

# DIRECTIVE 2000/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 March 2000

relating to cableway installations designed to carry persons

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF  
THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 47(2) and Articles 55 and 95 thereof,

Having regard to the proposal from the Commission <sup>(1)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>(2)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty <sup>(3)</sup>,

Whereas:

- (1) Cableway installations designed to carry persons (hereinafter referred to as 'cableway installations') are designed, manufactured, put into service and operated with the object of carrying persons. Principally, cableway installations are mountain lift systems used in high-altitude tourist resorts and consisting of funicular railways, cable cars, gondolas, chairlifts and drag lifts, but may also consist of cableway installations used in urban transport facilities. Some types of cableway installation may use other, completely different basic principles which cannot be excluded *a priori*. Therefore, provision should be made for introducing specific requirements designed to achieve the same safety objectives as those laid down in this Directive.
- (2) Cableway installations are principally operated in connection with tourism, particularly in mountain areas, which plays an important role in the economy of the regions concerned and is becoming an increasingly important factor in the trade balances of the Member States. From a technical point of view, the cableway installations sector also ranks among the industrial activities linked to the production of capital equipment and to activities in the building and civil engineering sector.
- (3) Member States are responsible for ensuring the safety of cableway installations at the time of manufacture, putting into service and during operation. Moreover,

they are responsible together with the competent authorities for such matters as land-use, regional planning and environmental protection. National regulations differ widely as a result of techniques peculiar to the national industry as well as local customs and knowhow. They stipulate specific dimensions and devices and particular characteristics. In the light of these circumstances, manufacturers are obliged to redefine their equipment for each market. This makes it difficult to provide standard solutions and adversely affects competitiveness.

- (4) The essential health and safety requirements must be observed in order to ensure that cableway installations are safe. Those requirements are to be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.
- (5) Further, cableway installations may straddle frontiers and the construction thereof may run up against conflicting national rules.
- (6) Steps should be taken to define, on a Community-wide basis, essential human safety and health requirements, environmental protection and consumer protection requirements applicable to cableway installations, subsystems and their safety components. Without this, mutual recognition of national regulatory provisions would create insoluble political and technical difficulties as regards interpretation and liability. By the same token, standardisation without prior definition of harmonised regulatory requirements is not sufficient to solve the problems.
- (7) Responsibility for approving cableway installations is generally vested in a service of the competent national authorities; in certain cases, approval of the components cannot be obtained beforehand but only when the customer applies for such approval. By the same token, the requisite inspection of the cableway installation prior to its entry into service may result in the rejection of certain components or in diverse technological solutions. Such a state of affairs leads to increased costs and longer delivery periods and is particularly penalising for foreign manufacturers. Moreover, cableway installations are also carefully monitored by the public services when they are operational. The causes of serious accidents may be linked to the choice of site, to the system of transport itself, to the structures, or to the way in which the system is operated and maintained.
- (8) In these circumstances, the safety of cableway installations depends equally on the surrounding

<sup>(1)</sup> OJ C 70, 8.3.1994, p. 8 and  
OJ C 22, 26.1.1996, p. 12.

<sup>(2)</sup> OJ C 388, 31.12.1994, p. 26.

<sup>(3)</sup> Opinion of the European Parliament of 6 April 1995 (OJ C 109, 1.5.1995, p. 122), confirmed on 27 October 1999 (not yet published in the Official Journal), Council common position of 28 June 1999 (OJ C 243, 27.8.1999, p. 1) and Decision of the European Parliament of 27 October 1999 (not yet published in the Official Journal). Council Decision of 16 December 1999.

conditions, on the quality of the industrial goods supplied and on the way in which they are assembled, installed on site and monitored during operation. This underlines the importance of having a general overview of cableway installations in order to assess the level of safety and of adopting a common approach at Community level to quality assurance. In these circumstances, in order to enable manufacturers to overcome their present difficulties and in order to enable users to derive the full benefit from cableway installations and to enjoy an equal level of development in all Member States, a set of requirements should be defined, together with control and inspection procedures to be applied uniformly in all Member States.

