►B REGULATION (EU) 2016/424 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 9 March 2016

on cableway installations and repealing Directive 2000/9/EC

(Text with EEA relevance)

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CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down rules on the making available on the market and the free movement of subsystems and safety components for cableway installations. It also contains rules on the design, construction and entry into service of new cableway installations.

Article 2

Scope

1. This Regulation applies to new cableway installations designed to transport persons, to modifications of cableway installations requiring a new authorisation, and to subsystems and safety components for cableway installations.

2. This Regulation does not apply to the following:

(a) lifts covered by Directive 2014/33/EU;

(b) cableway installations that are categorised by Member States as historic, cultural or heritage installations, that entered into service before 1 January 1986 and that are still in operation, and that have not had any significant changes in design or construction, including subsystems and safety components specifically designed for them;

(c) installations intended for agricultural or forestry purposes;

(d) cableway installations for the service of mountain shelters and huts intended only for the transport of goods and specifically designated persons;

(e) on-site or mobile equipment exclusively designed for leisure and amusement purposes and not as a means for transporting persons;

(f) mining installations or other industrial on-site installations used for industrial activities;

(g) installations in which the users or their carriers are waterborne.

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Article 3

Definitions

For the purposes of this Regulation the following definitions apply:

(1) ‘cableway installation’ means a whole on-site system, consisting of infrastructure and subsystems, which is designed, constructed, assembled and put into service with the objective of transporting persons, where the traction is provided by cables positioned along the line of travel;

(2) ‘subsystem’ means a system listed in Annex I, or a combination thereof, intended to be incorporated into a cableway installation;

(3) ‘infrastructure’ means a station structure or a structure along the line specifically designed for each cableway installation and constructed on-site, which takes into account the layout and the data of the system and which is needed for the construction and the operation of the cableway installation, including the foundations;

(4) ‘safety component’ means any component of equipment or any device intended to be incorporated into a subsystem or a cableway installation for the purpose of ensuring a safety function, the failure of which endangers the safety or health of passengers, operating personnel or third parties;

(5) ‘operability’ means all the technical provisions and measures which have an impact on design and construction and are necessary in order for the cableway installation to operate safely;

(6) ‘maintainability’ means all the technical provisions and measures which have an impact on design and construction and are necessary for maintenance, having been designed to ensure that the cableway installation operates safely;

(7) ‘cable car’ means a cableway installation where the carriers are suspended from and propelled by one or more cables;

(8) ‘drag lift’ means a cableway installation where passengers with appropriate equipment are towed along a prepared track;

(9) ‘funicular railway’ means a cableway installation in which the carriers are hauled by one or more ropes along a track that may lie on the ground or be supported by fixed structures;

(10) ‘making available on the market’ means any supply of a subsystem or a safety component for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(11) ‘placing on the market’ means the first making available of a subsystem or a safety component on the Union market;

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(12) ‘entry into service’ means the initial operation of a cableway installation with the explicit object of transporting persons;

(13) ‘manufacturer’ means any natural or legal person who manufactures a subsystem or a safety component or who has such a subsystem or a safety component designed or manufactured, and markets that subsystem or safety component under his name or trade mark or incorporates it into a cableway installation;

(14) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(15) ‘importer’ means any natural or legal person established within the Union who places a subsystem or a safety component from a third country on the Union market;

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

(17) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor of a subsystem or a safety component;

(18) ‘technical specification’ means a document that prescribes technical requirements to be fulfilled by a cableway installation, infrastructure, subsystem or safety component;

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

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

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

(22) ‘conformity assessment’ means the process demonstrating whether the essential requirements of this Regulation relating to a subsystem or safety component have been fulfilled;

(23) ‘conformity assessment body’ means a body that performs conformity assessment activities relating to a subsystem or safety component, including calibration, testing, certification and inspection;

(24) ‘recall’ means any measure aimed at achieving the return of a subsystem or a safety component that has already been made available to the person responsible for the cableway installation;

(25) ‘withdrawal’ means any measure aimed at preventing a subsystem or a safety component in the supply chain from being made available on the market;

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

(27) ‘CE marking’ means a marking by which the manufacturer indicates that the subsystem or the safety component is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 4

Making available on the market of subsystems and safety components

Subsystems and safety components shall only be made available on the market if they comply with this Regulation.

