

L.N. 333 of 2002

**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)**

**Cableway Installations Designed to Carry People 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:-

1.1. The title of these regulations is Cableway Installations Designed to Carry People Regulations, 2000. Citation and commencement

1.2. These regulations shall become operative on the 1st January, 2003:

Provided that the requirement to provide information to the European Commission referred to in regulations 9.6 of these regulations shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

2.1. These regulations shall apply to cableway installations designed to carry persons. Scope.

2.2. For the purposes of these regulations “cableway installations designed to carry persons” shall mean installations made up of several components, designed, manufactured, assembled and put into service with the object of carrying persons.

2.2.1. These on-site installations are used for the carriage of persons in vehicles or by towing devices, whereby the suspension and, or traction is provided by cables positioned along the line of travel.

2.3. The installations concerned are:

2.3.1. Funicular railways and other installations with vehicles mounted on wheels or on other suspension devices where traction is provided by one or more cables;

2.3.2. Cable cars where the cabins are lifted and, or displaced by one or more carrier cables; this category also includes gondolas and chair lifts;

2.3.3. Drag lifts, where users with appropriate equipment are dragged by means of a cable.

2.4. These regulations shall not apply to:

2.4.1. Lifts within the meaning of Directive 95/16/EC¹,

2.4.2. Cable-operated tramways of traditional construction,

2.4.3. Installations used for agricultural purposes,

2.4.4. On-site or mobile equipment for use in fairgrounds and, or amusement parks which are designed for leisure purposes and not as a means for transporting persons,

2.4.5. Mining installations or on-site installations used for industrial purposes,

2.4.6. Cable-operated ferries,

2.4.7. Rack railways,

2.4.8. Chain-driven installations.

Definitions.

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

3.1.1. "The Directive" means Council Directive 2000/9/EC² of the European Parliament and of the Council of 20th March, 2000 relating to cableway installations designed to carry persons;

3.1.2. "Installation" shall mean the whole on-site system, consisting of infrastructure and the subsystems listed in Annex I of the Directive, which is set out in Schedule I hereto, where infrastructure specially designed for each installation and

¹ OJ No. L 213, 07-09-95, p. 01-31.

² OJ No. L 106, 03-05-2000, p. 21.

constructed on site shall mean the layout, system data, station structures and structures along the line, which are needed for the construction and the operation of the installation, including the foundations;

3.1.3. "Safety component" shall mean any basic component, set of components, subassembly or complete assembly of equipment and any device incorporated in the installation for the purpose of ensuring a safety function and identified by the safety analysis, the failure of which endangers the safety or health of persons, by their users, operating personnel or third parties;

3.1.4. "Main contractor" shall mean any natural or legal person who commissions the construction of an installation;

3.1.5. "Operability" shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary in order for the installation to operate safely;

3.1.6. "Maintainability" shall mean all the technical provisions and measures which have an impact on design and realisation and are necessary for maintenance designed to ensure that the installation operates safely;

3.1.7. "European specification" shall mean a common technical specification, a European technical approval or a national standard transposing a European standard;

3.1.8. "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/EC³ of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC⁴ of the European Parliament and of the Council;

3.1.9. "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 OJ No. L204, 21-07-98, P.37

⁴ OJ No. L217, 05-08-98, P.18

3.1.10. "OJ" means the Official Journal of the European Communities;

3.1.11. "Community" means the European Community;

3.1.12. "Essential safety requirements" means the requirements in Annex II of the Directive which is set out in Schedule II hereto;

3.1.13. "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 16 of the Directive, to carry out one or more of the conformity assessment procedures mentioned and referred to in regulation 8 of these regulations;

3.1.14. "CE marking" means the CE conformity marking consisting of the symbol "CE" as set out in Schedule IV to these regulations;

3.1.15. "Manufacturer" means the person:

3.1.15.1. who is primarily responsible for the design and construction of the installation so that it complies with the requirements of these regulations;

3.1.15.2. who is responsible for "re-building" or modifying an existing installation, and who in so doing is creating an "as-new" installation;

3.1.15.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported installations;

3.1.16. "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;

3.1.17. "Importer" means any person who places an installation from a foreign country on to the Community or Maltese

market so that he supplies such installation on the first occasion that it is supplied in the Community or Malta;

3.1.18. "Person who supplies installations" means wholesalers, distributors, retailers etc;

3.1.19. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly:

Provided that "supply" does not include exhibition at trade fairs and exhibitions of installations in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the installation in question to the effect:-

3.1.19.1. that it does not satisfy those provisions; and

3.1.19.2. that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.20. "Responsible person" in relation to installations means:

3.1.20.1. the manufacturer thereof;

3.1.20.2. the manufacturer's authorised representative; or

3.1.20.3. where the manufacturer is not established in the Community or Malta and he has not appointed an authorised representative, the person who places the installations on the Community or Maltese market.

3.1.21. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

4.1. These regulations shall apply to:

Applicability.

4.1.1. Installations built and put into service, as from its entry into force,

4.1.2. Subsystems and safety components placed on the market, as from its entry into force.

4.2. It concerns such harmonisation provisions as are necessary and sufficient in order to ensure and guarantee

compliance with the essential requirements referred to in regulation 5.4 of these regulations.

4.3. In the event that important characteristics, subsystems or safety components of existing installations undergo modifications for which a new authorisation for entry into service is required, such modifications and their repercussions on the installation as a whole must satisfy the essential requirements referred to in regulation 5.4 of these regulations.

4.4. These regulations shall apply without prejudice to other Community Directives, although compliance with the essential requirements laid down in these regulations may call for the application of special European Specifications established for that purpose.

4.5. No person may construct, import, place on the market or put into service any installation which does not comply with the provisions of these regulations.

General
requirements.

