards used,
- where appropriate, name, address and identification number of the notified body which carried out the EC type-examination in accordance with regulation 6.3 (a) and (b) of these regulations,
- where appropriate, reference to the EC type-examination certificate issued by that notified body,
- where appropriate, name, address and identification number of the notified body which carried out the production checks in accordance with regulation 6.3 (a) of these regulations,
- where appropriate, name, address and identification number of the notified body which checked the system of quality assurance implemented by the manufacturer in accordance with regulation 6.3 (c) of these regulations,
- identification of the signatory empowered to act on behalf of the manufacturer of the safety components or his authorized representative.

B. Content of the EC declaration of conformity for installed lifts[9]

The EC declaration of conformity must contain the following information:

- name and address of the installer of the lift[10],
- description of the lift, details of the type or series, serial number and address where the lift is fitted,
- year of installation of the lift,

[7] The declaration must be drafted in the same language as the instruction manual referred to in Annex I of the Directive, which is set out in Schedule I, Section 6.1, and be either typewritten or printed

[8] Business name, full address, in the case of an authorized representative, also indicate the business name and address of the manufacturer of the safety components.

[9] This declaration must be drafted in the same language as the instruction manual referred to in Annex I of the Directive, which is set out in Schedule I, Section 6.2, and be either typewritten or printed

[10] Business name and full address

- all relevant provisions to which the lift conforms,

- where appropriate, reference to harmonized standards used,

- where appropriate, name, address and identification number of the notified body which carried out the EC type-examination of the model of the lift in accordance with regulation 6.2 (a) and (b) of these regulations,

- where appropriate, reference of the EC type-examination certificate,

- where appropriate, name, address and identification number of the notified body which carried out the verification of the lift in accordance with regulation 6.2 (d) of these regulations,

- where appropriate, name, address and identification number of the notified body which carried out the final inspection of the lift in accordance with the first indent of regulation 6.2 (a), (b) and (c) of these regulations.

- where appropriate, name, address, and identification number of the notified body which inspected the quality assurance system implemented by the installer in accordance with the second and third indents of regulation 6.2 (a), (b), (c) and (e) of these regulations,

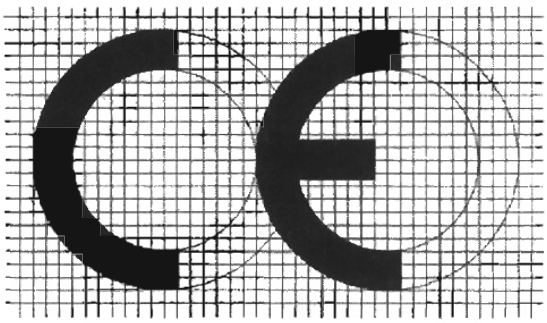
- identification of the signatory having been empowered to act on behalf of the lift installer.

Schedule III

Based on Annex III to the Directive

CE CONFORMITY MARKING

The CE conformity marking shall consist of the initials 'CE' taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

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

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale safety components.

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

- the procedures referred to in regulation 6.3 (b) or (c),
- the procedures referred to in regulation 6.2.

Schedule IV

Based on Annex IV of the Directive

LIST OF SAFETY COMPONENTS REFERRED TO IN REGULATION 2.1 AND REGULATION 6.3

1. Devices for locking landing doors.

2. Devices to prevent falls referred to in Section 3.2 of Annex I of the Directive, which is set out in Schedule I to these regulations, to prevent the car from falling or unchecked upward movements.

3. Overspeed limitation devices.

4. (a) Energy-accumulating shock absorbers:

- either non-linear,
- or with damping of the return movement.

(b) Energy-dissipating shock absorbers.

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

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

Schedule V

Based on Annex V of the Directive

EC TYPE-EXAMINATION (module B)

A. EC type-examination of safety components

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative specimen of a safety component will permit the lift to which it is correctly fitted to satisfy the relevant requirements of the regulations.

2. The application for EC type-examination must be lodged by the manufacturer of the safety component, or his authorized representative, with a notified body of his choice.

The application must include:

- the name and address of the manufacturer of the safety component and of his authorized representative, if the application is made by the latter, and the place of manufacture of the safety components,
- a written declaration that the same application has not been lodged with any other notified body,
- a technical dossier,
- a representative specimen of the safety component or details of the place where it can be examined. The notified body may make reasoned requests for further specimens.

3. The technical dossier must allow an assessment of the conformity and adequacy of the safety component to enable a lift to which it is correctly fitted to conform with the provisions of the regulations.

