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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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I

(Legislative acts)

REGULATIONS

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2000/9/EC of the European Parliament and of the Council ⁽³⁾ lays down rules for cableway installations that are designed, constructed and operated with a view to transporting persons.
- (2) Directive 2000/9/EC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ⁽⁴⁾. Thus, it sets out only the essential requirements applying to cableway installations, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽⁵⁾. Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 2000/9/EC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.
- (3) Experience acquired from the implementation of Directive 2000/9/EC has shown the need to modify some of its provisions in order to clarify and update them and thus ensure legal certainty, mainly as regards the scope and the conformity assessment of subsystems.

⁽¹⁾ OJ C 451, 16.12.2014, p. 81.

⁽²⁾ Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

⁽³⁾ Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (OJ L 106, 3.5.2000, p. 21).

⁽⁴⁾ OJ C 136, 4.6.1985, p. 1.

⁽⁵⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (4) Since the scope, essential requirements and conformity assessment procedures have to be identical in all Member States, there is almost no flexibility in transposing a directive based on the new approach principles into national law. In order to simplify the regulatory framework, Directive 2000/9/EC should be replaced by a regulation, which is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States and thus ensures a uniform implementation throughout the Union.
- (5) Decision No 768/2008/EC of the European Parliament and of the Council ⁽¹⁾ lays down common principles and reference provisions intended to apply across the legislation harmonising the conditions for the marketing of products in order to provide a coherent basis for revision or recasts of that legislation. Directive 2000/9/EC should therefore be adapted to that Decision.
- (6) Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽²⁾ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (7) The scope of this Regulation should reflect the scope of Directive 2000/9/EC. This Regulation should apply to cableway installations designed to transport persons used in particular in high-altitude tourist resorts, in urban transport facilities or in sports facilities. Cableway installations are mainly lift systems, such as funicular railways, aerial ropeways (cable cars, gondolas, chairlifts) and drag lifts. Traction by cable and the passenger transport function are the essential criteria in determining whether a cableway installation is covered by this Regulation.
- (8) This Regulation should apply in its entirety to new cableway installations, to modifications of cableway installations requiring a new authorisation and covers subsystems and safety components which are new to the Union market when they are placed on it; that is to say, they are either new subsystems and safety components made by a manufacturer established in the Union or subsystems and safety components, whether new or second-hand, imported from a third country. This Regulation does not apply to the relocation of cableway installations installed on the territory of the Union or to the relocation of subsystems or safety components that were incorporated into such installations, except where such relocation implies a major modification of the cableway installation.
- (9) New types of cableway installations have been developed that are intended for both transport and leisure activities. Such installations should be covered by this Regulation.
- (10) It is appropriate to exclude certain cableway installations from the scope of this Regulation, either because they are subject to other specific Union harmonisation legislation or because they can be adequately regulated at national level.
- (11) Lifts, including cable-operated lifts, whether vertical or inclined, permanently serving specific levels of buildings and constructions and not operating between cableway stations, are subject to specific Union legislation and should be excluded from the scope of this Regulation. Cableway installations covered by this Regulation are excluded from the scope of Directive 2014/33/EU of the European Parliament and of the Council ⁽³⁾.
- (12) Cableway installations that are categorised by Member States as historic, cultural or heritage installations, that entered into service before 1 January 1986 and are still in operation, and that have not had any significant changes in design or construction, should be excluded from the scope of this Regulation. This exclusion also applies to subsystems and safety components specifically designed for such cableway installations. Member States should ensure a high level of protection of the health and safety of persons and of property concerning such cableway installations, if necessary by way of national legislation.
- (13) In order to ensure legal certainty, the exclusion of cable-operated ferries should cover all cable-operated installations where the users or carriers are waterborne, such as cable-operated waterski installations.

⁽¹⁾ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

⁽²⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁽³⁾ Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).

- (14) In order to ensure that cableway installations and their infrastructure, subsystems and safety components guarantee a high level of protection of the health and safety of persons and of property, it is necessary to lay down rules for the design and the construction of cableway installations.
- (15) Member States should ensure the safety of cableway installations at the time of their construction, entry into service and during their operation.
- (16) This Regulation should not affect the right of the Member States to specify the requirements they deem necessary as regards land use and regional planning, and in order to ensure the protection of the environment and of the health and safety of persons, and in particular workers and operating personnel, when using cableway installations.
- (17) This Regulation should not affect the right of the Member States to specify adequate procedures for the authorisation of planned cableway installations, the inspection of cableway installations prior to their entry into service and their monitoring during operation.
- (18) This Regulation should take into account the fact that the safety of cableway installations depends equally on the surrounding conditions, on the quality of the industrial goods supplied and on the way in which they are assembled, installed on-site and monitored during operation. The causes of serious accidents may be linked to the choice of site, to the system of transport itself, to the structures, or to the way in which the system is operated and maintained.
- (19) Although this Regulation does not cover the actual operation of cableway installations, it should provide a general framework intended to ensure that such installations situated on the territory of Member States are operated in such a way as to offer passengers, operating personnel and third parties a high degree of protection.
- (20) Member States should take the necessary steps to ensure 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.
- (21) Member States should lay down procedures for authorising the construction of planned cableway installations and the modification of such installations and for their entry into service in order to ensure that the cableway installation is safely constructed and assembled on-site, in accordance with the safety analysis, the results of which are included in the safety report, and all relevant regulatory requirements.
- (22) The safety analysis for planned cableway installations should identify the components on which the safety of the cableway installation depends.
- (23) The safety analysis for planned cableway installations should take into account the constraints linked to the operation of cableway installations, albeit not in such a way as to jeopardise the principle of free movement of goods for subsystems and safety components or the safety of the cableway installations themselves.
- (24) Rules on authorising the entry into service of cableway installations fall within the competence of Member States. Authorisation for entry into service is granted by the competent authorities or bodies. Monitoring of the operating safety of cableway installations also falls within the competence of Member States. Member States should therefore determine the person responsible for the cableway installation and, accordingly, for the safety analysis of a planned cableway installation.
- (25) This Regulation aims to ensure the functioning of the internal market for subsystems of cableway installations and for safety components for cableway installations. Subsystems and safety components complying with this Regulation should benefit from the principle of free movement of goods.
- (26) Subsystems and safety components should be allowed to be incorporated in a cableway installation provided that they permit 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.

- (27) The essential requirements should be interpreted and applied so as to take account of the state of the art at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection.
- (28) Economic operators should be responsible for the compliance of subsystems and safety components with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons and protection of property, and to guarantee fair competition on the Union market.
- (29) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market subsystems and safety components which are in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (30) The manufacturer of subsystems or safety components, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer of the subsystem or the safety component.
- (31) In order to facilitate communication between economic operators and national market surveillance authorities, Member States should encourage economic operators to include a website address in addition to the postal address.
- (32) It is necessary to ensure that subsystems and safety components from third countries entering the Union market comply with the requirements of this Regulation, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those subsystems and safety components. Provision should therefore be made for importers to make sure that the subsystems or safety components they place on the market comply with the requirements of this Regulation and that they do not place on the market subsystems and safety components which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that subsystem and safety component marking and documentation drawn up by manufacturers are available for inspection by the competent national authorities.
- (33) The distributor makes a subsystem or a safety component available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the subsystem or the safety component does not adversely affect its compliance.
- (34) When placing on the market a subsystem or a safety component, every importer should indicate on the subsystem or safety component his name, registered trade name or registered trade mark and the postal address at which he can be contacted, as well as a website, where available. Exceptions should be provided for in cases where the size or nature of the subsystem or safety component does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the subsystem or safety component.
- (35) Any economic operator that either places a subsystem or a safety component on the market under his own name or trademark, or modifies a subsystem or a safety component in such a way that compliance with the requirements of this Regulation may be affected, should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (36) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the subsystems or the safety components concerned.
- (37) Ensuring traceability of a subsystem or a safety component throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant subsystems or safety components available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a subsystem or safety component or to whom they have supplied a subsystem or a safety component.