Article 5

Entry into service of cableway installations

1. Member States shall, in accordance with Article 9, take all appropriate measures to determine the procedures for ensuring that cableway installations enter into service only if they comply with this Regulation and are not liable to endanger the health or safety of persons or property when properly installed, maintained and operated in accordance with their intended purpose.

2. Member States shall, in accordance with Article 9, take all appropriate measures to determine the procedures for ensuring that the subsystems and safety components are incorporated into cableway installations only if they enable the construction of cableway installations which comply with this Regulation and are not liable to endanger the health or safety of persons or property when properly installed, maintained and operated in accordance with their intended purpose.

3. Cableway installations which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those standards or parts thereof.

4. This Regulation shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected when using the cableway installations in question, provided that this does not mean that the cableway installations are modified in a manner not covered by this Regulation.

Article 6

Essential requirements

The cableway installations and their infrastructure, subsystems and safety components shall meet the essential requirements set out in Annex II which apply to them.

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Article 7

Free movement of subsystems and safety components

Member States shall not prohibit, restrict or impede the making available on the market of subsystems and safety components which comply with this Regulation.

Article 8

Safety analysis and safety report for planned cableway installations

1. The person responsible for the cableway installation, determined by a Member State in accordance with national law, shall carry out a safety analysis of the planned cableway installation or have such a safety analysis carried out.

2. The safety analysis required for each cableway installation shall:

(a) take into account all modes of operation envisaged;

(b) follow a recognised or established method;

(c) take into account the current state of the art and the complexity of the cableway installation in question;

(d) ensure that the design and configuration of the cableway installation takes account of the local surroundings and the most adverse situations in order to ensure satisfactory safety conditions;

(e) cover all safety aspects of the cableway installation and its external factors in the context of the design, construction and entry into service;

(f) make it possible to identify from past experience risks liable to occur during the operation of the cableway installation.

3. The safety analysis shall also cover the safety devices and their effects on the cableway installation and related subsystems that they bring into action so that the safety devices:

(a) 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;

(b) are redundant and are monitored; or

(c) are such that the probability of their failure can be evaluated and their effects are of a standard equivalent to that achieved by safety devices that meet the criteria set out in points (a) and (b).

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4. The safety analysis shall be used to draw up the inventory of risks and dangerous situations, to recommend the measures envisaged to deal with such risks and to determine the list of subsystems and safety components to be incorporated into the cableway installation.

5. The result of the safety analysis shall be included in a safety report.

Article 9

Authorisation of cableway installations

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

2. The person responsible for the cableway installation, determined by a Member State in accordance with national law, shall submit the safety report referred to in Article 8, the EU declaration of conformity and the other documents relating to the conformity of subsystems and safety components as well as the documentation concerning the characteristics of the cableway installation to the authority or body responsible for authorising the cableway installation. The documentation concerning the cableway installation shall also include the necessary conditions, including the restrictions on operation, and full details for servicing, supervision, adjustment and maintenance of the cableway installation. A copy of those documents shall be kept at the cableway installation.

3. In the event that important characteristics, subsystems or safety components of existing cableway installations undergo modifications for which a new authorisation for entry into service is required by the Member State concerned, such modifications and their repercussions on the cableway installation as a whole shall satisfy the essential requirements set out in Annex II.

4. Member States shall not use the procedures referred to in paragraph 1 to prohibit, restrict or hinder, on grounds related to the aspects covered by this Regulation, the construction and the entry into service of cableway installations which comply with this Regulation and do not present a risk to the health or safety of persons or to property when properly installed in accordance with their intended purpose.

5. Member States shall not use the procedures referred to in paragraph 1 to prohibit, restrict or hinder the free movement of subsystems and safety components which comply with this Regulation.

Article 10

Operation of cableway installations

1. Member States shall ensure that a cableway installation remains in operation only if it complies with the conditions set out in the safety report.

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

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 11

Obligations of manufacturers

1. When placing their subsystems or safety components on the market or when incorporating them into a cableway installation, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex II.

2. Manufacturers of subsystems or safety components shall draw up the technical documentation set out in Annex VIII ('technical documentation') and carry out the relevant conformity assessment procedure referred to in Article 18 or have it carried out.