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

- a general description of the safety component, 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),
- design and manufacturing drawings or diagrams,
- essential requirement(s) taken into consideration and the means adopted to satisfy it (them) (e.g. a harmonized standard),
- results of any tests or calculations performed or subcontracted by the manufacturer,
- a copy of the assembly instructions for the safety components,
- steps taken at the manufacturing stage to ensure that series-produced safety components conform to the safety component examined.

4. The notified body must:

- examine the technical dossier to assess how far it can meet the desired aims,
- examine the safety component to check its adequacy in terms of the technical dossier,
- perform or have performed the appropriate checks and tests necessary to check whether the solutions adopted by the manufacturer of the safety component meet the requirements of the regulations allowing the safety component to carry out its function when correctly fitted on a lift.

5. If the representative specimen of the safety component complies with the provisions of the regulations applicable to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer of the safety component, the conclusions of the check, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

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

6. The manufacturer of the safety component or his authorized representative or Malta, must inform the notified body of any alterations, even of a minor nature, which he has made or plans to make to the approved safety component, including new extensions or variants not specified in the original technical dossier (see the first indent of Section 3). The notified body must examine the alterations and inform the applicant whether the EC type-examination certificate remains valid[1].

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

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

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

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

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

9. The manufacturer of the safety component or his authorized representative must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of 10 years after the last safety component has been manufactured.

Where neither the manufacturer of a safety component nor his authorized representative is established in the Community or Malta, the obligation to keep the technical documentation available falls to the person who places the safety component on the Community or Maltese market.

B. EC type-examination of lifts

1. EC type-examination is the procedure whereby a notified body ascertains and certifies that a model lift, or that a lift for which there is no provision for an extension or variant, satisfies the requirements of the regulations.

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

The application must include:

- the name and address of the installer of the lift,
- a written declaration that the same application has not been lodged with any other notified body,
- a technical dossier,
- details of the place where the model lift can be examined. The model lift submitted for examination must include the terminal parts and be capable of serving at least three levels (top, middle and bottom).

3. The technical dossier must allow an assessment of the conformity of the lift with the provisions of the regulations and an understanding of the design and operation of the lift.

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

- a general description of the representative model of the lift. The technical dossier should indicate clearly all possible extensions to the representative model of the lift under examination (see regulation 3 of these regulations),
- design and manufacturing drawings or diagrams,
- essential requirements taken into consideration and the means adopted to satisfy them (e.g. a harmonized standard),
- a copy of the EC declarations of conformity of the safety components used in the manufacture of the lift,
- results of any tests or calculations performed or subcontracted by the manufacturer,

- a copy of the lift instruction manual,
- steps taken at the installation stage to ensure that the series-produced lift conforms to the provisions of the regulations.

4. The notified body must:

- examine the technical dossier to assess how far it can meet the desired aims,
- examine the representative model of the lift to check that it has been manufactured in accordance with the technical dossier,
- perform or have performed the appropriate checks and tests necessary to check that the solutions adopted by the installer of the lift meet the requirements of the regulations and allow the lift to comply with them.

5. If the model lift complies with the provisions of the regulations applicable to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the name and address of the lift installer, the conclusions of the check, any conditions of validity of the certificate and the particulars necessary to identify the approved type.

The Commission, the Member States and the other notified bodies may obtain a copy of the certificate and, on a reasoned request, a copy of the technical dossier and reports of examinations, calculations and tests carried out.

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

6. The installer of the lift must inform the notified body of any alterations, even of a minor nature, which he has made or plans to make to the approved lift, including new extensions or variants not specified in the original technical dossier (see the first indent of Section 3). The notified body must examine the alterations and inform the applicant whether the EC type-examination certificate remains valid[1].

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

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

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

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

9. The installer of the lift must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of at least 10 years after the last lift has been manufactured in conformity with the representative model of the lift.

Schedule VI

Based on Annex VI of the Directive

FINAL INSPECTION

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

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

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

4. A notified body chosen by the installer of the lift shall carry out or have carried out the final inspection of the lift about to be placed on the market. The appropriate tests and checks defined by the applicable standard(s) referred to in Article 5 of the Directive and regulations 5.2 and 5.5 of these regulations, or equivalent tests, must be carried out in order to ensure conformity of the lift with the relevant requirements of the regulations.

These checks and tests shall cover in particular:

(a) examination of the documentation to check that the lift conforms with the representative model of the lift approved in accordance with Schedule V, Section B to these regulations;

(b) - 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.),

- 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,
- static test with a load equal to 1.25 times the nominal load.

The nominal load shall be that referred to in Annex I of the Directive, which is set out in Schedule I, Section 5 to these regulations.