- (38) This Regulation should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for cableway installations, subsystems and safety components which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, construction and operation of cableway installations.
- (39) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (40) In order to enable economic operators to demonstrate and the competent authorities to ensure that subsystems and safety components made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad hoc variants, conformity assessment procedures should be chosen from among those modules.
- (41) Manufacturers of subsystems and safety components should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of a subsystem or a safety component with the requirements of this Regulation and of other relevant Union harmonisation legislation. The EU declaration of conformity should accompany the subsystem or safety component.
- (42) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for a subsystem or a safety component should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of the relevant individual declarations of conformity.
- (43) The CE marking, indicating the conformity of a subsystem or a safety component, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship with other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Regulation.
- (44) A check on compliance of subsystems and safety components with the essential requirements provided for in this Regulation is necessary in order to provide effective protection for passengers, operating personnel and third parties.
- (45) The conformity assessment procedures set out in this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (46) Experience has shown that the criteria, set out in Directive 2000/9/EC, that conformity assessment bodies have to fulfil in order to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (47) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (48) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (49) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

- (50) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (51) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the subsystems and safety components to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.
- (52) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (53) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (54) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (55) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.
- (56) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to subsystems and safety components covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (57) Directive 2000/9/EC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of a subsystem or safety component. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (58) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to subsystems and safety components presenting a risk to the health or safety of persons or to property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such subsystems and safety components.
- (59) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

- (60) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (61) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (62) The examination procedure should be used for the adoption of implementing acts with respect to compliant subsystems and safety components which present a risk to the health or safety of persons or to property.
- (63) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant subsystems or safety components which present a risk to the health or safety of persons, imperative grounds of urgency so require.
- (64) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters 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.
- (65) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (66) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant subsystems or safety components are justified or not.
- (67) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market, without the need to comply with further product requirements, of subsystems and safety components that have already been placed on the market in accordance with Directive 2000/9/EC.
- (68) It is necessary to provide for transitional arrangements that allow the entry into service of cableway installations that have already been installed in accordance with Directive 2000/9/EC.
- (69) Member States should lay down rules on penalties applicable to infringements of this Regulation and of national law adopted pursuant to this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive. The penalties should have regard to the seriousness, the duration and, where applicable, the intentional character of the infringement. In addition, the penalties should have regard to whether the relevant economic operator has previously committed a similar infringement of this Regulation.
- (70) Since the objective of this Regulation, namely to ensure that cableway installations fulfil the requirements providing for a high level of protection of health and safety of persons and of property while guaranteeing the functioning of the internal market for subsystems and safety components, cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (71) Directive 2000/9/EC should therefore be repealed,

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

HAVE ADOPTED THIS REGULATION:

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

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.
-

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.

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.

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.
- 4.1.2. 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.

- 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.

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.

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.
 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.

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.

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;
- (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.
- 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.

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.

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.

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.

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.

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.

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.

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;
- (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.

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.

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.

- 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.

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.

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)
Article 1(4) second subparagraph	—
Article 1(4) third subparagraph	Article 9(3)
Article 1(5)	Article 3, points 1, 3 to 6
Article 1(6)	Article 2(2)
Article 2	—
Article 3(1)	Article 6
Article 3(2)	Article 17
—	Article 3, points 10 to 27
Article 4	Article 8
Article 5(1)	Article 4 and Article 5(1)
Article 5(2)	Article 5(4)
Article 6	Article 7
Article 7(1) to (3)	Articles 18 to 21
Article 7(4)	Article 19(3)
Article 8	Article 4
Article 9	Article 7
Article 10	Articles 18 to 21
Article 11(1)	Article 9(1)
Article 11(2)	Article 9(4)
Article 11(3)	—
Article 11(4)	Article 5(1)
Article 11(5)	Article 7
Article 11(6) and (7)	Article 9(2)
—	Articles 11 to 16
Article 12	Article 9(4)
Article 13	Article 10(1)
Article 14	Articles 39 to 43
Article 15	Article 10(2)
Article 16	Articles 22 to 38
Article 17	Article 44
Article 18	Articles 20 and 21
Article 19	—
Article 20	—
Article 21(3)	Article 46

Directive 2000/9/EC	This Regulation
Article 22	Article 48
—	Article 45
—	Article 47
Annex I	Annex I
Annex II	Annex II
Annex III	Article 8
Annex IV	Annex IX
Annex V	Annexes III to VII
Annex VI	Annex IX
Annex VII	Annexes III to VII
Annex VIII	Article 26
Annex IX	Article 20
—	Annex VIII

REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 9 March 2016****on personal protective equipment and repealing Council Directive 89/686/EEC****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Council Directive 89/686/EEC ⁽³⁾ was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for personal protective equipment (PPE) in all Member States and to remove obstacles to trade in PPE between Member States.
- (2) Directive 89/686/EEC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ⁽⁴⁾. Thus, it sets only the essential requirements applying to PPE, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽⁵⁾. Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 89/686/EEC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.
- (3) Experience with the application of Directive 89/686/EEC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of that experience and to provide clarification in relation to the framework within which products covered by this Regulation may be made available on the market, certain aspects of Directive 89/686/EEC should be revised and enhanced.
- (4) Since the scope, the essential health and safety requirements and conformity assessment procedures have to be identical in all the Member States there is almost no flexibility in transposing a directive based on the new approach principles into national law. Directive 89/686/EEC should therefore be replaced by a regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.
- (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽⁶⁾ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

⁽¹⁾ OJ C 451, 16.12.2014, p. 76.

⁽²⁾ Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

⁽³⁾ Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

⁽⁴⁾ OJ C 136, 4.6.1985, p. 1.

⁽⁵⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

⁽⁶⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

- (6) Decision No 768/2008/EC of the European Parliament and of the Council ⁽¹⁾ lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with PPE presenting a risk should be adapted to that Decision.
- (7) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (8) This Regulation covers PPE which is new to the Union market when it is placed on the market; that is to say it is either new PPE made by a manufacturer established in the Union or PPE, whether new or second-hand, imported from a third country.
- (9) This Regulation should apply to all forms of supply, including distance selling.
- (10) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure as high a level of protection for the user of those products as for the user of PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against heat, in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal decorative products do not claim to fulfil a protective function, are by definition not personal protective equipment and are therefore not concerned by that inclusion. Clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration is not personal protective equipment and is therefore not covered by this Regulation. As for products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including but not limited to seasonal clothing, umbrellas and dishwashing gloves, those should also fall outside of the scope of this Regulation. It is also appropriate to clarify the list of excluded PPE set out in Annex I to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore excluded from the scope of this Regulation.
- (11) Economic operators should be responsible for the compliance of PPE with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users, and to guarantee fair competition on the Union market.
- (12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only PPE which is in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (13) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (15) It is necessary to ensure that PPE from third countries entering the Union market complies with the requirements of this Regulation and, in particular, that appropriate conformity assessment procedures have been carried out by manufacturers. Provision should therefore be made for importers to make sure that PPE they place on the market complies with the requirements of this Regulation and that they do not place on the market PPE which does not comply with such requirements or which present a risk. Provision should also be made for importers to make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