- (9) Persons using cableways, from all Member States and beyond, must be ensured a satisfactory level of safety. In order to meet this requirement, it is necessary to define procedures and examination, control and inspection methods. This necessitates the use of standardised technical devices which must be incorporated in cableway installations.
- (10) Where Council Directive 85/337/EEC<sup>(1)</sup> so requires, the effects of cableway installations on the environment must be assessed; above and beyond the effects mentioned in that Directive, both environmental protection and requirements in connection with the sustainable development of tourism should be taken into account.
- (11) Cableway installation may come within the scope of Council Directive 93/38/EEC of 14 June 1993 coordinating the procurement procedures of entities operating in the water, energy, transport and telecommunications sectors<sup>(2)</sup>.
- (12) Technical specifications should be included in the general documentation or in the technical specifications peculiar to each contract. Those technical specifications must be defined by reference to European specifications where such specifications exist.
- (13) In order to make it easier to prove that the essential requirements have been complied with, it is useful to have harmonised European standards, compliance with which enables it to be presumed that the product is in conformity with the said essential requirements. Harmonised European standards are drawn up by private bodies and must retain their non-mandatory status. For this purpose, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as the bodies competent to adopt harmonised standards that follow the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984.
- (14) For the purposes of this Directive, a harmonised standard is a technical specification (European standard or harmonisation document) adopted by one or other of those bodies, or by both, at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services<sup>(3)</sup> and in accordance with the general guidelines referred to above. In relation to standardisation, the Commission should be assisted by the committee referred to in that Directive, which will, if necessary, consult technical experts.
- (15) Only safety components or subsystems of an installation which conform to a national standard transposing a harmonised standard the reference of which has been published in the *Official Journal of the European Communities*, are deemed to conform to the relevant essential requirements of this Directive, regardless of the need for any special justification.
- (16) In the absence of European specifications, the technical specifications should as far as possible be defined by reference to other standards in use in the Community. Main contractors may define the additional specifications needed to supplement the European specifications or other standards. These provisions must ensure that the harmonised Community-level requirements with which cableway installations must comply are satisfied.
- (17) It is, moreover, in the interest of the Member States to have an international standardisation system capable of producing standards which are actually used by international trading partners and satisfy the requirements of Community policy.
- (18) In certain Member States at the moment in the general documentation or specifications peculiar to each contract, main contractors may indicate the control and inspection procedures. Those procedures must in future, notably in the case of safety components, fall within the framework of the Council resolution of 21 December 1989 concerning a global approach to conformity assessment<sup>(4)</sup>. The concept of safety component applies not only to physical objects but also to intangible objects such as software. The procedures for assessing the conformity of safety components must be based on use of the modules provided for in Council Decision 93/465/EEC<sup>(5)</sup>. In the case of critical safety components, the principles and conditions for the application of design quality assurance should be defined; such an approach is necessary in order to

<sup>(1)</sup> Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (OJ L 175, 5.7.1985, p. 40). Directive as last amended by Directive 97/11/EC (OJ L 73, 14.3.1997, p. 5).

<sup>(2)</sup> OJ L 199, 9.8.1993, p. 84. Directive as last amended by Directive 98/4/EC (OJ L 101, 1.4.1998, p. 1).

<sup>(3)</sup> OJ L 204, 21.7.1998, p. 37. Directive as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

<sup>(4)</sup> OJ C 10, 16.1.1990, p. 1.

<sup>(5)</sup> Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation Directives (OJ L 220, 30.8.1993, p. 23).