Where compliance of a subsystem or a safety component with the applicable requirements has been demonstrated by the procedure referred to in the first subparagraph, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 30 years after the subsystem or the safety component has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in subsystem or safety component design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the subsystem or the safety component is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a subsystem or a safety component, manufacturers shall, to protect the health and safety of passengers, operating personnel and third parties, carry out sample testing of subsystems or safety components made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming subsystems and safety components and recalls of such subsystems and safety components, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that subsystems or safety components which they have placed on the market bear a type, batch or serial number or other element allowing their identification.

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Where the size or nature of the subsystem or safety component does not allow it, manufacturers shall ensure that the required information is provided on the packaging or in a document accompanying the subsystem or safety component.

6. Manufacturers shall indicate on the subsystem or the safety component their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on the packaging or in a document accompanying the subsystem or safety component. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and the market surveillance authorities. Where the manufacturer indicates a website address, he shall ensure that the information on that website is accessible and kept updated.

7. Manufacturers shall ensure that the subsystem or the safety component is accompanied by a copy of the EU declaration of conformity and by instructions and safety information, in a language which can be easily understood by users, as determined by the Member State concerned. Such instructions and safety information shall be clear, understandable and intelligible.

However, where a large number of subsystems or safety components are delivered to a single economic operator or user, the batch or consignment concerned may be accompanied by a single copy of the EU declaration of conformity.

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

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the subsystem or the safety component with this Regulation, in a language which can be easily understood by that authority. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have placed on the market.

Article 12

Authorised representatives

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

The obligations laid down in Article 11(1) and the obligation to draw up technical documentation shall not form part of the authorised representative's mandate.

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2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 30 years after the subsystem or the safety component has been placed on the market;

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

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

Article 13

Obligations of importers

1. Importers shall place only compliant subsystems or safety components on the market.

2. Before placing on the market a subsystem or a safety component, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 18 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the subsystem or the safety component bears the CE marking and that it is accompanied by a copy of the EU declaration of conformity, by instructions and safety information, and, where appropriate, by other required documents, and that the manufacturer has complied with the requirements set out in Article 11(5) and (6).

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

3. Importers shall indicate on the subsystem or the safety component their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the subsystem or safety component. The contact details shall be in a language easily understood by users and market surveillance authorities.

Where the importer indicates a website address, he shall ensure that the information on that website is accessible and kept updated.

4. Importers shall ensure that the subsystem or the safety component is accompanied by instructions and safety information, in a language which can be easily understood by users, as determined by the Member State concerned.

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

6. When deemed appropriate with regard to the risks presented by a subsystem or a safety component, importers shall, to protect the health and safety of the passengers, operating personnel and third parties, carry out sample testing of subsystems or safety components made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming subsystems and safety components and recalls of such subsystems and safety components, and shall keep distributors informed of any such monitoring.

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

8. Importers shall, for 30 years after the subsystem or the safety component has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

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

Article 14

Obligations of distributors

1. When making a subsystem or a safety component available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making a subsystem or a safety component available on the market, distributors shall verify that the subsystem or the safety component bears the CE marking and that it is accompanied by a copy of the EU declaration of conformity, by instructions and safety information, and, where appropriate, by other required documents, in a language which can be easily understood by users as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 11(5) and (6) and Article 13(3) respectively.

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

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

4. Distributors who consider or have reason to believe that a subsystem or a safety component which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that subsystem or safety component into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the subsystem or the safety component presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the subsystem or the safety component available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a subsystem or a safety component. That information and documentation may be provided in paper or electronic form. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by subsystems or safety components which they have made available on the market.

Article 15

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 11, where he places a subsystem or a safety component on the market under his name or trade mark or modifies a subsystem or a safety component already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

Article 16

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a subsystem or a safety component;

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(b) any economic operator and any person responsible for a cableway installation to whom they have supplied a subsystem or a safety component.

Economic operators shall be able to present the information referred to in the first paragraph for 30 years after they have been supplied with the subsystem or the safety component and for 30 years after they have supplied the subsystem or the safety component.

CHAPTER III

CONFORMITY OF SUBSYSTEMS AND SAFETY COMPONENTS

Article 17

Presumption of conformity of subsystems and safety components

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

Article 18

Conformity assessment procedures

1. Before a subsystem or a safety component is placed on the market, the manufacturer shall submit the subsystem or the safety component to a conformity assessment procedure in accordance with paragraph 2.