⁽¹⁾ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

- (16) The distributor makes PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of PPE does not adversely affect the compliance of the PPE.
- (17) When placing PPE on the market, every importer should indicate on the PPE his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the PPE.
- (18) Efforts should be made by economic operators to ensure that all relevant documentation, such as the user's instructions, whilst ensuring precise and comprehensible information, are easily understandable, take into account technological developments and changes to end-user behaviour, and are as up to date as possible. When PPE is made available on the market in packages containing multiple units, the instructions and information should accompany each smallest commercially available unit.
- (19) Any economic operator who either places PPE on the market under his own name or trademark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (20) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.
- (21) Ensuring traceability of PPE throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant PPE available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with PPE or to whom they have supplied PPE.
- (22) In order to simplify and adapt certain essential safety requirements of Directive 89/686/EEC to the current practice, the requirement to label PPE protecting against harmful noise with a comfort index should be removed as experience has shown that it is not possible to measure and establish such an index. As regards mechanical vibrations, it is appropriate to remove the requirement not to exceed the limit values set by Union legislation on the exposure of workers to vibrations since the use of PPE alone is not able to achieve this objective. As regards PPE protecting against radiation, it is no longer necessary to require that the instructions for use supplied by the manufacturer indicate transmission curves, since the indication of the protection factor is more useful and is sufficient for the user.
- (23) It is necessary to clearly specify the relationship with, and the scope of this Regulation as regards, the entitlement of Member States to lay down requirements for the use of PPE at the workplace, in particular pursuant to Council Directive 89/656/EEC ⁽¹⁾, in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. Article 4 of that Directive obliges employers to provide PPE which complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to that Article, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation.
- (24) Market surveillance authorities should have easy access to the EU declaration of conformity. In order to fulfil that requirement, manufacturers should ensure that PPE is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.
- (25) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for PPE should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.

⁽¹⁾ Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

- (26) In order to increase the efficiency of market surveillance, it is necessary to extend the obligation to draw up complete technical documentation to all PPE.
- (27) In order to ensure that PPE is examined on the basis of the state of the art, the limit of validity of the EU type-examination certificate should be set at a maximum of five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.
- (28) A simplified procedure should be applied in the case of renewal of the EU type-examination certificate where the manufacturer has not modified the approved type and the harmonised standards or other technical specifications applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art. In such cases, additional tests or examinations should not be necessary and the administrative burden and related costs should be kept to a minimum.
- (29) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.
- (30) In order to ensure compliance with the essential health and safety requirements laid down in this Regulation, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three categories that are subject to different conformity assessment procedures. In order to ensure a consistently high level of safety of all PPE, the range of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.
- (31) The conformity assessment procedures should be adapted to the specific conditions of the manufacture of PPE produced in series where each item is adapted to fit an individual user, and of PPE produced as a single unit to fit an individual user.
- (32) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (33) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (34) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (35) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (36) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

- (37) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.
- (38) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (39) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (40) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.
- (41) Member States should take all appropriate measures to ensure that PPE covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons. PPE covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.
- (42) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to PPE covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (43) Directive 89/686/EEC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (44) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health or safety of persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.
- (45) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (46) In order to take into account technical progress and knowledge or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the categories of risks against which the PPE is intended to protect users. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

- (47) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (48) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (49) The examination procedure should be used for the adoption of implementing acts with respect to compliant PPE which presents a risk to the health or safety of persons or to other aspects of public interest protection.
- (50) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.
- (51) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters 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.
- (52) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (53) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant PPE are justified or not.
- (54) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market.
- (55) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (56) Since the objective of this Regulation, namely to ensure that PPE on the market fulfils the requirements providing for a high level of protection of health and safety of users, whilst guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (57) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is to be made available on the market, in order to ensure protection of the health and safety of users and establish rules on the free movement of PPE in the Union.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

*Article 2***Scope**

1. This Regulation applies to PPE.
2. This Regulation does not apply to PPE:
 - (a) specifically designed for use by the armed forces or in the maintenance of law and order;
 - (b) designed to be used for self-defence, with the exception of PPE intended for sporting activities;
 - (c) designed for private use to protect against:
 - (i) atmospheric conditions that are not of an extreme nature,
 - (ii) damp and water during dishwashing;
 - (d) for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
 - (e) for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motorcycles and mopeds.

*Article 3***Definitions**

For the purposes of this Regulation, the following definitions apply:

- (1) 'personal protective equipment' (PPE) means:
 - (a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
 - (b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;
 - (c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use;
- (2) 'making available on the market' means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (3) 'placing on the market' means the first making available of PPE on the Union market;
- (4) 'manufacturer' means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark;
- (5) '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;
- (6) 'importer' means any natural or legal person established within the Union who places PPE from a third country on the Union market;
- (7) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;
- (8) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (9) 'technical specification' means a document that prescribes technical requirements to be fulfilled by PPE;
- (10) 'harmonised standard' means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (11) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

- (12) 'national accreditation body' means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (13) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;
- (14) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (15) 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end-user;
- (16) 'withdrawal' means any measure aimed at preventing PPE in the supply chain from being made available on the market;
- (17) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (18) 'CE marking' means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 4

Making available on the market

PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property.

Article 5

Essential health and safety requirements

PPE shall meet the essential health and safety requirements set out in Annex II which apply to it.

Article 6

Provisions concerning the use of PPE

This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE, provided that those requirements do not affect the design of PPE which is placed on the market in accordance with this Regulation.

Article 7

Free movement

1. Member States shall not impede, for the aspects covered by this Regulation, the making available on the market of PPE which complies with this Regulation.
2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the showing of PPE which does not comply with this Regulation, provided that a visible sign clearly indicates that the PPE does not comply with this Regulation and is not available on the market until it has been brought into conformity.

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1. When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE 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 the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

6. Manufacturers shall indicate, on the PPE, 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 PPE. 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 end-users and market surveillance authorities.

7. Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

8. The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

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

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

Article 9

Authorised representatives

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

The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) 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 the national market surveillance authorities for 10 years after the PPE 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 PPE;
 - (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

Article 10

Obligations of importers

1. Importers shall place only compliant PPE on the market.
2. Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

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

3. Importers shall indicate, on the PPE, 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 PPE. The contact details shall be in a language easily understood by end-users and market surveillance authorities.
4. Importers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.
5. Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.
6. When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.
7. Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.
8. Importers shall, for 10 years after the PPE 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, in paper or electronic form, necessary to demonstrate the conformity of PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

*Article 11***Obligations of distributors**

1. When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE 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 PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.
4. Distributors who consider or have reason to believe that PPE 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 it into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where the PPE presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity 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, in paper or electronic form, necessary to demonstrate the conformity of the PPE. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.

*Article 12***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 he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with this Regulation may be affected.

*Article 13***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 PPE;
- (b) any economic operator to whom they have supplied PPE.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the PPE and for 10 years after they have supplied the PPE.

CHAPTER III

CONFORMITY OF THE PPE*Article 14***Presumption of conformity of PPE**

PPE which is 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 health and safety requirements set out in Annex II covered by those standards or parts thereof.

*Article 15***EU declaration of conformity**

1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety 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 IV, VI, VII and VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is placed or made available on the market.
3. Where PPE 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 PPE with the requirements laid down in this Regulation.

*Article 16***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 17***Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.
2. The CE marking shall be affixed before the PPE is placed on the market.
3. For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII.

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, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating the risk against which the PPE is intended to protect.
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

CONFORMITY ASSESSMENT*Article 18***Risk categories of PPE**

The PPE shall be classified according to the risk categories set out in Annex I.

*Article 19***Conformity assessment procedures**

The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:

- (a) Category I: internal production control (module A) set out in Annex IV;
- (b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI;
- (c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:
 - (i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII;
 - (ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in point (b) may be followed.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES*Article 20***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 21***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 26.
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 22. In addition, that body 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 22***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 23***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 24***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 PPE 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 PPE 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, purchaser, owner, user or maintainer of the PPE which they assess, nor the representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE 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, marketing, use or maintenance of PPE, 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 V, VII and VIII 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 of PPE for 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 PPE 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 health and safety 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 personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member 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 V, VII and VIII 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 Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

*Article 25***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 24 in so far as the applicable harmonised standards cover those requirements.