- promote the general adoption of the quality assurance system in undertakings.
- (19) When conducting methodical safety analysis of cableway installations, it is necessary to identify the components on which the safety of the cableway installation depends.
- (20) In their contractual documents, main contractors lay down, by reference to European specifications, the characteristics which manufacturers are under a contractual obligation to observe, particularly for safety components. In these circumstances, the conformity of the components is linked principally to their field of use and not solely to free movement on the Community market.
- (21) Safety components should bear the CE marking to be affixed either by the manufacturer or by his authorised representative established within the Community. The CE marking means that the safety component complies with the provisions of this Directive and those of other applicable Community Directives on CE marking.
- (22) It is not necessary to affix the CE marking to subsystems subject to the provisions of this Directive but, on the basis of the assessment of conformity following the procedures laid down for this purpose in this Directive, the declaration of conformity will suffice. This is without prejudice to the obligation incumbent on manufacturers to affix the CE marking to certain subsystems in order to certify that they conform with other Community provisions applicable to them.
- (23) Member States' responsibility for safety, health and other aspects covered by the essential requirements on their territory must be recognised in a safeguard clause providing for the appropriate Community procedures.
- (24) A procedure is necessary for the inspection of subsystems of cableway installations before they are put into service. Such inspection must enable the authorities to satisfy themselves that at each stage of the design, manufacturing and entry into service, the result obtained conforms with the applicable provisions of this Directive. This must enable manufacturers to count on equal treatment, irrespective of the Member State in question. The principles and conditions governing EC verification of subsystems of installations should therefore be defined.
- (25) The constraints linked to the operation of cableway installations must be taken into account in the safety analysis, albeit not in such a way as to jeopardise the principle of free movement of goods or the safety of cableway installations. Consequently, although this Directive does not cover the actual operation of cableway installations, the Commission should propose to the Member States a series of recommendations designed to ensure that such installations situated on their territory are operated in such a way as to offer users, operating personnel and third parties a high degree of protection.
- (26) In the case of cableway installations, full-scale tests can be carried out on technological innovations only on the construction of a new installation. In these circumstances, a procedure should be provided for which, while ensuring that the essential requirements are complied with, also enables special conditions to be established.
- (27) Cableway installations for which authorisation has been given but in connection with which building work has not yet started or which are already under construction must comply with the provisions of this Directive, unless Member States decide otherwise, giving their reasons, and an equally high level of protection is achieved. The provisions of this Directive must be complied with where existing cableway installations are modified if national legislation requires such modifications to be authorised.
- (28) It is not necessary to require all existing cableway installations to be brought into conformity with the provisions applicable to new installations. However, this may prove necessary if the essential safety objectives are not complied with. In that event, the Commission should propose to the Member States a series of recommendations designed to ensure that existing cableway installations on their territory afford users a high degree of protection in the light of the provisions applicable in this field to new installations.
- (29) Particularly in the absence of a European specification, the notified bodies responsible for procedures for assessing the conformity both of safety components and of subsystems of cable installations must coordinate their decisions as closely as possible. The Commission must ensure that they do so.
- (30) Implementation of the essential requirements, particularly with regard to the safety of the installation, and coordination of all procedures call for the establishment of a committee.
- (31) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(1)</sup>.

HAVE ADOPTED THIS DIRECTIVE:

#### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

1. This Directive shall apply to cableway installations designed to carry persons.
2. For the purposes of this Directive '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.

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

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.

3. The installations concerned are:

- (a) funicular railways and other installations with vehicles mounted on wheels or on other suspension devices where traction is provided by one or more cables;
- (b) cable cars where the cabins are lifted and/or displaced by one or more carrier cables; this category also includes gondolas and chair lifts;
- (c) drag lifts, where users with appropriate equipment are dragged by means of a cable.

4. This Directive shall apply to:

- installations built and put into service, as from its entry into force,
- subsystems and safety components placed on the market, as from its entry into force.

It concerns such harmonisation provisions as are necessary and sufficient in order to ensure and guarantee compliance with the essential requirements referred to in Article 3(1).

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 by the Member State in question, such modifications and their repercussions on the installation as a whole must satisfy the essential requirements referred to in Article 3(1).