5.1. The references of European specifications, which may be common technical specifications, European technical approvals within the meaning of Directive 93/38/EEC⁵ or national standards used to transpose harmonised European standards, shall be published in the Official Journal of the European Communities.

5.2. In the absence of harmonised European standards, necessary measures shall be taken to inform parties concerned of those existing national standards and technical specifications which are regarded as important or useful for ensuring proper transposition of the essential requirements referred to in regulation 5.4 of these regulations.

5.3. Those technical specifications which are also required to supplement European specifications or other standards must not jeopardise compliance with the essential requirements referred to in regulation 5.4 of these regulations.

5.4. The installations and their infrastructure, subsystems and safety components of an installation must comply with the essential requirements which are laid down in Annex II of the Directive, which is set out in Schedule II hereto, and are applicable to them.

5.5. Where a national standard transposing a harmonised European standard the reference for which has been published in the Official Journal of the European Communities covers the essential safety

⁵OJ No. L 199, 09-08-93, p. 084-138.

requirements laid down in Annex II of the Directive, which is set out in Schedule II hereto, the installations and their infrastructure, subsystems and safety components of any installation constructed in accordance with the standard shall be presumed to comply with the relevant essential requirements.

5.6. At the request of the main contractor or his authorised contractor, all planned installations shall be subject to a safety analysis as defined in Annex III of the Directive, which is set out in Schedule III hereto, which covers all safety aspects of the system and its surroundings in the context of the design, realization and putting into service and makes it possible to identify from past experience risks liable to occur during operation.

5.7. The safety analysis shall be the subject of a safety report recommending the measures envisaged to deal with any such risks and including a list of the safety components and subsystems which must be covered by the provisions of Chapter II or III of the Directive, which are set out in regulations 5, 6, 7, 8, 9 and 11 of these regulations, as the case may be.

5.8. All necessary measures shall be taken to ensure that safety components:

5.8.1. are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in regulation 5.4 of these regulations,

5.8.2. are put into service only if they permit the construction of installations which are not liable to endanger the health or safety of persons or, where applicable, the safety of property when properly installed and maintained and used for their intended purpose.

5.9. These regulations shall not affect the entitlement to lay down, in compliance with the Treaty, such requirements as may be deemed necessary, to ensure that persons and in particular workers are protected when using the installations in question, provided that this does not mean that the installations are modified in a way not specified in the regulations.

5.10. All necessary measures shall be taken to ensure that subsystems within the meaning of Annex I of the Directive, which is set out in Schedule I hereto, are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in regulation 5.4 of these regulations.

5.11. Procedures for authorizing the construction and the putting into service of installations shall be laid down.

5.12. All appropriate measures shall be taken and procedures determined, to ensure that safety components and subsystems referred to in Annex I of the Directive, which is set out in Schedule I hereto, incorporated in installations are installed and put into service only if they permit the construction of installations which are not liable to endanger the safety and health of persons or, where applicable, the safety of property, when properly installed and maintained and used in accordance with their intended purpose.

5.13. Where it is considered that a safety component or subsystem referred to in Annex I has been designed or constructed using an innovative approach, all appropriate measures shall be taken and may make the construction and/or putting into service of an installation in which such innovative components or subsystems are to be used subject to special conditions.

5.14. All appropriate measures shall be taken to ensure that the installations are constructed and put into service only if they have been designed and constructed in such a way as to guarantee compliance with the essential requirements referred to in regulation 5.4 of these regulations.

5.15. The safety analysis, the EC declarations of conformity and the accompanying technical documentation relating to the safety components and subsystems referred to in Annex I of the Directive which is set out in Schedule I hereto, must be submitted by the main contractor or his authorised representative to the authority responsible for approving the installation, and a copy of them shall be kept at the installation.

5.16. It must be ensured that the safety analysis, the safety report and the technical documentation are provided and include all the documentation concerning the characteristics of the installation and, where appropriate, all the documents certifying the conformity of the safety components and subsystems referred to in Annex I of the Directive, which is set out in Schedule I hereto.

5.16.1. Documents must exist setting out the necessary conditions, including the restrictions of operation, and full details of servicing supervision, adjustment and maintenance.

5.17. It shall be ensured that an installation remains in operation only if it conforms to the conditions set out in the safety report.

5.18. Installations for which authorization has been given before the entry into force of these regulations and for which construction has not yet started must comply with the provisions of these regulations.

6.1. The free movement, placing on the market or putting into service in the Maltese territory of safety components intended to be used in an installation where such components comply with the provisions of these regulations, shall not be prohibited, restricted or impeded. Free movement.

6.2. The placing on the market of subsystems which comply with the provisions of these regulations, for use in an installation, may not be prohibited, restricted or impeded.

6.3. On the basis of the provisions referred to in regulation 5.11 of these regulations, the free movement of safety components and subsystems referred to in Annex I of the Directive, which is set out in Schedule I hereto, which are accompanied by an EC declaration of conformity within the meaning of Article 7 or Article 10 of the Directive⁶ may not be prohibited, restricted or hindered.

6.4. Without prejudice to other legislative provisions, the construction and putting into service of installations which comply with these regulations, may not be prohibited, restricted or impeded.

7.1. Safety components referred to in regulation 5.7 of these regulations bearing the CE conformity marking shown in Annex IX of the Directive, which is set out in Schedule IX hereto, and accompanied by the EC declaration of conformity provided for in Annex IV of the Directive, which is set out in Schedule IV hereto, shall be regarded as conforming with all the relevant provisions of these regulations. Presumption of conformity.

7.2. Subsystems within the meaning of Annex I of the Directive, which is set out in Schedule I hereto, which are accompanied by the EC declaration of conformity based on the model provided for in Annex VI of the Directive, which is set out in Schedule VI hereto, and by the technical documentation provided for in paragraph 3 of Article 10 of the Directive, which is set out in regulation 11.2 of these regulations, as conforming with the relevant essential requirements referred to in regulation 5.4 of these regulations.