2. The conformity of subsystems and safety components shall be assessed, at the choice of the manufacturer, by means of any of the following conformity assessment procedures:

(a) EU-type examination (Module B — production type), set out in Annex III combined with one of the following:

(i) conformity to type based on quality assurance of the production process (Module D), set out in Annex IV;

(ii) conformity to type based on subsystem or safety component verification (Module F), set out in Annex V;

(b) conformity based on unit verification (Module G), set out in Annex VI;

(c) conformity based on full quality assurance plus design examination (Module H 1), set out in Annex VII.

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3. Records and correspondence relating to the conformity assessment procedures shall be drawn up in an official language of the Member State where the notified body carrying out the procedures referred to in paragraph 2 is established or in a language accepted by that body.

Article 19

EU declaration of conformity

1. The EU declaration of conformity for a subsystem or a safety component shall state that the fulfilment of the essential requirements set out in Annex II has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex IX, shall contain the elements specified in the relevant modules set out in Annexes III to VII and shall be continuously updated. It shall accompany the subsystem or the safety component and shall be translated into the language or languages required by the Member State in which the subsystem or the safety component is placed or made available on the market.

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

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the subsystem or the safety component with the requirements laid down in this Regulation.

Article 20

General principles of the CE marking

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

Article 21

Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the subsystem or the safety component or to its data plate. Where that is not possible or not warranted on account of the nature of the subsystem or the safety component, it shall be affixed to the packaging and to the accompanying documents.

2. The CE marking shall be affixed before the subsystem or the safety component is placed on the market.

3. The CE marking shall be followed by the identification number of the notified body involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

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

5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 22

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 23

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 28.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24. In addition, it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 24

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

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3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 25

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 26

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the subsystem or the safety component it assesses.

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

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

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A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those subsystems or safety components, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

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

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

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

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

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

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

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

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

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

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

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

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

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

8. The impartiality of the conformity assessment bodies, their top-level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top-level management and of the personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out, nor on the results of those assessments.

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

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

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

Article 27

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 26 in so far as the applicable harmonised standards cover those requirements.

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Article 28

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26 and shall inform the notifying authority accordingly.

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

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

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes III to VII.

Article 29

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the subsystem/safety component or subsystems/safety components for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 30

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 26.

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

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the subsystem/safety component or subsystems/safety components concerned and the relevant attestation of competence.

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4. Where a notification is not based on an accreditation certificate as referred to in Article 29(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

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

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 31

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 32

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26 or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

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

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Article 33

Challenge of the competence of notified bodies

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

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

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 34

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III to VII.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the subsystem or safety component technology in question and the mass or serial nature of the production process.

In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the subsystem or the safety component with this Regulation.

3. Where a notified body finds that the essential requirements set out in Annex II or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

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

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

Article 35

Appeal against decisions of notified bodies

Notified bodies shall ensure that an appeal procedure against their decisions is available.

Article 36

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

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

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

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

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

2. Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same subsystems or safety components with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 38

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of the coordination group of notified bodies for cableway installations.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

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CHAPTER V

UNION MARKET SURVEILLANCE, CONTROL OF SUBSYSTEMS AND SAFETY COMPONENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 39

Union market surveillance and control of subsystems and safety components entering the Union market

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

Article 40

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

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a subsystem or safety component covered by this Regulation presents a risk to the health or safety of persons or to property, they shall carry out an evaluation in relation to the subsystem or safety component concerned, covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

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

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

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

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

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

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

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

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

(a) failure of the subsystem or safety component to meet requirements relating to the health or safety of persons or the protection of property; or

(b) shortcomings in the harmonised standards referred to in Article 17 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the subsystem or safety component concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the subsystem or safety component from the market, are taken in respect of the subsystem or safety component concerned without delay.

Article 41

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 40(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

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2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant subsystem or safety component is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the subsystem or safety component is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 40(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 42

Compliant subsystems or safety components which present a risk

1. Where, having carried out an evaluation under Article 40(1), a Member State finds that although a subsystem or safety component is in compliance with this Regulation, it presents a risk to the health or safety of persons or to property, it shall require the relevant economic operator to take all appropriate measures to ensure that the subsystem or safety component concerned, when placed on the market, no longer presents that risk, to withdraw the subsystem or safety component from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

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

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

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

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5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 43

Formal non-compliance

1. Without prejudice to Article 40, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 21 of this Regulation;

(b) the CE marking has not been affixed;

(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 21 or has not been affixed;

(d) the EU declaration of conformity does not accompany the subsystem or safety component;

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

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

(g) the technical documentation is either not available or not complete;

(h) the information referred to in Article 11(6) or Article 13(3) is absent, false or incomplete;

(i) any other administrative requirement provided for in Article 11 or Article 13 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the subsystem or safety component being made available on the market, or ensure that it is recalled or withdrawn from the market.