5. For the purposes of this Directive:

- 'installation' shall mean the whole on-site system, consisting of infrastructure and the subsystems listed in Annex I where infrastructure specially designed for each installation and 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,
- '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, be they users, operating personnel or third parties,
- 'main contractor' shall mean any natural or legal person who commissions the construction of an installation,

— '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,

— '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.

6. This Directive shall not apply to:

- lifts within the meaning of Directive 95/16/EC<sup>(1)</sup>,
- cable-operated tramways of traditional construction,
- installations used for agricultural purposes,
- 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,
- mining installations or on-site installations used for industrial purposes,
- cable-operated ferries,
- rack railways,
- chain-driven installations.

## Article 2

1. This Directive shall apply without prejudice to other Community Directives, although compliance with the essential requirements laid down in this Directive may call for the application of special European specifications established for that purpose.

2. 'European specification' shall mean a common technical specification, a European technical approval or a national standard transposing a European standard.

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

4. Member States shall publish the references of national standards used to transpose harmonised European standards.

5. In the absence of harmonised European standards, Member States shall take the necessary measures 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 Article 3(1).

<sup>(1)</sup> Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1).

6. 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 Article 3(1).

7. Where a Member State or the Commission considers that a European specification as referred to in paragraph 2 does not entirely satisfy the essential requirements referred to in Article 3(1), the Commission or the Member State concerned shall bring the matter before the committee referred to in Article 17 giving the reasons therefor. The committee shall deliver an opinion without delay.

In the light of the committee's opinion and following consultations with the committee set up pursuant to Directive 98/34/EC in the case of harmonised European standards, the Commission shall inform the Member States whether or not it is necessary to withdraw the European specifications in question from the published information referred to in paragraph 3.

#### Article 3

1. 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 and are applicable to them.

2. 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 requirements laid down in Annex II, 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.

#### Article 4

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

2. 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, as the case may be.

### CHAPTER II

#### SAFETY COMPONENTS

#### Article 5

1. Member States shall take all necessary measures to ensure that safety components:

— are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1),

— 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.

2. This Directive shall not affect Member States' entitlement to lay down, in compliance with the Treaty, such requirements as they may deem 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 Directive.

#### Article 6

Member States may not, on the basis of this Directive, prohibit, restrict or impede the placing on their national markets of safety components intended to be used in an installation where such components comply with the provisions of this Directive.

#### Article 7

1. Member States shall regard safety components referred to in Article 4(2) bearing the CE conformity marking shown in Annex IX and accompanied by the EC declaration of conformity provided for in Annex IV as conforming with all the relevant provisions of this Directive.

2. Before a safety component is placed on the market, the manufacturer or his authorised representative established in the Community must:

(a) submit the safety component to a conformity assessment procedure in accordance with Annex V, and

(b) affix the CE conformity marking on the safety component and, on the basis of the modules laid down in Decision 93/465/EEC, draw up an EC declaration of conformity in accordance with Annex IV.

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

4. 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.

5. Where neither the manufacturer nor his authorised representative established in the Community has complied with the obligations of paragraphs 1 to 4, those obligations shall devolve on whomsoever places the safety component on the market in the Community. The same obligations shall apply to whomsoever manufactures safety components for his own use.

## CHAPTER III

**SUBSYSTEMS***Article 8*

Member States shall take all necessary measures to ensure that subsystems within the meaning of Annex I are placed on the market only if they permit the construction of installations complying with the essential requirements referred to in Article 3(1).

*Article 9*

Member States may not, on the basis of this Directive, prohibit, restrict or impede the placing on their national markets for use in an installation, of subsystems which comply with the provisions of this Directive.

*Article 10*

1. Member States shall regard subsystems within the meaning of Annex I which are accompanied by the EC declaration of conformity based on the model provided for in Annex VI and by the technical documentation provided for in paragraph 3 of this Article, as conforming with the relevant essential requirements referred to in Article 3(1).