⁶ Regulations 7.1, 7.2, 8.1, 8.2, 10.6, 11.1, 11.1.1 and 11.2 of these regulations.

8.1. Before a safety component is placed on the market, the manufacturer or his authorised representative must:

8.1.1. Submit the safety component to a conformity assessment procedure in accordance with Annex V of the Directive, which is set out in Schedule V hereto, and

8.1.2. Affix the CE conformity marking on the safety component and, on the basis of the modules laid down in Decision 93/465/EEC⁷, draw up the EC declaration of conformity in accordance with Annex IV of the Directive, which is set out in Schedule IV hereto.

8.2. The procedure for assessing safety component conformity shall be carried out at the request of the manufacturer or his authorised representative by the notified body referred to in Article 16 of the Directive, and appointed by him for this purpose.

9.1. Where it is ascertained that a safety component bearing the CE conformity marking placed on the market and used in accordance with its intended purpose or a subsystem with an EC declaration of conformity as referred to in regulation 7.2 of these regulations, in accordance with its intended purpose, is liable to endanger the safety and health of persons, and, where applicable, the safety of property, the Director of Consumer Affairs shall take all appropriate measures to restrict the conditions of use of the component or subsystem or prohibit its use.

9.2. The Director of Consumer Affairs shall inform the Consumer and Industrial Goods Directorate⁸ of the Malta Standards Authority and shall give the reasons for the decision, stating in particular whether the failure to conform is due to:

- (a) failure to satisfy the essential requirements referred to in regulation 5.4 of these regulations,
- (b) incorrect application of the European specifications referred to in regulation 3.1.7 of these regulations in so far as application of those specifications is invoked,
- (c) shortcomings in the European specifications referred to in regulation 3.1.7 of these regulations.

⁷ OJ No. L 220, 30-08-93, p. 23-39.

⁸ 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.

9.3. Any decision taken pursuant to these regulations which restricts the placing on the market and putting into service of safety components shall state the exact grounds on which it is based.

9.3.1 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.

9.4. Necessary measures shall be taken to ensure that the manufacturer, or his authorised representative, shall send to the responsible authority of the Member State where he resides or where he places on the market or puts into service the installations referred to in regulation 3 of these regulations and to the Commission a copy of the EC declaration of conformity.

9.5. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulation 9.3 of these regulations.

9.6. Where neither the manufacturer nor his authorised representative has complied with the obligations of regulations 7.1, 8.1, 8.2 and 10.6 of these regulations, those obligations shall devolve on whomsoever places the safety component on the Maltese market. The same obligations shall apply to whomsoever manufactures safety components for his own use.

10.1. The CE conformity marking shall consist of the initials 'CE'. CE Marking.

10.1.1. The form of the marking to be used is shown in Annex IX of the Directive, which is set out in Schedule IX to these regulations.

10.2. The CE marking shall be affixed to each safety component distinctly and visibly or, where that is not possible, on a label inseparably attached to the component.

10.3. The affixing on safety components of markings which are likely to mislead third parties as to the meaning and form of the CE conformity marking shall be prohibited.

10.4. Any other marking may be affixed to the safety component, provided that the visibility and legibility of the CE conformity marking are not thereby reduced.

10.5. Without prejudice to regulation 9:

10.5.1. Where it is established that the CE conformity marking has been wrongly affixed, the manufacturer of the safety component or the authorised representative of the latter shall be obliged to make the product conform as regards the provisions concerning the CE conformity marking and to end the infringement under the conditions laid down by the Director of Consumer Affairs. Where neither the manufacturer nor his authorised representative is established in the Community or Malta, the person who places the safety component on the Community or Maltese market shall undertake these obligations.

10.5.2. 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 in accordance with the procedures provided for in regulation 9 of these regulations.

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

EC Declaration of conformity.

11.1. The EC procedure for examining subsystems shall be carried out at the request of the manufacturer or his authorised representative or, in their absence, any natural or legal person who places the subsystem in question on the market, by the notified body referred to in Article 16 of the Directive, which the manufacturer or his authorised representative or the abovementioned person appointed for that purpose.

11.1.1. The EC declaration of conformity shall be drawn up by the manufacturer or his authorised representative or the abovementioned person on the basis of the EC examination in accordance with Annex VII of the Directive, which is set out in Schedule VII hereto.

11.2. The notified body shall draw up the EC examination certificate in accordance with Annex VII of the Directive, which is set out in Schedule VII hereto, and the technical documentation which accompanies it. The technical documentation must include all the necessary documents concerning the characteristics of the subsystem and, where appropriate, all the documents certifying the conformity of the safety component. It must also contain all the relevant details of the conditions of, and restrictions on, use and of the instructions for servicing.

Schedule I**Based on Annex I of the Directive****SUBSYSTEMS OF AN INSTALLATION**

For the purposes of these regulations, an installation is divided up into infrastructure and the subsystems listed below, with exploitability and maintainability having to be taken into account in each case:

1. Cables and cable connections
2. Drives and brakes
3. Mechanical equipment
 - 3.1. Cable winding gear
 - 3.2. Station machinery
 - 3.3. Line engineering
4. Vehicles
 - 4.1. Cabins, seats or drag devices
 - 4.2. Suspension gear
 - 4.3. Driving gear
 - 4.4. Connections to the cable
5. Electrotechnical devices
 - 5.1. Monitoring, control and safety devices
 - 5.2. Communication and information equipment
 - 5.3. Lightning protection equipment
6. Rescue equipment
 - 6.1. Fixed rescue equipment
 - 6.2. Mobile rescue equipment

Schedule II

Based on Annex II of the Directive

ESSENTIAL REQUIREMENTS

1. Purpose

This Schedule sets out the essential requirements, including maintainability and operability, applicable to the design, construction and entry into service of installations referred to in regulation 3 of these regulations.