*Article 26***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 24 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 V, VII and VIII.

*Article 27***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 kinds of PPE 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 24.
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 24.

*Article 28***Notification procedure**

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.
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 kinds of PPE concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate referred to in Article 27(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 24.

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 29

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 30

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 24, 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 31

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 the withdrawal of the notification if necessary.

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

*Article 32***Operational obligations of notified bodies**

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.

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 PPE 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 PPE with the requirements of this Regulation.

3. Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the 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 PPE 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 33***Appeal against decisions of notified bodies**

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

*Article 34***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 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 kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.

*Article 35***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 36***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 a sectoral group of notified bodies.

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

CHAPTER VI

UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE*Article 37***Union market surveillance and control of PPE entering the Union market**

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2(1) of this Regulation.

*Article 38***Procedure at national level for dealing with PPE presenting a risk**

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the PPE 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 PPE 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 action to bring the PPE into compliance with those requirements, to withdraw the PPE 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 PPE concerned that it 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 PPE being made available on their national market, to withdraw the PPE 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 PPE, the origin of the PPE, 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 PPE to meet requirements relating to the health or safety of persons; or
- (b) shortcomings in the harmonised standards referred to in Article 14 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 PPE 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 PPE from the market, are taken in respect of the PPE concerned without delay.

Article 39

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 38(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 PPE 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 PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 40

Compliant PPE which presents a risk

1. Where, having carried out an evaluation under Article 38(1), a Member State finds that although PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to withdraw the PPE 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 PPE 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 PPE concerned, the origin and the supply chain of the PPE, 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 41

Formal non-compliance

1. Without prejudice to Article 38, 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 17 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 17 or has not been affixed;
- (d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;
- (e) the technical documentation is either not available or not complete;
- (f) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;
- (g) any other administrative requirement provided for in Article 8 or Article 10 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 PPE being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VII

DELEGATED AND IMPLEMENTING ACTS

Article 42

Delegated power

1. In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Commission shall be empowered to adopt delegated acts in accordance with Article 43 in order to amend Annex I by reclassifying the risk from one category to another.

2. A Member State which has concerns about the classification of a risk into a specific risk category referred to in Annex I shall immediately inform the Commission of its concerns and provide reasons in support.

3. Prior to adopting a delegated act, the Commission shall carry out a thorough assessment of the risks that require reclassification and the impact of such reclassification.

*Article 43***Exercise of the delegation**

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for a period of five years from 21 April 2018. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The delegation of powers referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

*Article 44***Committee procedure**

1. The Commission shall be assisted by a committee. 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.

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS*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. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

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

Repeal

Directive 89/686/EEC 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 47

Transitional provisions

1. Without prejudice to paragraph 2, Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019.

2. EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date.

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 20 to 36 and Article 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

ANNEX I

RISK CATEGORIES OF PPE

This Annex lays down the categories of risk against which PPE is intended to protect users.

Category I

Category I includes exclusively the following minimal risks:

- (a) superficial mechanical injury;
- (b) contact with cleaning materials of weak action or prolonged contact with water;
- (c) contact with hot surfaces not exceeding 50 °C;
- (d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- (e) atmospheric conditions that are not of an extreme nature.

Category II

Category II includes risks other than those listed in Categories I and III;

Category III

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

- (a) substances and mixtures which are hazardous to health;
 - (b) atmospheres with oxygen deficiency;
 - (c) harmful biological agents;
 - (d) ionising radiation;
 - (e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
 - (f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less;
 - (g) falling from a height;
 - (h) electric shock and live working;
 - (i) drowning;
 - (j) cuts by hand-held chainsaws;
 - (k) high-pressure jets;
 - (l) bullet wounds or knife stabs;
 - (m) harmful noise.
-

ANNEX II

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

PRELIMINARY REMARKS

1. The essential health and safety requirements laid down in this Regulation are compulsory.
2. Obligations related to essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.
3. The essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety protection.
4. The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment.
5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against the risks against which it is intended to protect.

- 1.1. Design principles

- 1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

- 1.1.2. Levels and classes of protection

- 1.1.2.1. Optimum level of protection

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.

- 1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

- 1.2. Innocuousness of PPE

- 1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness.

PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.3.4. Protective clothing containing removable protectors

Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

- (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
- (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;

- (c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
- (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
- (f) where applicable, the type of packaging suitable for transport;
- (g) the significance of any markings (see point 2.12);
- (h) the risk against which the PPE is designed to protect;
- (i) the reference to this Regulation and, where applicable, the references to other Union harmonisation legislation;
- (j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;
- (k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;
- (l) the internet address where the EU declaration of conformity can be accessed.

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

2.2. PPE enclosing the parts of the body to be protected

PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.

2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.5. PPE which may be caught up during use

Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.7. PPE intended for rapid intervention or to be put on or removed rapidly

Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.

Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

2.10. PPE for connection to complementary equipment external to the PPE

Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.

2.11. PPE incorporating a fluid circulation system

Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

2.13. PPE capable of signalling the user's presence visually

PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

2.14. Multi-risk PPE

PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.

3.1.2.2. Prevention of falls from a height

PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.

Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's instructions must specify, in particular, all relevant information relating to:

- (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;
- (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.

3.1.3. Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

3.2. Protection against static compression of a part of the body

PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.

3.3. Protection against mechanical injuries

PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.

3.4. Protection in liquids

3.4.1. Prevention of drowning

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.

Under the foreseeable conditions of use:

- (a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;
- (b) inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- (a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;
- (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- (c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.

3.4.2. Buoyancy aids

Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.

3.5. Protection against the harmful effects of noise

PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council ⁽¹⁾.

⁽¹⁾ Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (Seventeenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 42, 15.2.2003, p. 38).

Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.

3.6. Protection against heat and/or fire

PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.

3.6.1. PPE constituent materials and other components

Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.

PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

- (a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.7. Protection against cold

PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.

3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use. Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use, the following requirements apply:

- (a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.8. Protection against electric shock

3.8.1. Insulating equipment

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.

3.9. Radiation protection

3.9.1. Non-ionising radiation

PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.

The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.

3.9.2. Ionising radiation

3.9.2.1. Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.

3.9.2.2. Protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.

The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).

PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.

3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.

The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

3.11. Diving equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

Where the foreseeable conditions of use so require, the diving equipment must comprise the following:

- (a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);
 - (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);
 - (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).
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ANNEX III

TECHNICAL DOCUMENTATION FOR PPE

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

The technical documentation shall include at least the following elements:

- (a) a complete description of the PPE and of its intended use;
 - (b) an assessment of the risks against which the PPE is intended to protect;
 - (c) a list of the essential health and safety requirements that are applicable to the PPE;
 - (d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
 - (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
 - (f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
 - (g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
 - (h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
 - (i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
 - (j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
 - (k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;
 - (l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
 - (m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.
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ANNEX IV

INTERNAL PRODUCTION CONTROL

(Module A)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable requirements of this Regulation.

2. Technical documentation

The manufacturer shall establish the technical documentation described in Annex III.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.

4. CE marking and EU declaration of conformity

- 4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable requirements of this Regulation.

- 4.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it, together with the technical documentation, at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE 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 point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX V

EU TYPE-EXAMINATION

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE 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 PPE through examination of the technical documentation, plus examination of a specimen, representative of the production envisaged, of the complete PPE (production type).

3. Application for EU type-examination

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 described in Annex III;
- (d) the specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.