2. The EC procedure for examining subsystems shall be carried out at the request of the manufacturer or his authorised representative established in the Community 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 which the manufacturer or his authorised representative or the abovementioned person appointed for that purpose. 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.

3. The notified body shall draw up the EC examination certificate in accordance with Annex VII 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 components. It must also contain all the relevant details of the conditions of, and restrictions on, use and of the instructions for servicing.

## CHAPTER IV

**INSTALLATIONS***Article 11*

1. Each Member State shall lay down procedures for authorising the construction and the putting into service of installations which are located within its territory.

2. Member States shall take all appropriate measures and determine the procedures to ensure that safety components and subsystems referred to in Annex I incorporated in installations constructed in their territory 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.

3. Where a Member State considers a safety component or subsystem referred to in Annex I to have been designed or constructed using an innovative approach, it shall take all appropriate measures 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. It shall immediately inform the Commission thereof, stating its reasons. The Commission shall immediately refer the matter to the committee provided for in Article 17.

4. Member States shall take all appropriate measures 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 Article 3(1).

5. On the basis of the provisions referred to in paragraph 1, Member States may not prohibit, restrict or hinder the free movement of safety components and subsystems referred to in Annex I which are accompanied by an EC declaration of conformity within the meaning of Article 7 or Article 10.

6. 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 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.

7. Member States must ensure 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. In addition, documents must exist setting out the necessary conditions, including the restrictions on operation, and full details of servicing supervision, adjustment and maintenance.

*Article 12*

Without prejudice to other legislative provisions, Member States may not prohibit, restrict or impede the construction and putting into service within their territories of installations which comply with this Directive.

*Article 13*

Member States shall ensure that an installation remains in operation only if it conforms to the conditions set out in the safety report.

## CHAPTER V

### SAFEGUARDS

#### Article 14

1. Where a Member State ascertains 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 Article 10(1), used in accordance with its intended purpose, is liable to endanger the safety and health of persons, and, where applicable, the safety of property, it shall take all appropriate measures to restrict the conditions of use of the component or subsystem or prohibit its use.

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

- (a) failure to satisfy the essential requirements referred to in Article 3(1),
- (b) incorrect application of the European specifications referred to in Article 2(2) in so far as application of those specifications is invoked,
- (c) shortcomings in the European specifications referred to in Article 2(2).

2. The Commission shall enter into consultation with the parties concerned at the earliest opportunity. Where, after such consultation, the Commission finds that:

- the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is based on shortcomings in the European specifications, the Commission shall, after consulting the parties concerned, initiate the procedure referred to in Article 2(7) if the Member State which has taken the decision intends to maintain it,
- the measures relating to a safety component are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community and the Member State which took the measures,
- the measures relating to a subsystem are unjustified, it shall immediately so inform the manufacturer or his authorised representative established in the Community or, in their absence, any natural or legal person having placed the subsystem in question on the market, and the Member State which took the measures.

3. Where a safety component bearing the CE conformity marking is found not to comply, the competent Member State shall take appropriate action against whomsoever affixed that marking and drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

4. Where a subsystem with an EC declaration of conformity is found not to comply, the competent Member State shall take appropriate action against whomsoever drew up the EC declaration of conformity and shall so inform the Commission and the other Member States.

5. The Commission shall ensure that the Member States are kept informed of the outcome of the procedure.

#### Article 15

If a Member State finds that an approved installation which is used in accordance with its intended purpose is liable to endanger the safety and the health of persons and, where appropriate, the safety of property, it shall take all appropriate measures to restrict the conditions of operation of the installation or to prohibit the operation thereof.

## CHAPTER VI

### NOTIFIED BODIES

#### Article 16

1. Member States shall notify the Commission and the other Member States of the bodies responsible for carrying out the conformity assessment procedure referred to in Articles 7 and in Article 10, specifying the field of competence of each body. The Commission shall assign identification numbers to them. The Commission shall publish in the *Official Journal of the European Communities* the list of notified bodies, together with their identification number and their fields of competence, and shall ensure that the list is kept up to date.