2. General requirements

2.1. Safety of persons

The safety of users, workers and third parties is a fundamental requirement for the design, construction and operation of installations.

2.2. Principles of safety

All installations must be designed, operated and serviced in accordance with the following principles, which are to be applied in the order given:

- eliminate or, if that is not possible, reduce risks by means of design and construction features,

- define and implement all necessary measures to protect against risks which cannot be eliminated by the design and construction features,

- define and state the precautions which should be taken to avoid the risks which it has not been possible to eliminate completely by means of the provisions and measures referred to in the first and second indents.

2.3. Consideration of external factors

Installations must be so designed and constructed as to make it possible to operate them safely, taking into account the type of installation, the nature and physical features of the terrain on which it is installed, its surroundings and atmospheric and meteorological factors, as well as possible structures and obstacles located in the vicinity either on the ground or in the air.

2.4. Dimensions

The installation, the subsystems and all its safety components must be dimensioned, designed and constructed to withstand, with a sufficient degree of safety, all stresses encountered under all foreseeable conditions, including those which occur when not in operation, and taking account in particular of outside influences, dynamic effects and fatigue phenomena, while complying with the acknowledged rules of the art, in particular with regard to the choice of materials.

2.5. *Assembly*

2.5.1. The installation, the subsystems and all the safety components must be designed and constructed in such a way as to ensure that they can be safely assembled and put into place.

2.5.2. The safety components must be so designed as to make assembly mistakes impossible, either as a result of construction or by means of appropriate markings on the components themselves.

2.6. *Integrity of the installation*

2.6.1. The safety components must be designed and constructed and be usable in such a way as to ensure that, in every case, their own operational integrity and/or the safety of the installation is ensured, as defined in the safety analysis in Annex III, so that their failure is highly improbable and with an adequate safety margin.

2.6.2. The installation must be designed and constructed in such a way as to ensure that, during its operation, any failure of a component which might affect safety, even indirectly, is met by an appropriate measure being taken in good time.

2.6.3. The safeguards referred to in points 2.6.1 and 2.6.2 must apply throughout the period between two scheduled inspections of the component concerned. The time period for the scheduled inspection of the safety components must be clearly indicated in the instruction manual.

2.6.4. Safety components which are incorporated into installations as spare parts must satisfy the essential requirements of these regulations and the conditions relating to the smooth interaction with the other parts of the installations.

2.6.5. Measures must be taken to ensure that the effects of a fire in the installation do not endanger the safety of persons being transported and workers.

2.6.6. Special measures must be taken to protect installations and persons from the effects of lightning.

2.7. *Safety devices*

2.7.1. Any defect in the installation which could result in a failure endangering safety must, where practicable, be detected, reported and processed by a safety device. The same applies to any normally foreseeable external event which may endanger safety.

2.7.2. It must be possible at all times to shut down the installation manually.

2.7.3. After the installation has been shut down by a safety device, it must not be possible to restart it unless appropriate action has been taken.

2.8. *Maintainability*

The installation must be designed and constructed so as to enable routine or special maintenance and repair operations and procedures to be carried out safely.

2.9. *Nuisance*

The installation must be designed and constructed in such a way as to ensure that any internal or external nuisance resulting from noxious gases, noise emissions or vibrations falls within the prescribed limits.

3. *Infrastructure requirements*

3.1. *Layout, speed, distance between vehicles*

3.1.1. The installation must be designed to operate safely taking into account the characteristics of the terrain and its surroundings, atmospheric and meteorological conditions, any possible structures and obstacles located in the vicinity either on the ground or in the air in such a way as to cause no nuisance or pose no danger under any operational or servicing conditions or in the event of an operation to rescue persons.

3.1.2. Sufficient distance must be maintained laterally and vertically between vehicles, towing devices, tracks, cables, etc., and possible structures and obstacles located in the vicinity either on the ground or in the air, taking account of the vertical, longitudinal and lateral movement of the cables and vehicles or of the towing devices under the most adverse foreseeable operating conditions.

3.1.3. The maximum distance between vehicles and ground must take account of the nature of the installation, the type of vehicles and the rescue procedures. In the case of open cars it must also take account of the risk of fall as well as the psychological aspects associated with the distance between vehicles and ground.

3.1.4. The maximum speed of the vehicles or towing devices, the minimum distance between them and their acceleration and braking performance must be chosen to ensure the safety of persons and the safe operation of the installation.

3.2. *Stations and structures along the line*

3.2.1. Stations and structures along the line must be designed, installed and equipped so as to ensure stability. They shall permit safe guidance of the cables, vehicles and the towing devices, and enable maintenance to be safely carried out, under all operating conditions.

3.2.2. The entry and exit areas of the installation must be designed so as to guarantee the safety of the traffic of vehicles, towing devices and persons. The movement of vehicles and towing devices in the stations must be capable of taking place without risk to persons, taking into account their possible active collaboration to their movement.

4. Requirements relating to cables, drives and brakes and to mechanical and electrical installations

4.1. *Cables and their supports*

4.1.1. All measures must be taken in line with the latest technological developments:

- to avoid cables or their attachments breaking,
- to cover their minimum and maximum stress values,
- to ensure that they are safely mounted on their supports and prevent derailment,
- to enable them to be monitored.

4.1.2. It is not possible to prevent all risk of cable derailment, measures must be taken to ensure that cables can be retrieved and the installations shut down without risk to persons in the event of derailment.