4. EU type-examination

The notified body shall:

- (a) examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III need not be taken into account;
- (b) for PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;
- (c) for PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy;
- (d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which 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 technical specifications;
- (e) 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;
- (f) 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, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

5. Evaluation report

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. EU type-examination certificate

6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.

The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.

6.2. The EU type-examination certificate shall contain at least the following information:

- (a) the name and identification number of the notified body;
- (b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the latter's name and address;
- (c) identification of the PPE covered by the certificate (type number);
- (d) a statement that the PPE type complies with the applicable essential health and safety requirements;
- (e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;
- (f) where other technical specifications have been applied, their references;
- (g) where applicable, the performance level(s) or protection class of the PPE;
- (h) for PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model;
- (i) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;
- (j) any conditions attached to the issue of the certificate;
- (k) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19.

6.3. The EU type-examination certificate may have one or more annexes attached.

6.4. Where the type does not satisfy the applicable essential health and safety requirements, 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. Review of the EU type-examination certificate

7.1. 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 essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.

- 7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.
- 7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:
- (a) in the case of a modification to the approved type referred to in point 7.2;
 - (b) in the case of a change in the state of the art referred to in point 7.3;
 - (c) at the latest, before the date of expiry of the certificate.

In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

- 7.5. The notified body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.
- 7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:
- (a) his name and address and data identifying the EU type-examination certificate concerned;
 - (b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or other technical specifications applied;
 - (c) confirmation that there has been no change in the state of the art as referred to in point 7.3;
 - (d) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and
 - (e) for category III products, where not already available to the notified body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII, or on the results of audits of his quality system carried out in accordance with Annex VIII.

Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In such cases, the notified body shall renew the EU type-examination certificate.

The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.

If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

- 7.7. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.
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.

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 a reasoned 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, for a period of five years after 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 10 years after the PPE has been placed on the market.
 10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.
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ANNEX VI

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

(Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

3. CE marking and EU declaration of conformity

- 3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
 - 3.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE 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.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX VII

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS

(Module C2)

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

3. Application for supervised product checks at random intervals

Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.

The application shall include the following:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation described in Annex III;
- (b) a copy of the EU type-examination certificate.

4. Product checks

- 4.1. The notified body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
- 4.2. The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type-examination certificate.
- 4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be 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 the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
- 4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.
- 4.5. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.

- 4.6. If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.
5. Test report
 - 5.1. The notified body shall provide the manufacturer with a test report.
 - 5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
 - 5.3. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.
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 item of PPE that is in conformity with the 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 PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE 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.

7. 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 manufacturer's obligations set out in point 2.

ANNEX VIII

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

(Module D)

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, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE 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 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) the address of the manufacturer's premises where the audits can be carried out;
 - (c) a written declaration that the same application has not been lodged with any other notified body;
 - (d) the identification of the PPE concerned;
 - (e) the documentation concerning the quality system.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation of the PPE described in Annex III;
 - (b) a copy of the EU type-examination certificate.

- 3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate and complies with the applicable requirements of this Regulation.

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.

The quality system documentation 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 product quality;
 - (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
 - (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 and qualification reports on the personnel concerned; and
 - (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.

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 PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements.

The result of that assessment 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 its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

- 3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

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 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 and qualification reports on the personnel concerned.
- 4.3. The notified body shall carry out periodic audits, at least once a year, 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 examinations or tests of the PPE, 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 item of PPE 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 PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE 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 10 years after the PPE 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 related 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. The 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 such quality system approvals refused, suspended or otherwise restricted.

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

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.

ANNEX IX

EU DECLARATION OF CONFORMITY No ... ⁽¹⁾

1. PPE (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 PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):
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, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) ... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate).
8. Where applicable, the PPE is subject to the conformity assessment procedure ... (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) ... under surveillance of the notified body ... (name, number).
9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

⁽¹⁾ It is optional for the manufacturer to assign a number to the declaration of conformity.

ANNEX X

CORRELATION TABLE

Directive 89/686/EEC	This Regulation
Article 1(1)	Articles 1 and 2(1)
Article 1(2) and (3)	Article 3 point (1)
Article 1(4)	Article 2(2)
Article 2(1)	Article 4
Article 2(2)	Article 6
Article 2(3)	Article 7(2)
Article 3	Article 5
Article 4(1)	Article 7(1)
Article 4(2)	—
Article 5(1), (4), (5)	—
Article 5(2)	Article 14
Article 6	Article 44
Article 7	Articles 37-41
Article 8(1)	Article 8(2) first subparagraph
Article 8(2)-(4)	Articles 18 and 19 and Annex I
Article 9	Articles 20, 24(1), 25, and 30(1)
Article 10	Annex V
Article 11(A)	Annex VII
Article 11(B)	Annex VIII
Article 12(1)	Article 15
Articles 12(2) and 13	Articles 16 and 17
Article 14	—
Article 15	—
Article 16(1) first subparagraph and (2)	—
Article 16(1) second subparagraph	Article 48(2)
Annex I	Article 2(2)
Annex II	Annex II
Annex III	Annex III
Annex IV	Article 16
Annex V	Article 24(2)-(11)
Annex VI	Annex IX

REGULATION (EU) 2016/426 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 9 March 2016****on appliances burning gaseous fuels and repealing Directive 2009/142/EC****(Text with EEA relevance)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Directive 2009/142/EC of the European Parliament and of the Council ⁽³⁾ lays down rules for the placing on the market and the putting into service of appliances burning gaseous fuels ('appliances').
- (2) Directive 2009/142/EC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards ⁽⁴⁾. Thus, it sets out only the essential requirements applying to appliances, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽⁵⁾. Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 2009/142/EC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.
- (3) Experience acquired from the implementation of Directive 2009/142/EC has shown the need to modify some of its provisions in order to clarify and update them and thus ensure legal certainty as regards the definitions relating to its scope, the content of the Member States' communications of the types of gas and corresponding supply pressures used on their territory and certain essential requirements.
- (4) Since the scope, essential requirements and conformity assessment procedures have to be identical in all Member States, there is almost no flexibility in transposing a directive based on the new approach principles into national law. In order to simplify the regulatory framework, Directive 2009/142/EC should be replaced by a regulation, which is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition by Member States and thus ensures uniform implementation throughout the Union.

⁽¹⁾ OJ C 458, 19.12.2014, p. 25.

⁽²⁾ Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

⁽³⁾ Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10).

⁽⁴⁾ OJ C 136, 4.6.1985, p. 1.

⁽⁵⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (5) Decision No 768/2008/EC of the European Parliament and of the Council ⁽¹⁾ lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. In order to ensure consistency with other sectoral product legislation, Directive 2009/142/EC should be adapted to that Decision.
- (6) Regulation (EC) No 765/2008 of the European Parliament and of the Council ⁽²⁾ lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.
- (7) The scope of this Regulation should reflect the scope of Directive 2009/142/EC. This Regulation should apply to domestic and non-domestic appliances intended for a number of specified applications and to fittings designed to be incorporated into such appliances.
- (8) This Regulation covers appliances and fittings which are new to the Union market when they are placed on the market; that is to say, they are either new appliances and fittings made by a manufacturer established in the Union or appliances and fittings, whether new or second-hand, imported from a third country.
- (9) Appliances possessing a historic or artistic value within the meaning of Article 36 of the Treaty on the Functioning of the European Union (TFEU) and not put into service, such as antique and other appliances serving exhibition or collection purposes, should not be considered as appliances covered by this Regulation.
- (10) This Regulation should apply to all forms of supply, including distance selling.
- (11) This Regulation should aim to ensure the functioning of the internal market of appliances and of fittings as regards gas safety risks and energy efficiency.
- (12) This Regulation should not apply in respect of aspects covered more specifically by other Union harmonisation legislation. This includes the measures adopted pursuant to Directive 2009/125/EC of the European Parliament and of the Council ⁽³⁾.
- (13) This Regulation should prevent Member States from imposing stricter requirements on health, safety and energy conservation which would prohibit, restrict or impede the making available on the market and the putting into service of appliances which comply with this Regulation. However, this should not affect the possibility for Member States, when implementing other Union acts, to impose requirements which affect the energy efficiency of products, including appliances, as long as such measures are compatible with the TFEU.
- (14) Directive 2009/28/EC of the European Parliament and of the Council ⁽⁴⁾ requires Member States to introduce in their building regulations and codes appropriate measures in order to increase the share of all kinds of energy from renewable sources in the building sector. Directive 2010/31/EU of the European Parliament and of the Council ⁽⁵⁾ requires Member States to set minimum energy performance requirements for buildings and building elements and system requirements in respect of the overall energy performance of the technical building systems which are installed in existing buildings. Directive 2012/27/EU of the European Parliament and of the Council ⁽⁶⁾ requires Member States to take sufficient measures to progressively reduce energy consumption in different areas, including in buildings.