CHAPTER VI

COMMITTEE PROCEDURE, TRANSITIONAL AND FINAL PROVISIONS

Article 44

Committee procedure

1. The Commission shall be assisted by the Committee on cableway installations. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

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5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

Article 45

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation and of national law adopted pursuant to this Regulation. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive and may be increased where the relevant economic operator has previously committed a similar infringement of this Regulation.

Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them.

2. Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.

Article 46

Transitional provisions

Member States shall not impede the making available on the market of subsystems or safety components covered by Directive 2000/9/EC which are in conformity with that Directive and which were placed on the market before 21 April 2018.

Member States shall not impede the entry into service of cableway installations covered by Directive 2000/9/EC which are in conformity with that Directive and which were installed before 21 April 2018.

For safety components, certificates and approval decisions issued under Directive 2000/9/EC shall be valid under this Regulation.

Article 47

Repeal

Directive 2000/9/EC is repealed with effect from 21 April 2018.

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

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Article 48

Entry into force and application

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

2. This Regulation shall apply from 21 April 2018, with the exception of:

(a) Articles 22 to 38 and 44, which shall apply from 21 October 2016;

(b) Article 45(1), which shall apply from 21 March 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

SUBSYSTEMS

A cableway installation is divided up into infrastructure and the subsystems listed below:

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.

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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 cableway installations, and applicable to subsystems and safety components.

2. General requirements

2.1. Safety of persons

The safety of passengers, operating personnel and third parties is a fundamental requirement for the design, construction and operation of cableway installations.

2.2. Principles of safety

All cableway installations shall 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

Cableway installations must be so designed and constructed as to make it possible to operate them safely, taking into account the type of cableway 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 cableway installation, the subsystems and all its safety components shall 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 cableway installation, the subsystems and all the safety components shall 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 shall 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.

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2.6. Integrity of the cableway installation

2.6.1. The safety components shall 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 cableway installation is ensured, as defined in the safety analysis provided for in Article 8, so that their failure is highly improbable and with an adequate safety margin.

2.6.2. The cableway installation shall be designed and constructed in such a way as to ensure that, during its operation, any failure of a component which might endanger safety, 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 shall apply throughout the period between two scheduled inspections of the component concerned. The time period for the scheduled inspection of the safety components shall be clearly indicated in the instruction manual.

2.6.4. Safety components which are incorporated into cableway installations as spare parts shall satisfy the essential requirements of this Regulation and the conditions relating to the smooth interaction with the other parts of the cableway installations.

2.6.5. Measures shall be taken to ensure that the effects of a fire in the cableway installation do not endanger the safety of persons.

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

2.7. Safety devices

2.7.1. Any defect in the cableway installation which could result in a failure endangering safety shall, 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 shall be possible at all times to shut down the cableway installation manually.

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

2.8. Maintainability

The cableway installation shall 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 cableway installation shall 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.

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3. Infrastructure requirements

3.1. Layout, speed, distance between vehicles

3.1.1. The cableway installation shall 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 shall 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 shall take account of the nature of the cableway installation, the type of vehicles and the rescue procedures. In the case of open cars it shall 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 shall be chosen to ensure the safety of persons and the safe operation of the cableway installation.

3.2. Stations and structures along the line

3.2.1. Stations and structures along the line shall 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 cableway installation shall 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 shall 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 shall 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.

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4.1.2. ►C1 If it is not possible to prevent all risk of cable derailment, measures shall be taken to ensure that ◄ cables can be retrieved and the cableway installations shut down without risk to persons in the event of derailment.

4.2. Mechanical installations

4.2.1. Drives

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

4.2.2. Standby drive

The cableway installation shall 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 shall be possible to shut down the cableway 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 shall be as short as the security of the cableway installation dictates.