4.2. *Mechanical installations*

4.2.1. Drives

The drive system of an installation must be of a suitable performance and capability, adapted to the various operating systems and modes.

4.2.2. Standby drive

The installation must have a standby drive with an energy supply which is independent of that of the main drive system. A standby drive is not, however, necessary if the safety analysis shows that people can leave the vehicles and, in particular, towing devices easily, quickly and safely even if a standby drive is not available.

4.2.3. Braking

4.2.3.1. In an emergency, it must be possible to shut down the installation and/or the vehicles at any moment, under the most unfavourable conditions in terms of authorised load and pulley adhesion during operation. The stopping distance must be as short as the security of the installation dictates.

4.2.3.2. Deceleration values must be within adequate limits fixed in such a way to ensure both the safety of the persons and the satisfactory behaviour of the vehicles, cables and other parts of the installation.

4.2.3.3. In all installations there must be two or more braking systems, each capable of bringing the installation to a halt, and coordinated in such a way that they automatically replace the active system when its efficiency becomes inadequate. The traction cable's last braking system must act directly on the driving pulley. These provisions do not apply to drag lifts.

4.2.3.4. The installation must be fitted with an effective clamp and locking mechanism to guard against premature restarts.

4.3. *Control devices*

The control devices must be designed and constructed so as to be safe and reliable, to withstand normal operating stresses and external factors such as humidity, extreme temperatures or electromagnetic interference and so as not to cause dangerous situations, even in the event of operational error.

4.4. *Communication devices*

Suitable facilities must be provided to enable operational staff to communicate with one another at all times and to inform users in case of emergency.

5. **Vehicles and towing devices**

5.1. Vehicles and/or towing devices must be designed and fitted out in such a way that under foreseeable operating conditions no person can fall out or encounter any other risks.

5.2. The fittings of vehicles and towing devices must be dimensioned and constructed so as not to:

- damage the cable, or

- slip, except where slippage does not significantly affect the safety of the vehicle, the towing device or the installation under the most unfavourable conditions.

5.3. Vehicle doors (on cars, cabins) must be designed and constructed in such a way as to make it possible to close and lock them. The vehicle floor and walls must be designed and constructed so as to withstand pressure and loads exerted by users under any circumstances.

5.4. If for reasons of operational safety an operator is required on board the vehicle, the vehicle must be fitted with the equipment required for him to carry out his tasks.

5.5. Vehicles and/or towing devices and, in particular, their suspension mechanisms must be designed and fitted so as to ensure the safety of workers servicing them in accordance with appropriate rules and instructions.

5.6. In the case of vehicles equipped with disconnectable fittings, all measures must be taken to bring to a halt, without risk to users, at the moment of departure, any vehicle whose fitting has been incorrectly connected to the cable and, at the moment of arrival, any vehicle whose fitting has not been disconnected, and to prevent the vehicle from falling.

5.7. Funicular vehicles and, in so far as the configuration of the installation so permits, bi-cable cable cars must be equipped with an automatic braking device on the track, when the possibility of carrier cable breaking cannot reasonably be excluded.

5.8. Where all risk of derailment of the vehicle cannot be eliminated by other measures, the vehicle must be fitted with an anti-derailment device which enables the vehicle to be brought to a halt without risk to persons.

6. Equipment for users

The access to embarkation areas and exit from disembarkation areas and the embarkation and disembarkation of users must be organised with regard to the movement and stopping of vehicles in such a way as to ensure the safety of persons, in particular in areas where there is a risk of falling.

It must be possible for children and persons with reduced mobility to use the installation safely if the installation is designed for the transport of such persons.

7. Operability

7.1. Safety

7.1.1. All technical provisions and measures must be taken to ensure that the installation is used for its intended purpose according to its technical specification and to the specified operating conditions and that the instructions on safe operation and maintenance can be complied with. The instruction manual and the corresponding

notes shall be drawn up in Maltese or in any other language of the Community acceptable to the Maltese authorities.

7.1.2. The persons responsible for operating the installation must be provided with the appropriate material resources and must be qualified to carry out the task in hand.

7.2. Safety in the event of immobilisation of the installation

All technical provisions and measures must be adopted to ensure that users can be brought to safety within a set time appropriate to the type of installation and its surroundings when the installation is immobilised and cannot be restarted quickly.

7.3. Other special provisions concerning safety

7.3.1. Operators' stands and workplaces

Movable parts which are normally accessible in the stations must be designed, constructed and installed in such a way as to preclude any risks or, where such risks exist, be fitted with protective devices so as to prevent any contact with parts of the installation which may cause accidents. These devices must be of a type that cannot easily be removed or rendered inoperative.

7.3.2. Risk of falling

Workplaces and working areas, including those used only occasionally, and the access to them, must be designed and constructed in such a way as to prevent persons required to work or move in them from falling. Should the construction not be adequate, they must also be provided with anchorage points for personal protective equipment to prevent falls.

Schedule III

Based on Annex III of the Directive

SAFETY ANALYSIS

The safety analysis required for every cableway installation referred to in regulation 3.1.2 of these regulations must take into account every mode of operation envisaged. The analysis must follow a recognised or established method and take into account the current state of the art and the complexity of the installation in question. The aim is also to ensure that the design and configuration of the installation should take account of the local surroundings and the most adverse situations in order to ensure satisfactory safety conditions.

The analysis must also cover the safety devices and their effect on the installation and related subsystems that they bring into action so that either:

- they are capable of reacting to an initial breakdown or failure detected so as to remain either in a state that guarantees safety, in a lower operating mode or in a fail-safe state,
- they are redundant and are monitored, or
- they are such that the probability of their failure can be evaluated and they are of a standard equivalent to that achieved by safety devices that meet the criteria in the first and second indents.