⁽¹⁾ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

⁽²⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

⁽³⁾ Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10).

⁽⁴⁾ Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

⁽⁵⁾ Directive 2010/31/EU of the European Parliament and of the Council of 19 May 2010 on the energy performance of buildings (OJ L 153, 18.6.2010, p. 13).

⁽⁶⁾ Directive 2012/27/EU of the European Parliament and of the Council of 25 October 2012 on energy efficiency, amending Directives 2009/125/EC and 2010/30/EU and repealing Directives 2004/8/EC and 2006/32/EC (OJ L 315, 14.11.2012, p. 1).

- (15) This Regulation should not affect the obligation for Member States to adopt measures with respect to the promotion of the use of energy from renewable sources and to the energy efficiency of buildings, in accordance with Directives 2009/28/EC, 2010/31/EU and 2012/27/EU. It is consistent with the objectives of those Directives that national measures may in certain circumstances limit the installation of appliances which comply with the rational use of energy requirement of this Regulation, provided that such measures do not constitute an unjustifiable market barrier.
- (16) Member States should take the necessary steps to ensure that appliances are made available on the market and put into service only where they do not compromise the health and safety of persons, domestic animals or property, when normally used.
- (17) This Regulation should not affect the Member States' entitlement to lay down rules concerning commissioning or periodic inspections of appliances or other measures such as installer training or certification, in order to ensure the correct installation, use and maintenance of appliances, including precautionary safety measures. Those rules and measures are essential in preventing gas poisoning, including from carbon monoxide (CO), and the leakage of any substances harmful to health and safety.
- (18) This Regulation should not affect the Member States' entitlement to lay down requirements as they may deem necessary concerning installation aspects, space ventilation conditions and aspects relating to the safety of the building itself and its energy performance, provided that those requirements do not impose design requirements on appliances.
- (19) As this Regulation does not cover risks caused by appliances in the case of incorrect installation, maintenance or use, Member States should be encouraged to take measures to ensure that the public is made aware of the health and safety risks related to combustion products and the need for proper precautionary safety measures, inter alia in relation to emissions of carbon monoxide.
- (20) Although this Regulation does not regulate the gas supply conditions in the Member States, it should take into account the fact that different conditions as regards types of gas and supply pressures are in force in the Member States in the absence of harmonisation of the technical characteristics of the gaseous fuel. The composition and specifications of the types of gas and the supply pressures at the place where an appliance is put into service is very important for its safe and correct functioning, therefore that aspect should be taken into consideration at the design phase of the appliance in order to ensure its compatibility with the gas type(s) and supply pressure(s) it is intended for.
- (21) In order to avoid barriers to trade with regard to appliances on grounds relating to the fact that the gas supply conditions are not yet harmonised and to ensure that economic operators are sufficiently informed, Member States should communicate to the other Member States and to the Commission the types of gas and corresponding supply pressures used on their territory and any changes thereof in good time.
- (22) The communication of the gas types and supply pressures by Member States should contain the necessary information for economic operators. In that framework, the primary source of the gaseous fuel supplied is not relevant for the characteristics, the performance and the compatibility of appliances with the communicated gas supply conditions.
- (23) When determining the gas families and gas groups used on their territory, Member States are encouraged to take into account the ongoing standardisation work concerning gas qualities and thus ensure, across the Union, a coherent and coordinated approach towards harmonisation of gaseous fuels via standardisation.
- (24) When, in accordance with Directive 2009/73/EC of the European Parliament and of the Council ⁽¹⁾ and the ongoing standardisation work of CEN on gas quality specifications, Member States take concrete measures for a wider use of biogas by injecting such gas into the gas distribution network or by distributing such gas through isolated systems, they should ensure that they update in a timely manner their communication of the types of gas in the event that the quality of the supplied gas does not remain within the already communicated quality range.

⁽¹⁾ Directive 2009/73/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC (OJ L 211, 14.8.2009, p. 94).

- (25) When Member States establish their national action plans in accordance with Directive 2009/28/EC in order to comply with their obligation to increase the percentage of renewable energies and in particular biogas in the total energy consumption, they are encouraged to consider the possibilities of injecting such gases into the gas distribution network.
- (26) Member States should take the necessary measures to ensure that the gas supply conditions do not constitute barriers to trade and that they do not restrict the putting into service of appliances that are compatible with the local gas supply conditions.
- (27) Appliances covered by this Regulation and complying with it should benefit from the principle of free movement of goods. Such appliances should be allowed to be put into service provided that they are compatible with the local gas supply conditions.
- (28) The appliance category marking indicated on the appliance or its data plate establishes a direct link with the gas families and/or gas groups for which an appliance has been designed to burn safely at the desired performance level and thus ensures the compatibility of the appliance with the local gas supply conditions.
- (29) The essential requirements laid down in this Regulation should be observed in order to ensure that appliances are safe when normally used at the desired performance level.
- (30) The essential requirements should be interpreted and applied so as to take account of the state of the art at the time of design and manufacture as well as of technical and economic considerations which are consistent with a high degree of health and safety protection and rational use of energy.
- (31) Economic operators should be responsible for the compliance of appliances and of fittings with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety of persons and domestic animals, protection of consumers and of property, and rational use of energy, and to guarantee fair competition on the Union market.
- (32) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market appliances or fittings which are in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.
- (33) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.
- (34) The manufacturer should provide sufficient and detailed information on the intended use of the appliance so as to allow its correct and safe installation and putting into service, use and maintenance. Such information may need to include the technical specifications of the interface between the appliance and its installation environment.
- (35) This Regulation should not apply to any natural person who manufactures an appliance on a non-professional basis and uses it exclusively for his own purposes.
- (36) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.
- (37) It is necessary to ensure that appliances and fittings from third countries entering the Union market comply with the requirements of this Regulation, and in particular that appropriate conformity assessment procedures have been carried out by manufacturers with regard to those appliances and fittings. Provision should therefore be made for importers to make sure that the appliances and fittings they place on the market comply with the requirements of this Regulation and that they do not place on the market appliances and fittings which do not

comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that the CE marking on appliances and fittings and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