2. Member States must apply the criteria laid down in Annex VIII in assessing the bodies to be notified. Bodies meeting the assessment criteria laid down in the relevant harmonised European standards shall be presumed to fulfil those criteria.

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

4. Should the need arise, coordination of the notified bodies shall be implemented in accordance with Article 17.

## CHAPTER VII

### COMMITTEE

#### Article 17

- 1. The Commission shall be assisted by a committee.
- 2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
- 3. The committee shall draw up its rules of procedure.

## CHAPTER VIII

### CE CONFORMITY MARKING

#### Article 18

1. The CE conformity marking shall consist of the letters 'CE'. Annex IX sets out the model to be used.

2. The CE conformity 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.

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. 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.

4. Without prejudice to Article 14:

- (a) where a Member State establishes that the CE conformity marking has been wrongly affixed, the manufacturer of the safety component or the authorised representative of the latter established in the Community 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 imposed by the Member State;
- (b) should non-conformity persist, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the safety component in question, or to ensure that it is withdrawn from the market in accordance with the procedures provided for in Article 14.

#### CHAPTER IX

#### FINAL PROVISIONS

##### Article 19

Any decision taken pursuant to this Directive which restricts the use of safety components or of a subsystem in an installation or the placing on the market thereof shall state the grounds on which it is based. Such a decision shall be notified at the earliest opportunity to the party concerned, who shall at the same time be informed of the legal remedies available to him under the law in force in the Member States concerned and of the time limits to which such remedies are subject.

##### Article 20

Installations for which authorisation has been given before the entry into force of this Directive and for which construction has not yet started must comply with the provisions of this Directive, unless Member States decide otherwise, stating their reasons, and an equally high level of protection is achieved.

##### Article 21

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive not later than 3 May 2002. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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

3. Member States shall, for a period of four years following entry into force of this Directive, allow:

- the construction and putting into service of installations,
- the placing on the market of subsystems and safety components

which conform with the provisions in force in their territories on the date of entry into force of this Directive.

4. The Commission shall report to the European Parliament and the Council on the implementation of this Directive, and in particular Article 1(6) and 17 thereof, not later than 3 May 2004 and, if necessary, submit any proposal for appropriate amendments.

##### Article 22

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

##### Article 23

This Directive is addressed to the Member States.

Done at Brussels, 20 March 2000.

For the European Parliament  
The President  
N. FONTAINE

For the Council  
The President  
J. GAMA



## ANNEX I

**SUBSYSTEMS OF AN INSTALLATION**

For the purposes of this Directive, 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
-

## ANNEX II

## ESSENTIAL REQUIREMENTS

1. **Purpose**

This Annex sets out the essential requirements, including maintainability and operability, applicable to the design, construction and entry into service of installations referred to in Article 1(5) of this Directive.

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 this Directive 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 an official language or languages of the Community which may be determined in accordance with the Treaty by the Member State in the territory of which the installation is constructed.

- 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.

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*ANNEX III***SAFETY ANALYSIS**

The safety analysis required for every cableway installation referred to in Article 1(5) of this Directive 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 Article 4(1) of this Directive and to determine the list of safety components referred to in Article 4(2) thereof. The result of the safety analysis must be summarised in a safety report.

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## ANNEX IV

**SAFETY COMPONENTS: EC DECLARATION OF CONFORMITY**

This Annex applies to the safety components referred to in Article 1(5) of this Directive with a view to establishing their compliance with the essential requirements which concern them referred to in Article 3(1) of the Directive and defined in Annex II.

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.

The declaration must state the following particulars:

- the references of this Directive,
  - name, business name and full address of the manufacturer or his authorised representative established in the Community. 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),
  - 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 established in the Community.
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## ANNEX V

## SAFETY COMPONENTS: ASSESSMENT OF CONFORMITY

1. **Scope**

This Annex applies to safety components with a view to checking compliance with the essential requirements referred to in Article 3(1) of this Directive and defined in Annex II. 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

- 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 this Directive.
- The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community 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.