Safety analysis must be used to draw up the inventory of risks and dangerous situations in accordance with regulation 5.6 of these regulations and to determine the list of safety components referred to in regulation 5.7 of these regulations. The result of the safety analysis must be summarised in a safety report.

Schedule IV

Based on Annex IV of the Directive

SAFETY COMPONENTS: EC DECLARATION OF CONFORMITY

This Schedule applies to the safety components referred to in regulation 3.1.3 of these regulations with a view to establishing their compliance with the essential requirements which concern them referred to in regulation 5.4 of these regulations and defined in Annex II of the Directive, which is set out in schedule II hereto.

The EC declaration of conformity and the accompanying documentation must be dated and signed. It must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II of the Directive, which is set out in Schedule II hereto.

The declaration must state the following particulars:

- the references of these regulations,
- name, business name and full address of the manufacturer or his authorised representative. An authorised representative must also give the name, business name and full address of the manufacturer,
- description of the component (make, type, etc.),
- details of the conformity declaration procedure used (Article 7 of this Directive, which is set out in regulations 7.1, 8.1, 8.2, 9.7 and 10.6 of these regulations),
- all relevant provisions with which the component must comply and, in particular, the conditions of use,
- the name and address of any body notified, involved in the conformity procedure and the date of the EC examination certificate with details, where appropriate, of the duration and conditions of validity of the certificate,
- where appropriate, the reference of the harmonised standards applicable,
- identification of the person empowered to sign on behalf of the manufacturer or his authorised representative.

Schedule V

Based on Annex V of the Directive

SAFETY COMPONENTS: ASSESSMENT OF CONFORMITY

1. Scope

This Schedule applies to safety components with a view to checking compliance with the essential requirements referred to in regulation 5.4 of these regulations and defined in Annex II of the Directive, which is set out in Schedule II hereto. It concerns the assessment by one or more notified bodies of the intrinsic conformity of a component, considered in isolation, with the prescribed technical specifications.

2. Procedures

The assessment procedures implemented by the notified bodies both at the design and production stage are based on the modules defined in Council Decision 93/465/EEC along the lines indicated in the following table. The solutions in this table are considered to be equivalent and can be used at the manufacturer's discretion.

ASSESSMENT OF THE CONFORMITY OF SAFETY COMPONENTS

Design	Production
1. EC type-examination Module 'B'	1(a) Production quality assurance Module 'D'
	1(b) Product verification Module 'F'
2. Full quality assurance Module 'H'	2. Full quality assurance Module 'H'
3. Unit verification Module 'G'	3. Unit verification Module 'G'

Modules must be applied taking into account the specific supplementary conditions in each module.

MODULE B: EC TYPE-EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of these regulations.

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

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
- a written declaration that the same application has not been lodged with any other notified body,
- the technical documentation, as described in point 3 of this module.

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

3. The technical documentation must enable the conformity of the component with the requirements of these regulations to be assessed. It must, as far as is relevant for such assessment, cover the design, manufacture and operation of the component.

The documentation must contain as far as is relevant to assessment:

- a general type-description,
- conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of the said drawings and schemes and the operation of the product,
- the list of the European specifications referred to in regulation 3.1.7 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the European specifications referred to in regulation 3.1.7 of these regulations do not exist,
- the results of design calculations made, examinations carried out, etc.,
- test reports.

It must also indicate the field of use of the component.

4. The notified body:

4.1. must examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the European specifications referred to in regulation 3.1.7 of these regulations, as well as those which have been designed without applying the relevant provisions of those European specifications;

4.2. must perform or have performed the appropriate examinations and necessary tests to check whether, where the European specifications referred to in regulation 3.1.7 of these regulations have not been applied, the solutions adopted by the manufacturer meet the essential requirements of these regulations;

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

4.4. must agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type meets the provisions of these regulations, the notified body must issue an EC type-examination certificate to the applicant. The certificate must state the name and address of the manufacturer, the conclusions of the examination, the conditions for its validity, the duration thereof and give the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body. If the notified body refuses to issue an EC-type certificate to the manufacturer, the former must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications of the approved component which must receive additional approval where such changes may affect the conformity of the component with the essential requirements for the prescribed conditions for its use. This additional approval is given in the form of an addition to the original EC type-examination certificate.

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

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

9. The manufacturer or his authorised representative must keep with the technical documentation copies of EC type-examination certificates and their additions for at least 30 years after the last component has been manufactured.

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

MODULE D: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 of this module ensures and declares that the components concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of these regulations. The manufacturer or his authorised representative must affix the CE marking to each component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for monitoring as specified in point 4 of this module.

2. The manufacturer must operate an approved quality system for production, final component inspection and testing as specified in point 3 of this module, and is subject to monitoring as specified in section 4 of this module.

3. Quality system

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

The application must include:

- all relevant information for the component category envisaged,
- the documentation concerning the quality system,
- if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. The quality system must ensure compliance with the type as described in the EC type-examination certificate and with the requirements of these regulations. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies,

procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must in particular contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to competent quality,
- 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 manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required component quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standards.

The auditing team must have at least one member with experience of evaluating in the component technology concerned. The evaluation procedure must include an inspection visit to the manufacturer's premises.

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

3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner at a proper and efficient level.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 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

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

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

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

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

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

5. The manufacturer must, for period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second subparagraph of point 3.1 of this module,
- the updating referred to in the second paragraph of point 3.4 of this module,
- the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4 of this module.

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

MODULE F: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorised representative checks and attests that the components subject to the provisions of point 3 of this module are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of these regulations.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the components with the type as described in the EC type-examination certificate and with the requirements of these regulations. He shall affix the CE marking to each component and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the components to the requirements of these regulations, either by examination and testing of every component as specified in point 4 or by examination and testing of components on a statistical basis, as specified in point 5, at the choice of the manufacturer.