- (38) The distributor makes an appliance or a fitting available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of the appliance or fitting does not adversely affect its compliance.
- (39) When placing an appliance or a fitting on the market, every importer should indicate on the appliance or fitting his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the appliance or fitting does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the appliance or fitting.
- (40) Any economic operator that either places an appliance or a fitting on the market under his own name or trademark or modifies an appliance or a fitting in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (41) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the appliance or fitting concerned.
- (42) Ensuring traceability of an appliance or a fitting throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant appliances or fittings available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with an appliance or a fitting or to whom they have supplied an appliance or a fitting.
- (43) This Regulation should be limited to the expression of the essential requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for presumption of conformity for appliances and fittings which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 for the purpose of expressing detailed technical specifications of those requirements, especially with regard to the design, manufacture, operation, testing, the rational use of energy and installation of appliances.
- (44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.
- (45) In order to enable economic operators to demonstrate and the competent authorities to ensure that appliances and fittings made available on the market conform to the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad hoc variants, conformity assessment procedures should be chosen from among those modules.
- (46) Manufacturers should draw up an EU declaration of conformity to provide information required under this Regulation on the conformity of an appliance or a fitting with the requirements of this Regulation and of other relevant Union harmonisation legislation.
- (47) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for an appliance or a fitting should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

- (48) The CE marking, indicating the conformity of an appliance or a fitting, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship with other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on appliances and fittings should be laid down in this Regulation. Exceptions should be provided for in cases where the size or nature of the appliance or fitting does not allow the CE marking to be affixed to it.
- (49) Fittings are not appliances but intermediate products intended for appliance manufacturers and designed to be incorporated into an appliance. However, fittings should satisfy the essential requirements so as to fulfil correctly their intended purpose when incorporated into an appliance or assembled to constitute an appliance. With a view to simplification and in order to avoid any confusion and misunderstanding for manufacturers in meeting their obligations, it is considered justified that fittings should also bear the CE marking.
- (50) A check on compliance of appliances and of fittings with the essential requirements is necessary in order to provide effective protection of the health and safety of persons, of domestic animals and of property.
- (51) In order to ensure compliance of appliances and fittings with the essential requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Those procedures should be set from the conformity assessment modules laid down in Decision No 768/2008/EC.
- (52) The conformity assessment procedures set out in this Regulation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.
- (53) Experience has shown that the criteria set out in Directive 2009/142/EC, that conformity assessment bodies have to fulfil to be notified to the Commission, are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.
- (54) In order to ensure a consistent level of conformity assessment quality, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.
- (55) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.
- (56) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.
- (57) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.
- (58) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the appliances and the fittings to be placed on the Union market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.

- (59) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.
- (60) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.
- (61) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.
- (62) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.
- (63) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to appliances and fittings covered by this Regulation. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.
- (64) Directive 2009/142/EC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of an appliance or fitting. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.
- (65) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to appliances and fittings presenting a risk to the health or safety of persons or to domestic animals or property. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such appliances and fittings.
- (66) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.
- (67) The power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the content of the Member States' communications on the gas supply conditions on their territory. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (68) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽¹⁾.
- (69) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.
- (70) The examination procedure should be used for the adoption of implementing acts to define the form for the Member States' communications on the gas supply conditions on their territory.

⁽¹⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (71) The examination procedure should also be used for the adoption of implementing acts with respect to compliant appliances and fittings which present a risk to the health or safety of persons or to domestic animals or property.
- (72) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant appliances or fittings which present a risk to the health or safety of persons, imperative grounds of urgency so require.
- (73) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters 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.
- (74) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should, in line with existing practice, receive full information and documentation and, where appropriate, an invitation to attend such meetings.
- (75) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant appliances or fittings are justified or not.
- (76) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and the putting into service without the need to comply with further product requirements, of appliances and fittings that have already been placed on the market in accordance with Directive 2009/142/EC before the date of application of this Regulation. Distributors should therefore be able to supply appliances and fittings that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of this Regulation.
- (77) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.
- (78) Since the objective of this Regulation, namely to ensure that appliances and fittings on the Union market fulfil the requirements providing for a high level of protection of health and safety of persons, of domestic animals and of property and for rational use of energy, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (79) Directive 2009/142/EC should therefore be repealed,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1. This Regulation applies to appliances and fittings.
2. For the purposes of this Regulation, an appliance is considered to be 'normally used' where the following conditions are met:
 - (a) it is correctly installed and regularly serviced in accordance with the manufacturer's instructions;
 - (b) it is used with a normal variation in the gas quality and a normal fluctuation in the supply pressure as set out by Member States in their communication pursuant to Article 4(1);
 - (c) it is used in accordance with its intended purpose or in a way which can be reasonably foreseen.

3. This Regulation does not apply to appliances specifically designed:

- (a) for use in industrial processes carried out on industrial premises;
- (b) for use on aircrafts and railways;
- (c) for research purposes for temporary use in laboratories.

For the purposes of this paragraph, an appliance is considered to be 'specifically designed' when the design is only intended to address a specific need for a specific process or use.

4. Where, for appliances or fittings, the aspects covered by this Regulation are covered more specifically by other acts of Union harmonisation legislation, this Regulation does not apply or ceases to apply to such appliances or fittings in respect of those aspects.

5. The rational use of energy essential requirement laid down in point 3.5 of Annex I to this Regulation does not apply to appliances covered by a measure adopted pursuant to Article 15 of Directive 2009/125/EC.

6. This Regulation shall not affect the obligation upon Member States to adopt measures with respect to the promotion of the use of energy from renewable sources and to the energy efficiency of buildings, in accordance with Directives 2009/28/EC, 2010/31/EU and 2012/27/EU. Such measures shall be compatible with the TFEU.

Article 2

Definitions

For the purposes of this Regulation the following definitions apply:

- (1) 'appliances' means appliances burning gaseous fuels used for cooking, refrigeration, air-conditioning, space heating, hot water production, lighting or washing, and also forced draught burners and heating bodies to be equipped with such burners;
- (2) 'fittings' means safety devices, controlling devices or regulating devices and sub-assemblies thereof, designed to be incorporated into an appliance or to be assembled to constitute an appliance;
- (3) 'burning' means a process in which gaseous fuel reacts with oxygen producing heat or light;
- (4) 'washing' means the entire washing process, including drying and ironing;
- (5) 'cooking' means the art or practice of preparing or warming food for consumption with the use of heat and employing a wide range of methods;
- (6) 'gaseous fuel' means any fuel which is in a gaseous state at a temperature of 15 °C under an absolute pressure of 1 bar;
- (7) 'industrial process' means the extraction, growth, refining, processing, production, manufacture or preparation of materials, plants, livestock, animal products, food or other products with a view to their commercial use;
- (8) 'industrial premises' means any place where the main activity carried out is an industrial process that would be subject to specific national health and safety regulations;
- (9) 'gas family' means a group of gaseous fuels with similar burning behaviour linked together by a range of Wobbe indices;
- (10) 'gas group' means a specified range of Wobbe indices within that of the gas family concerned;
- (11) 'Wobbe index' means an indicator of the interchangeability of fuel gases used to compare the combustion energy output of different composition fuel gases in an appliance;

- (12) 'appliance category' means the identification of gas families and/or gas groups that an appliance is designed to burn safely and at the desired performance level, as indicated by the appliance category marking;
- (13) 'energy efficiency' means the ratio of output of performance of an appliance to input of energy;
- (14) 'making available on the market' means any supply of an appliance or a fitting for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (15) 'placing on the market' means the first making available of an appliance or a fitting on the Union market;
- (16) 'putting into service' means the first use of an appliance in the Union by its end-user;
- (17) 'manufacturer' means any natural or legal person who manufactures an appliance or a fitting or who has an appliance or a fitting designed or manufactured, and markets that appliance or fitting under his name or trademark or uses the appliance for his own purposes;
- (18) '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;
- (19) 'importer' means any natural or legal person established within the Union who places an appliance or a fitting from a third country on the Union market;
- (20) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes an appliance or a fitting available on the market;
- (21) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- (22) 'technical specification' means a document that prescribes technical requirements to be fulfilled by an appliance or a fitting;
- (23) 'harmonised standard' means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;
- (24) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;
- (25) 'national accreditation body' means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;
- (26) 'conformity assessment' means the process demonstrating whether the essential requirements of this Regulation relating to an appliance or a fitting have been fulfilled;
- (27) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;
- (28) 'recall' means any measure aimed at achieving the return of an appliance that has already been made available to the end-user or of a fitting that has already been made available to an appliance manufacturer;
- (29) 'withdrawal' means any measure aimed at preventing an appliance or a fitting in the supply chain from being made available on the market;
- (30) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;
- (31) 'CE marking' means a marking by which the manufacturer indicates that the appliance or the fitting is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 3

Making available on the market and putting into service

1. Appliances shall only be made available on the market and put into service if, when normally used, they comply with this Regulation.

