

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)

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.

*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;
- (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;
- (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.

#### *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).
- 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.

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.

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.

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.

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.

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;
- (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.

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.

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.

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.

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.

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.

### 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.

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.

#### *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.

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.

## 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.

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.

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).

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.

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.

*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.

Done at Strasbourg, 9 March 2016.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

J.A. HENNIS-PLASSCHAERT