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

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

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

4.3. Control devices

The control devices shall 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 shall be provided to enable operational staff to communicate with one another at all times and to inform passengers in case of emergency.

5. Vehicles and towing devices

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

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5.2. The fittings of vehicles and towing devices shall 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) shall be designed and constructed in such a way as to make it possible to close and lock them. The vehicle floor and walls shall be designed and constructed so as to withstand pressure and loads exerted by passengers and operating personnel under any circumstances.

5.4. If, for reasons of operational safety, an operator is required on board the vehicle, the vehicle shall 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 shall 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 shall be taken to bring to a halt, without risk to passengers or operating personnel, 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. The installations which have their vehicles running on a fixed track (such as funicular vehicles and multi-rope cable cars) shall be equipped with an automatic braking device on the track, when the possibility of traction cable breaking cannot reasonably be excluded.

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

6. Equipment for passengers and operating personnel

The access to embarkation areas and exit from disembarkation areas and the embarkation and disembarkation of passengers and operating personnel shall be organised with regard to the movement and stopping of vehicles in such a way as to ensure the safety of passengers and operating personnel, 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 cableway installation safely if the cableway installation is designed for the transport of such persons.

7. Operability

7.1. Safety

7.1.1. All technical provisions and measures shall be taken to ensure that the cableway 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 a language which can be easily understood by users, as determined by the Member State in the territory of which the cableway installation is constructed.

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

7.2. Safety in the event of immobilisation of the cableway installation

All technical provisions and measures shall be adopted to ensure that passengers and operating personnel can be brought to safety within a set time appropriate to the type of cableway installation and its surroundings when the cableway 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 shall 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 cableway installation which may cause accidents. Those devices shall 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, shall 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 shall also be provided with anchorage points for personal protective equipment to prevent falls.

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ANNEX III

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE B: EU-TYPE EXAMINATION — PRODUCTION TYPE

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a subsystem or a safety component and verifies and attests that the technical design meets the requirements of this Regulation that apply to it.

2. EU-type examination shall be carried out by assessment of the adequacy of the technical design of the subsystem or the safety component through examination of the technical documentation referred to in point 3, plus examination of a specimen, representative of the production envisaged, of the complete subsystem or safety component (production type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

   The application shall include:

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

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

   (c) the technical documentation for the subsystem or the safety component according to Annex VIII;

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

4. The notified body shall:

4.1. examine the technical documentation to assess the adequacy of the technical design of the subsystem or the safety component;

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

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Regulation;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

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5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Regulation, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, any conditions for its validity, the necessary data for identification of the approved type (subsystem or safety component) and if relevant, descriptions of its functioning. The certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems and safety components with the examined type to be evaluated and to allow for in-service control. It shall also indicate any conditions to which its issue may be subject and be accompanied by the descriptions and drawings necessary for identification of the approved type.

The certificate shall have a maximum validity period of 30 years from the date of its issue.

Where the type does not satisfy the applicable requirements of this Regulation, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of any modifications to the approved type that may affect the conformity of the subsystem or the safety component with the essential requirements of this Regulation or the conditions for validity of the certificate.

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

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

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

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The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

10. The manufacturer's obligations set out in points 7 and 9, may be fulfilled by his authorised representative, provided that they are specified in the mandate.

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ANNEX IV

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the subsystems or safety components concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

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

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice.

The application shall include:

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

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

(c) all relevant information for the subsystems or safety components approved under module B;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate(s);

(f) details of the premises where the subsystem or the safety component is manufactured.

3.2. The quality system shall ensure that the subsystems or safety components are in conformity with the type(s) described in the EU-type examination certificate(s) and comply with the requirements of this Regulation that apply to them.

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

It shall, in particular, contain an adequate description of:

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

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

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

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

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

The audit shall include an assessment visit to the premises where the subsystems or the safety components are manufactured, inspected and tested.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of cableway installations and in the technology of the subsystems or safety components concerned, and knowledge of the applicable requirements of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e), to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the subsystems or safety components with those requirements.

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

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

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

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

It shall notify the manufacturer of the outcome of the evaluation. In case of a reassessment, it shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits of at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

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

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual subsystem or safety component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or safety component model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period of 30 years after the subsystem or safety component has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

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

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, giving the reasons for its decision, and, upon request, of quality system approvals which it has issued.