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.

- The technical documentation must enable the conformity of the component with the requirements of this Directive 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 Article 2(2) of this Directive, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the European specifications referred to in Article 2(2) of this Directive 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 Article 2(2) of this Directive 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 Article 2(2) of this Directive have not been applied, the solutions adopted by the manufacturer meet the essential requirements of this Directive;
  - 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 this Directive, 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 within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the component on the Community market.

#### MODULE D: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 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 this Directive. The manufacturer or his authorised representative established within the Community 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.
2. The manufacturer must operate an approved quality system for production, final component inspection and testing as specified in point 3, and is subject to monitoring as specified in section 4.
3. Quality system
- 3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body or 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 this Directive.

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 harmonised standards.

The auditing team must have a 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,
- the updating referred to in the second paragraph of point 3.4,
- the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.

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 established within the Community checks and attests that the components subject to the provisions of point 3 are in conformity with the type described in the EC type-examination certificate and satisfy the requirements of this Directive.
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 this Directive. 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 this Directive 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 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 Article 2 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 this Directive.
- 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 Article 2(2) of this Directive, or equivalent tests, shall be carried out to ensure their conformity with the requirements of this Directive 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, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative established within the Community 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 Article 2(2) of this Directive, or equivalent tests, to ensure its conformity with the relevant requirements of this Directive.

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 this Directive 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, sub-assemblies, 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 Article 2(2) of this Directive, 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 Article 2(2) 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 must ensure and declare that the components concerned satisfy the relevant requirements of this Directive. The manufacturer or his authorised representative established within the Community 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.
2. The manufacturer must operate an approved quality system for design, manufacture and final component inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

#### 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 this Directive.

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 Article 2(2) of this Directive, 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 this Directive 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. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonised 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 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,
- the updating referred to in the second subparagraph of point 3.4,
- the decisions and reports from the notified body which are referred to in points 3.4, 4.3 and 4.4.

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 this Directive to be assessed.

It must include:

- the technical design specifications, including the European specifications referred to in Article 2(2) of this Directive that have been applied,
  - the necessary supporting evidence for their adequacy, in particular where the European specifications referred to in Article 2(2) of this Directive 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 this Directive, 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 Article 3(1) of this Directive 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.
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## ANNEX VI

**SUBSYSTEMS: EC DECLARATION OF CONFORMITY**

This Annex applies to the subsystems referred to in Article 9 of this Directive in order to ensure that they fulfil the essential requirements concerning them referred to in Article 3(1) of this Directive.

The EC declaration of conformity must be drawn up by the manufacturer, or his authorised representative established in the Community, 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 and must contain the following information:

- the reference of this Directive,
  - 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 this Directive,
  - 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),
  - 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.
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## ANNEX VII

**SUBSYSTEMS: ASSESSMENT OF CONFORMITY**

1. EC examination is the procedure whereby, at the request of the manufacturer or his authorised representative established in the Community 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 Directive 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 Article 4(2) of this Directive which are used in the subsystem,
    - copies of the EC declaration of conformity as provided for in Annex IV 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.
  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 this Directive. 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.
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## ANNEX VIII

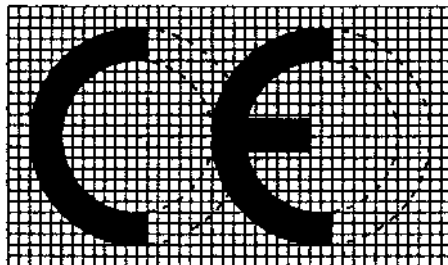
**MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES**

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.
  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 this Directive or any provision of national law giving effect to it.
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## ANNEX IX

**CE CONFORMITY MARKING**

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



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

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

The CE marking shall be followed by the 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 Article 7(3) of this Directive.

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