The manufacturer or his authorised representative resident within the Community or Malta must keep a copy of the declaration of conformity for a period ending at least 30 years after the last component has been manufactured.

4. Verification by examination and testing of every component

4.1. All components must be individually examined and appropriate tests as set out in the relevant European specification(s) referred to in regulation 3.1.7 of these regulations or equivalent tests shall be carried out in order to verify their conformity with the type described in the EC type-examination certificate and to the requirements of these regulations.

4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved component and draw up a written certificate of conformity relating to the tests carried out.

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

5. Statistical verification

5.1. The manufacturer must present his components in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All components must be available for verification in the form of homogeneous lots. A random sample must be drawn from each lot. Components in a sample must be individually examined and appropriate tests as set out in the European specification(s) referred to in regulation 3.1.7 of these regulations, or equivalent tests, shall be carried out to ensure their conformity with the requirements of these regulations and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure must use the following elements:

- a statistical method,
- a sampling plan with its operational characteristics.

5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification number to each component, and shall draw up a written certificate of conformity relating to the tests carried out. All components in the lot may be put on the market, except those components from the sample which were found not to be in conformity.

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

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

5.5. The manufacturer or his authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.

MODULE G: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the component concerned, which has been issued with the certificate referred to in point 2 of this module, conforms to the requirements of these regulations that apply to it. The manufacturer or his authorised representative must affix the CE marking to the component and must draw up a declaration of conformity.

2. The notified body must examine the component and must carry out the appropriate tests as set out in the relevant European specifications referred to in regulation 3.1.7 of these regulations, or equivalent tests, to ensure its conformity with the relevant requirements of these regulations.

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

3. The aim of the technical documentation is to enable conformity with the requirements of these regulations to be assessed and the design, manufacture and operation of the component to be understood.

For the purposes of assessment, the documentation must include the following:

- a general description of the type,

- conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the component,
- a list of the relevant European specifications applied in total or partially referred to in regulation 3.1.7 of these regulations, as well as a description of the solutions adopted by the manufacturer to meet the essential requirements of the Directive, where the European specifications referred to in regulation 3.1.7 of these regulations have not been applied,
- the results of the design calculations made, examinations carried out, etc.,
- test reports,
- fields of use of components.

MODULE H: FULL QUALITY ASSURANCE

1. This module describes the procedure whereby a manufacturer who satisfies the obligations of paragraph 2 of this module must ensure and declare that the components concerned satisfy the relevant requirements of these regulations. The manufacturer or his authorised representative must affix the CE marking to the component and must draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4 of this module.

2. The manufacturer must operate an approved quality system for design, manufacture and final component inspection and testing as specified in point 3 of this module and shall be subject to surveillance as specified in point 4 of this module.

3. Quality system

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

The application must include:

- all relevant information for the category of component envisaged,
- the documentation relating to the quality system.

3.2. The quality system must ensure compliance of the components with the relevant requirements of these regulations.

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

It must in particular include an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and component quality,
- the technical design specifications, including the European specifications referred to in regulation 3.1.7 of these regulations, that will be applied and, where the European specifications will not be applied in full, the means that will be used to ensure that the essential requirements of these regulations that apply to the products will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the components pertaining to the category of components covered,
- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,
- the means to monitor the achievement of the required design and component quality and the effective operation of the quality assurance system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard.

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

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

3.4. The manufacturer must undertake to fulfil the obligations arising from the quality system as approved and to uphold it so that it remains adequate and efficient. The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 of this module or whether a reassessment is required.

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

4. Surveillance under the responsibility of the notified body

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

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

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

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

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. 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 system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 30 years after the last component has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second subparagraph of point 3.1 of this module,

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- the updating referred to in the second subparagraph of point 3.4 of this module,

- the decisions and reports form the notified body which are referred to in points 3.4, 4.3 and 4.4 of this module.

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

7. Supplementary requirements; design examination

7.1. The manufacturer must lodge an application for examination of the design with a single notified body.

7.2. The application must enable the design, manufacture and operation of the component to be understood, and shall enable conformity with the requirements of these regulations to be assessed.

It must include:

- the technical design specifications, including the European specifications referred to in regulation 3.1.7 of these regulations that have been applied,

- the necessary supporting evidence for their adequacy, in particular where the European specifications referred to regulation 3.1.7 of these regulations have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

7.3. The notified body must examine the application and where the design meets the provisions of these regulations, must issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the component's functioning.

7.4. The applicant must keep the notified body that issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect conformity to the essential requirements referred to in regulation 5.4 of these regulations or the prescribed conditions for use of the component. This additional approval is given in the form of an addition to the original EC design examination certificate.

7.5. The notified bodies must forward to the other notified bodies the relevant information concerning:

- the EC design examination certificates and additions issued,

- the EC design approvals and additional approvals withdrawn,
- the EC design examination certificates and additions refused.

Schedule VI

Based on Annex VI of the Directive

SUBSYSTEMS: EC DECLARATION OF CONFORMITY

This Schedule applies to the subsystems referred to in regulation 6 of these regulations in order to ensure that they fulfil the essential requirements concerning them referred to in regulation 5.4 of these regulations.

The EC declaration of conformity must be drawn up by the manufacturer, or his authorised representative, or, where such a person is not available, any natural or legal person, who places the subsystem on the market; the declaration and the accompanying technical documentation must be dated and signed. This EC declaration of conformity and the technical documentation must be drawn up in the same language or languages as the instruction manual, referred to in point 7.1.1 of Annex II of the Directive, which is set out in Schedule II hereto and must contain the following information:

- the reference of these regulations,
- the name and address of the person who ordered EC examination,
- a description of the subsystem,
- the name and address of the notified body which carried out the EC examination, referred to in Article 11 of the Directive⁹,
- all relevant provisions with which the subsystem must comply, in particular any operating restrictions or operating conditions,
- the outcome of EC examination referred to in Annex VII (EC conformity certificate) of the Directive, which is set out in Schedule VII hereto,
- particulars of the person who is authorised to sign a legally binding declaration for the manufacturer, or his authorised representative or, where such a person is not available, the natural or legal person, who places the subsystem on the market.