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

5. The notified body must receive the following documents:

- the plan of the complete lift,
- the plans and diagrams necessary for final inspection, in particular control circuit diagrams,
- a copy of the instruction manual referred to in Annex I of the Directive, which is set out in Schedule I, Section 6.2 of these regulations.

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

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

The notified body shall fill in the corresponding pages in the logbook referred to in Annex I, Section 6.2 of the Directive, which is set out in Schedule I to these regulations.

If the notified body refuses to issue the final inspection certificate, it must state the detailed reasons for refusal and recommend means whereby acceptance may be obtained.

Where the installer of the lift again applies for final inspection, he must apply to the same notified body.

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

Schedule VII

Based on Annex VII of the Directive

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

1. The body, its director and the staff responsible for carrying out verification operations may not be the designer, builder, supplier or manufacturer of safety components or installer of the lifts which they inspect, nor the authorized representative of any of these parties. Similarly, the body, its director and the staff responsible for supervising the quality assurance systems referred to in Article 8 of the Directive and regulation 6 of these regulations may not be the designer, builder, supplier or manufacturer of safety components or installer of the lifts which they inspect, nor the authorized representative of any of these parties. They may not become involved either directly or as authorized representatives in the design, construction, marketing or maintenance of the safety components or in the installation of lifts. This does not preclude the possibility of exchanges of technical information between the manufacturer of the safety components or the installer of the lift and the body.

2. The body and its staff must carry out the inspection or supervision operations with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of inspection or supervision.

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

4. The staff responsible for inspection must have:

- sound technical and professional training,

- satisfactory knowledge of the requirements for the tests they carry out and adequate experience of such tests,

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

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

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

7. The staff of the body must observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under these regulations or any provision of national law giving effect to it.

Schedule VIII

Based on Annex VII of the Directive

PRODUCT QUALITY ASSURANCE (module E)

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

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

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

3. Quality assurance system

3.1. The manufacturer of the safety component must lodge an application for assessment of his quality assurance system for the safety components concerned with a notified body of his choice.

The application must include:

- all relevant information for the safety components envisaged,
- the documentation on the quality assurance system,
- the technical documentation of the approved safety components and a copy of the EC type-examination certificates.

3.2. Under the quality assurance system, each safety component must be examined and appropriate tests as set out in the relevant standards referred to in Article 5 of the Directive and regulations 5.2 and 5.5 of these regulations or equivalent tests must be carried out in order to ensure its conformity to the relevant requirements of the regulations.

All the elements, requirements and provisions adopted by the manufacturer of the safety components must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality assurance system

documentation must ensure a common understanding of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

(a) the quality objectives;

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

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

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

(e) 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 must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard[12].

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the premises of the safety component manufacturer.

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

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

The manufacturer of the safety components or his authorized representative or Malta, must keep the notified body which has approved the quality assurance system informed of any intended updating of the quality assurance system.

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

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

[12] This harmonized standard will be MSA EN ISO 9001:2000, supplemented where necessary to take account of the specific features of safety components.

4. Surveillance under the responsibility of the notified body

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

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

- the quality assurance system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to ensure that the manufacturer of the safety components maintains and applies the quality assurance system and must provide an audit report to the manufacturer of the safety components.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer of the safety component.

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

5. The manufacturer must, for a period ending 10 years after the last safety component has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the third indent of the second paragraph of Section 3.1,
- the updating referred to in the second paragraph of Section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.4 and in Sections 4.3 and 4.4.

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

Schedule IX

Based on Annex IX of the Directive

FULL QUALITY ASSURANCE (module H)

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

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

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

3. Quality assurance system

3.1. The manufacturer must lodge an application for assessment of his quality assurance system with a notified body. The application must include:

- all relevant information on safety components,
- the documentation on the quality assurance system.

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

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

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and quality of the safety components,
- the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 5 of the Directive and regulations

5.2 and 5.5 of these regulations will not be applied in full, the means that will be used to ensure that the essential requirements of the regulations that apply to the safety components will be met,

- the design control and design verification techniques, processes and systematic actions that will be used when designing the safety components,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.,
- the means of monitoring the achievement of the required design and product quality and the effective operation of the quality assurance system.

3.3. The notified body must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume compliance with these requirements in respect of quality assurance systems that implement the relevant harmonized standard[13].

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the manufacturer's premises.

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

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

The manufacturer of the safety components or his authorized representative must keep the notified body which has approved the quality assurance system informed of any intended updating of the quality assurance system.

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

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

4. Surveillance under the responsibility of the notified body

[13] This harmonized standard will be MSA EN ISO 9001:2000, supplemented where necessary to take account of the specific features of safety components.