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

The notified body shall keep a copy of each approval decision issued and its annexes and additions.

8. Authorised representative

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

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ANNEX V

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE F: CONFORMITY TO TYPE BASED ON SUBSYSTEM OR SAFETY COMPONENT VERIFICATION

1. Conformity to type based on subsystem or safety component verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the subsystems or safety components concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured subsystems or safety components with the approved type described in the EU-type examination certificate and with the requirements of this Regulation that apply to them.

3. Verification

3.1. The manufacturer shall lodge an application for subsystem or safety component verification with the notified body of his choice.

The application shall include:

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

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

(c) all relevant information for the subsystems or safety components approved under module B;

(d) the technical documentation of the approved type and a copy of the EU-type examination certificate(s);

(e) details of the premises where the subsystem or the safety component can be examined.

3.2. The notified body shall carry out appropriate examinations and tests, or have them carried out, in order to check the conformity of the subsystems or safety components with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

The examinations and tests to check the conformity of the subsystems or safety components with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every subsystem or safety component as specified in point 4 or by examination and testing of the subsystems or safety components on a statistical basis as specified in point 5.

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4. Verification of conformity by examination and testing of every subsystem or safety component

4.1. All subsystems or safety components shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Regulation.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved subsystem or safety component or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 30 years after the subsystem or safety component has been placed on the market.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his subsystem or safety component for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot. All the subsystems or safety components in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the applicable requirements of this Regulation and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. If a lot is accepted, all the subsystems or safety components of the lot shall be considered approved, except for those subsystems or safety components from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved subsystem or safety component or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

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

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6. CE marking and EU declaration of conformity

6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual subsystem or safety component that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or safety component model for which it has been drawn up.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the subsystems or safety components.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the subsystems or safety components during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the obligations set out in points 2 and 5.1.

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ANNEX VI

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3.1 and 4, and ensures and declares on his sole responsibility that the subsystem or safety component concerned, which has been subject to the provisions of point 3, is in conformity with the requirements of this Regulation that apply to it.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured subsystem or safety component with the applicable requirements of this Regulation.

3. Verification

3.1. The manufacturer shall lodge an application for unit verification of a subsystem or a safety component with the notified body of his choice.

The application shall include:

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

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

(c) the technical documentation for the subsystem or the safety component according to Annex VIII;

(d) details of the premises where the subsystem or the safety component can be examined.

3.2. The notified body shall examine the technical documentation for the subsystem or the safety component and shall carry out the appropriate examinations and tests set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the subsystem or the safety component with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved subsystem or safety component, or have it affixed under its responsibility.

If the notified body refuses to issue a certificate of conformity, it shall state in detail the reasons for the refusal and indicate the necessary corrective measures to be taken.

When the manufacturer reapplies for unit verification of the subsystem or the safety component concerned, he shall apply to the same notified body.

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

The manufacturer shall keep the technical documentation and the certificate of conformity at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each subsystem or safety component that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or the safety component for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in points 3.1 and 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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ANNEX VII

CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS AND SAFETY COMPONENTS: MODULE H 1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the subsystems or safety components concerned satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for the design, manufacture and final inspection and testing of subsystems or safety components as specified in point 3 and shall be subject to surveillance as specified in point 4. The adequacy of the technical design of the subsystems or safety components shall have been examined in accordance with point 3.6.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the subsystems or safety components concerned.

The application shall include:

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

(b) all necessary information on the subsystems or safety components to be manufactured;

(c) the technical documentation in accordance with Annex VIII for one representative type of each category of subsystem or safety component to be manufactured;

(d) the documentation concerning the quality system;

(e) the address of the premises where the subsystems or safety components are designed, manufactured, inspected and tested;

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

3.2. The quality system shall ensure compliance of the subsystems or the safety components with the requirements of this Regulation that apply to them.

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

It shall, in particular, contain an adequate description of:

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

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(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means, including other relevant technical specifications, that will be used to ensure that the essential requirements of this Regulation will be met;

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

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

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

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

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

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

The audit shall include an assessment visit to the premises where the subsystems or the safety components are designed, manufactured, inspected and tested.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as assessor in the field of cableway installations and in the technology of the subsystems or safety components concerned, and knowledge of the applicable requirements of this Regulation.