⁹ Regulations 5.11, 5.12, 5.13, 5.14, 5.15, 5.16 and 6.3 of these regulations.

Schedule VII

Based on Annex VII of the Directive

SUBSYSTEMS: ASSESSMENT OF CONFORMITY

1. EC examination is the procedure whereby, at the request of the manufacturer or his authorised representative or, where such a person is not available, any natural or legal person who assumes responsibility for placing the subsystem on the market, a notified body checks and attests that a subsystem is:

- in conformity with the provisions of the regulations and other relevant provisions in compliance with the Treaty,
- in conformity with the technical documentation, and
- completed.

2. The examination of the subsystem is carried out at each of the following stages:

- design,
- construction and acceptance trials once the subsystem has been completed.

3. The technical documentation accompanying the examination certificate must comprise the following:

- construction plans and calculations, electrical and hydraulic diagrams, control circuit diagrams, description of computer and automatic systems, operating and servicing instructions, etc.,
- a list of the safety components referred to in regulation 5.7 of these regulations which are used in the subsystem,
- copies of the EC declaration of conformity as provided for in Annex IV of the Directive, which is set out in Schedule IV hereto, for these safety components together with the corresponding construction plans and a copy of the reports on any other tests and trials carried out.

4. Documentation and correspondence in connection with EC examination procedures must be drawn up in the same language or languages as the instruction manual referred to in point 7.1.1 of Annex II of the Directive, which is set out in Schedule II hereto.

5. Surveillance

5.1. It shall be ensured by means of surveillance that during construction of the subsystem the obligations arising from the technical documentation are fulfilled.

5.2. The notified body responsible for EC examination must have permanent access to the production shops, storage areas and, where necessary, to prefabrication areas, testing plants and more generally to any locations it feels it needs to visit in order to perform its task. The manufacturer or his authorised representative or, where such a person is not available, the natural or legal person who places the subsystem on the market must provide it with, or arrange for it to be provided with, any documents required to that end, notably the plans and technical documentation relating to the subsystem.

5.3. The notified body responsible for EC examination must periodically carry out audits to ensure compliance with the provisions of these regulations. On each visit it must provide the site supervisor responsible with an audit report. It may ask to be brought in to inspect various stages of the work.

5.4. In addition, the notified body may pay unexpected visits to the production shops. During such visits it may carry out full or partial audits. The notified body must draw up a report on the visit and, where necessary, submit an audit report to the site supervisor responsible.

6. Each notified body must publish periodically the relevant information concerning:

- all applications for EC examination received,
- all EC examination certificates issued,
- all EC examination certificates refused.

Schedule VIII

Based on Annex VIII of the Directive

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

1. The notified body, its director and the staff responsible for carrying out the verification operations may not be either the designer, manufacturer, supplier or installer of the safety components or subsystems which they inspect or the authorised representative of any of those parties or the natural or legal person, who places these safety components or subsystems on the market. They may not become involved, either directly or as authorised representatives, in the design, manufacture, construction, marketing, servicing or operation of these safety components or subsystems. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its inspection staff must carry out the verification 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 judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of the verifications.

3. The notified body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with the verification operations; 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 of the tests they carry out and adequate experience of such tests,
- the ability required to draw up the certificates, records and reports required to authenticate the performance of the tests.

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

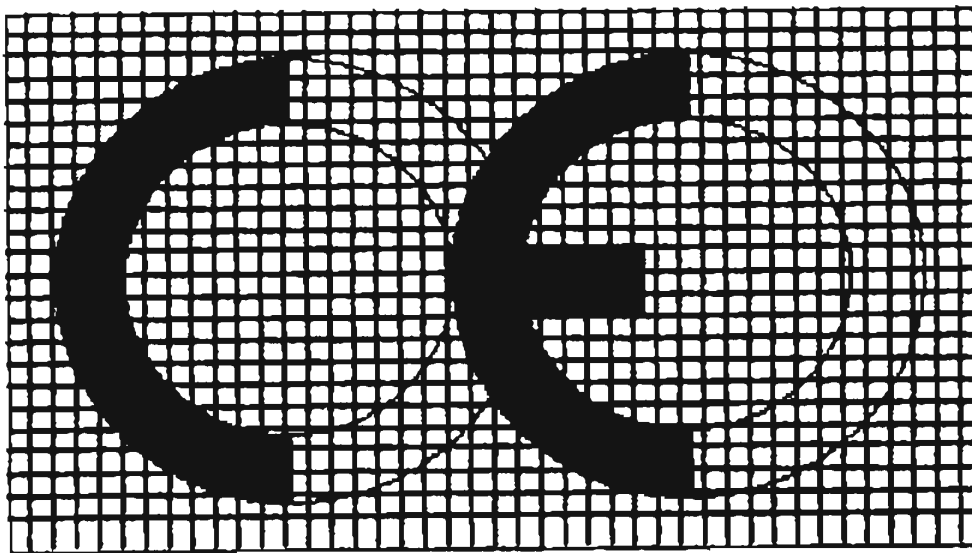
6. The notified body must take out civil liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the inspections.

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

Schedule XI**Based on Annex XI of the Directive****CE CONFORMITY MARKING**

The CE conformity marking shall consist of the letters “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 last two figures of the year in which it was affixed and by the identification number of the notified body that deals with the procedures referred to in regulation 8.2 of these regulations.