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

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

- the quality assurance system documentation,
- the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,
- the quality records provided for in the manufacturing part of the quality assurance system, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

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

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

5. The manufacturer of the safety components or his authorized representative must, for a period of 10 years after the last safety component has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second paragraph of Section 3.1,
- the updating referred to in the second paragraph of Section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.4 and in Sections 4.3 and 4.4.

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

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

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

Schedule X

Based on Annex X of the Directive

UNIT VERIFICATION
(module G)

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

2. The lift installer shall apply to a notified body of his choice for unit verification.

The application shall contain:

- the name and address of the installer of the lift and the location where the lift is installed,
- a written declaration to the effect that a similar application has not been lodged with another notified body,
- a technical dossier.

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

So far as relevant for conformity assessment, the technical dossier shall contain the following:

- a general description of the lift,
- design and manufacturing drawings and diagrams,
- the essential requirements in question and the solution adopted to meet them (e.g. harmonized standard),
- the results of any tests or calculations carried out or subcontracted by the installer of the lift,
- a copy of the instructions for use of the lift,
- a copy of the EC type-examination certificates of the safety components used.

4. The notified body must examine the technical dossier and the lift and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive and regulations 5.2 and 5.5 of these regulations, or equivalent tests, to ensure its conformity with the relevant requirements of these regulations.

If the lift meets the requirements of these regulations, the notified body shall affix, or cause to be affixed, its identification number adjacent to the CE marking in

accordance with Annex III of the Directive, which is set out in Schedule III to these regulations and shall draw up 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 Section 6.2 of Annex I of the Directive, which is set out in Schedule I to these regulations.

If the notified body refuses to issue the certificate of conformity, it must state in detail its reasons for refusing and indicate how conformity can be achieved. When the installer of the lift reapplies for verification he must apply to the same notified body.

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

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

Schedule XI

Based on Annex XI of the Directive

CONFORMITY TO TYPE WITH RANDOM CHECKING (module C)

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

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

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

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

Where neither the manufacturer of the safety components nor his authorized representative is established in the Community or Malta, the obligation to keep the technical documentation available falls to the person who places the safety components on the Community market or Maltese market.

4. A notified body chosen by the manufacturer must carry out or have carried out checks on safety components at random intervals. An adequate sample of the finished safety components, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 and regulations 5.2 and 5.5 of these regulations, or equivalent tests, must be carried out to check the conformity of production to the relevant requirements of the exultations. In those cases where one or more of the safety components checked do not conform, the notified body must take appropriate measures.

The points to be taken into account when checking the safety components 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 referred to in Annex IV of the Directive, which is set out in Schedule IV to these regulations.

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

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

Schedule XII

Based on Annex XII of the Directive

PRODUCT QUALITY ASSURANCE FOR LIFTS (module E)

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

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

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

3. Quality assurance system

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

The application must include:

- all relevant information for the lifts envisaged,
- the documentation on the quality assurance system,
- the technical documentation on the approved lifts and a copy of the EC type-examination certificates.

3.2. Under the quality assurance system, each lift must be examined and appropriate tests as set out in the relevant standards referred to in Article 5 and regulations 5.2 and 5.5 of these regulations or equivalent tests must be carried out in order to ensure its conformity to the relevant requirements of the regulations.

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

It must contain in particular an adequate description of:

(a) the quality objectives,

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

(c) the examinations and tests that will be carried out before placing on the market, including at the very least the tests laid down in Annex VI, 4 (b) of the Directive, which is set out in Schedule VI to these regulations,

(d) the means to verify the effective operation of the quality assurance system,

(e) 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 must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard[14].

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the premises of the lift installer and a visit to the installation site.

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

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

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

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

It must notify its decision to the lift installer. The notification must 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 installer of a lift duly fulfils the obligations arising out of the approved quality assurance system.

[14] This harmonized standard will be MSA EN ISO 9001:2000, supplemented where necessary to take account of the specific features of the lifts.

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

- the quality assurance system documentation,
- the technical documentation,
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

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

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 carry out tests or have them carried out in order to check the proper functioning of the quality assurance system where necessary and of the lift; it must provide the lift installer with a visit report and, if a test has been carried out, with a test report.

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

- the documentation referred to in the third indent of the second paragraph of Section 3.1,
- the updating referred to in the second paragraph of Section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.4 and in Sections 4.3 and 4.4.

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

Schedule XIII

Based on Annex XIII of the Directive

FULL QUALITY ASSURANCE FOR LIFTS (module H)

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

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

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

3. Quality assurance system

3.1. The installer of a lift must lodge an application for assessment of his quality assurance system with a notified body.