The auditing team shall review the technical documentation referred to in point 3.1 to verify the manufacturer's ability to identify the applicable requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the subsystems or the safety components with those requirements.

The notified body shall notify its decision to the manufacturer or his authorised representative. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

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

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

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

3.6. Design examination

3.6.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

3.6.2. The application shall make it possible to understand the design, manufacture and operation of the subsystem or safety component, and to assess the conformity with the requirements of this Regulation that apply to it.

It shall include:

(a) the name and address of the manufacturer;

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

(c) the technical documentation as described in Annex VIII.

3.6.3. The notified body shall examine the application and, where the design meets the requirements of this Regulation that apply to the subsystem or safety component, it shall issue an EU design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured subsystems or safety components with the examined design to be evaluated and to allow for in-service control, where applicable.

Where the design does not satisfy the applicable requirements of this Regulation, the notified body shall refuse to issue an EU design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

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

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval from the notified body that issued the EU design examination certificate in the form of an addition to the original EU design examination certificate.

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

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

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

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

3.6.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 30 years after the subsystem or safety component has been placed on the market.

4. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

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

(c) 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 on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report. The frequency of periodic audits shall be such that a full reassessment is carried out every three years.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer.

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

5. CE marking and EU declaration of conformity.

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual subsystem or safety component that satisfies the applicable requirements of this Regulation.

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5.2. The manufacturer shall draw up a written EU declaration of conformity for each subsystem or safety component model and keep it at the disposal of the national authorities for 30 years after the subsystem or the safety component has been placed on the market. The EU declaration of conformity shall identify the subsystem or the safety component model for which it has been drawn up and shall refer to the number of the EU design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period of 30 years after the subsystem or safety component has been placed on the market, keep at the disposal of the national authorities:

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

(b) the documentation concerning the quality system referred to in point 3.1(d);

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

(d) the decisions and reports of the notified body referred to in points 3.3, 3.5, 4.3 and 4.4.

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

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

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

The notified body shall keep a copy of the quality system approval decision(s) issued, its annexes and additions, as well as the technical file, for a period of 30 years from the date of their issue.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.6.4, 3.6.6, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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ANNEX VIII

TECHNICAL DOCUMENTATION FOR SUBSYSTEMS AND SAFETY COMPONENTS

1. The technical documentation shall make it possible to assess the conformity of the subsystem or the safety component with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the conformity assessment, the design, manufacture and operation of the subsystem or safety component.

2. The technical documentation shall contain, at least the following elements:

   (a) a general description of the subsystem or the safety component;

   (b) design and manufacturing drawings and diagrams of components, subassemblies, circuits, etc. and the descriptions and explanations necessary for the understanding of those drawings and diagrams and of the operation of the subsystem or safety component;

   (c) a list of the harmonised standards referred to in Article 17, applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, and where those harmonised standards have not been applied descriptions of the solutions adopted to meet the essential requirements of this Regulation including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

   (d) the supporting evidence for the adequacy of the design, including the results of any design calculations, examinations or tests carried out by or for the manufacturer and the related reports;

   (e) a copy of the instructions for the subsystem or the safety component;

   (f) for subsystems, copies of the EU declarations of conformity for the safety components incorporated into the subsystem.

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ANNEX IX

EU DECLARATION OF CONFORMITY FOR SUBSYSTEMS AND SAFETY COMPONENTS No … (*)

1. Subsystem/safety component or subsystem/safety component model (product, type, batch, or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of the subsystem or safety component allowing traceability. It may, where necessary for the identification of the subsystem or safety component, include an image):
   — description of the subsystem or safety component,
   — all relevant provisions with which the safety component must comply and, in particular, the conditions of use.
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: …
6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:
7. The notified body … (name, address, number) … performed … (description of intervention) … and issued the certificate(s): … (details, including its date, and where appropriate, information on the duration and conditions of its validity).
8. Additional information:

Signed for and on behalf of: …

(place and date of issue):

(name, function) (signature):

(*) It is optional for the manufacturer to assign a number to the declaration of conformity.

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ANNEX X

CORRELATION TABLE

Directive 2000/9/EC	This Regulation
—	Article 1
Article 1(1)	Article 2(1)
Article 1(2)	Article 3, point 1
Article 1(3)	Article 3, points 7 to 9
Article 1(4) first subparagraph	Article 2(1)
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