The application must include:

- all relevant information on the lifts, in particular information which makes for an understanding of the relationship between the design and operation of the lift and enables conformity with the requirements of the regulations to be assessed,
- the documentation on the quality assurance system.

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

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

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and quality of the lifts,
- the technical design specifications, including standards that will be applied and, where the standards referred to in Article 5 of the Directive and regulations

5.2 and 5.5 of these regulations will not be applied in full, the means that will be used to ensure that the requirements of the regulations that apply to the lifts will be met,

- the design control and design verification techniques, processes and systematic actions that will be used when designing the lifts,

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

- the corresponding assembly, installation and quality control techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before (inspection of installation conditions: shaft, housing of machinery, etc.), during and after installation (including at the very least the tests laid down in Annex VI, Section 4 (b) of the Directive, which is set out in Schedule VI to these regulations),

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

- the means of monitoring the achievement of the required design and installation quality and the effective operation of the quality assurance system.

3.3. Design inspection

When the design is not entirely in accordance with harmonized standards, the notified body must ascertain whether the design conforms to the provisions of the regulations and, if it does, issue an 'EC 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.

3.4. Assessment of the quality assurance system

The notified body must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume compliance with these requirements in respect of quality assurance systems that implement the relevant harmonized standard[15].

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the lift installer's premises and a visit to an installation site.

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

3.5. The lift installer must undertake to discharge the obligations arising from the quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

[15] This harmonized standard will be MSA EN ISO 9001:2000, supplemented where necessary to take account of the specific features of the lifts.

The lift installer must keep the notified body that has approved the quality assurance system informed of any intended updating of the quality assurance system.

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

It must notify its decision to the lift installer. The notification must 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 installer of a lift duly fulfils the obligations arising out of the approved quality assurance system.

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

- the quality assurance system documentation,
- the quality records provided for in the design part of the quality assurance system, such as results of analyses, calculations, tests, etc.,
- the quality records provided for in the part of the quality assurance system concerning acceptance of supplies and installation, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

4.3. The notified body must periodically carry out audits to make sure that the installer of a lift maintains and applies the quality assurance system and must provide the installer with an audit report.

4.4. Additionally, the notified body may pay unexpected visits to the premises of a lift installer or to the assembly site of a lift. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality assurance system where necessary; it must provide the lift installer with a visit report and, if a test has been carried out, with a test report.

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

- the documentation referred to in the second indent of the second paragraph of Section 3.1,
- the updating referred to in the second paragraph of Section 3.5,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.5 and in Sections 4.3 and 4.4.

Where the installer is not established in the Community or Malta, this obligation falls to the notified body.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality assurance systems issued and withdrawn.

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

Schedule XIV

Based on Annex XIV of the Directive

PRODUCTION QUALITY ASSURANCE (module D)

1. Production quality assurance is the procedure whereby the installer of a lift who satisfies the obligations of Section 2 ensures and declares that the lifts satisfy the requirements of the regulations that apply to them. The installer of the lift must affix the CE marking to each lift and draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in Section 4.

2. The installer of the lift must operate an approved quality assurance system for production, installation, final lift inspection and testing as specified in Section 3 and is subject to surveillance as specified in Section 4.

3. Quality assurance system

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

The application must include:

- all relevant information for the lifts,
- the documentation concerning the quality assurance system,
- the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. The quality assurance system must ensure compliance of the lifts with the requirements of the regulations that apply to them.

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

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the lifts,
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after installation[16],

[16] These tests include at least the tests provided for in Annex VI, Section 4 (b) of the Directive, which is set out in Schedule VI to these regulations.

- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required lift quality and the effective operation of the quality assurance system.

3.3. The notified body must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It presumes conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard[17].

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include an inspection visit to the installer's premises.

The decision must be notified to the installer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

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

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

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

It must notify its decision to the installer. The notification must 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 installer duly fulfils the obligations arising out of the approved quality assurance system.

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

- the quality assurance system documentation,
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

[17] This harmonized standard will be MSA EN ISO 9001:2000, supplemented where necessary to take account of the specific nature of the lifts.

4.3. The notified body must periodically carry out audits to make sure that the installer maintains and applies the quality assurance system and must provide an audit report to the installer.

4.4. Additionally the notified body may pay unexpected visits to the installer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The notified body must provide the installer with a visit report and, if a test has taken place, with a test report.

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

- the documentation referred to in the second indent of Section 3.1,
- the updating referred to in the second paragraph of Section 3.4,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.4, Sections 4.3 and 4.4.

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

7. Documentation and correspondence relating to the production quality assurance procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to it.

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