2. Fittings shall only be made available on the market if they comply with this Regulation.
3. This Regulation shall not affect Member States' entitlement to lay down such requirements as they may deem necessary to ensure that persons, domestic animals and property are protected during the normal use of the appliances, provided that this does not mean modifications to the appliances.

Article 4

Gas supply conditions

1. By 21 October 2017, Member States shall communicate to the Commission and the other Member States in accordance with Annex II and using the relevant form the types of gas and corresponding supply pressures of gaseous fuels used on their territory. They shall communicate any changes thereof within six months after the announcement of the envisaged changes.
2. The Commission shall be empowered to adopt delegated acts in accordance with Article 41 concerning modifications to the content of the Member States' communications of the gas supply conditions on their territory, as set out in Annex II, in order to take into account the technical developments with regard to the gas supply conditions.
3. The Commission may, by means of implementing acts, define the harmonised form of the Member States' communications referred to in paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).
4. The Commission shall ensure that the information provided by Member States in accordance with paragraph 1 is published in the *Official Journal of the European Union*.

Article 5

Essential requirements

Appliances and fittings shall meet the essential requirements set out in Annex I which apply to them.

Article 6

Free movement

1. Member States shall not, on grounds relating to the aspects covered by this Regulation, prohibit, restrict or impede the making available on the market and the putting into service of appliances which comply with this Regulation.
2. Member States shall not, on grounds relating to the risks covered by this Regulation, prohibit, restrict or impede the making available on the market of fittings which comply with this Regulation.
3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not prevent the showing of appliances or fittings which do not comply with this Regulation, provided that a visible sign clearly indicates that such appliances or fittings do not comply with this Regulation and that they are not for sale until they have been brought into conformity. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons, domestic animals and property.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 7

Obligations of manufacturers

1. When placing their appliances or fittings on the market or when using the appliances for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I.

2. Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the relevant conformity assessment procedure referred to in Article 14 or have it carried out.

Where compliance of an appliance or a fitting 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 10 years after the appliance or the fitting 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 appliance or fitting design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the appliance or the fitting is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by an appliance, manufacturers shall, to protect the health and safety of consumers and other users, carry out sample testing of appliances made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming appliances and fittings and recalls of such appliances and fittings, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their appliances and fittings bear a type, batch or serial number or other element allowing their identification, and the inscriptions provided for in Annex IV.

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

6. Manufacturers shall indicate on the appliance 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 appliance. 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 consumers and other end-users and the market surveillance authorities.

Manufacturers shall indicate on the fitting 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 fitting. 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 appliance manufacturers and the market surveillance authorities.

7. Manufacturers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

Manufacturers shall ensure that the fitting is accompanied by a copy of the EU declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.

However, where a large number of fittings are delivered to a single 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 an appliance or a fitting which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that appliance or fitting into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the appliance or the fitting presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the appliance or the fitting 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 appliance or the fitting 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 appliances or fittings which they have placed on the market.

Article 8

Authorised representatives

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

The obligations laid down in Article 7(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 10 years after the appliance or the fitting 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 appliance or the fitting;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by appliances or fittings covered by the authorised representative's mandate.

Article 9

Obligations of importers

1. Importers shall place only compliant appliances or fittings on the market.

2. Before placing an appliance on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the appliance bears the CE marking and is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

Before placing a fitting on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the fitting bears the CE marking and is accompanied by a copy of the EU declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, and that the manufacturer has complied with the requirements set out in Article 7(5) and (6).

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

3. Importers shall indicate on the appliance 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 appliance. The contact details shall be in a language easily understood by consumers and other end-users and the market surveillance authorities.

Importers shall indicate on the fitting 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 fitting. The contact details shall be in a language easily understood by appliance manufacturers and the market surveillance authorities.

4. Importers shall ensure that the appliance is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

Importers shall ensure that the fitting is accompanied by a copy of the EU declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned.

5. Importers shall ensure that, while an appliance or a fitting is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.

6. When deemed appropriate with regard to the risks presented by an appliance, importers shall, to protect the health and safety of consumers and other users, carry out sample testing of appliances made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming appliances and fittings and recalls of such appliances and fittings, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that an appliance or a fitting which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that appliance or fitting into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the appliance or the fitting presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the appliance or the fitting 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 10 years after the appliance or the fitting 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 an appliance or a fitting 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 appliances or fittings which they have placed on the market.

Article 10

Obligations of distributors

1. When making an appliance or a fitting available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making an appliance available on the market, distributors shall verify that the appliance bears the CE marking and that it is accompanied by instructions and safety information in accordance with point 1.5 of Annex I, in a language which can be easily understood by consumers and other end-users, as determined by the Member State in which the appliance is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Before making a fitting available on the market, distributors shall verify that the fitting bears the CE marking and that it is accompanied by a copy of the EU declaration of conformity containing, inter alia, instructions for incorporation or assembly, adjustment, operation and maintenance in accordance with point 1.7 of Annex I, in a language which can be easily understood by appliance manufacturers, as determined by the Member State concerned, and that the manufacturer and the importer have complied with the requirements set out in Article 7(5) and (6) and Article 9(3) respectively.

Where a distributor considers or has reason to believe that an appliance or a fitting is not in conformity with the essential requirements set out in Annex I, he shall not make the appliance or the fitting available on the market until it has been brought into conformity. Furthermore, where the appliance or the fitting 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 an appliance or a fitting is under their responsibility, storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I.
4. Distributors who consider or have reason to believe that an appliance or a fitting 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 appliance or fitting into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the appliance or the fitting presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the appliance or the fitting 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 an appliance or a fitting. 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 appliances or fittings which they have made available on the market.

Article 11

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 he shall be subject to the obligations of the manufacturer under Article 7, where he places an appliance or a fitting on the market under his name or trademark or modifies an appliance or a fitting already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

Article 12

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 an appliance or a fitting;
- (b) any economic operator to whom they have supplied an appliance or a fitting.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the appliance or the fitting and for 10 years after they have supplied the appliance or the fitting.

CHAPTER III

CONFORMITY OF APPLIANCES AND FITTINGS

Article 13

Presumption of conformity of appliances and fittings

Appliances and fittings 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 I covered by those standards or parts thereof.

Article 14

Conformity assessment procedures for appliances and fittings

1. Before an appliance or a fitting is placed on the market, the manufacturer shall submit it to a conformity assessment procedure in accordance with paragraph 2 or 3.

2. The conformity of series-manufactured appliances and fittings with the requirements of this Regulation shall be assessed by means of the EU type-examination (Module B — production type) set out in point 1 of Annex III, combined with one of the following modules, at the choice of the manufacturer:

- (a) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2), set out in point 2 of Annex III;
- (b) conformity to type based on quality assurance of the production process (Module D), set out in point 3 of Annex III;
- (c) conformity to type based on product quality assurance (Module E), set out in point 4 of Annex III;
- (d) conformity to type based on product verification (Module F), set out in point 5 of Annex III.

3. In the case of an appliance or a fitting produced as a single unit or in small quantities, the manufacturer may choose one of the procedures set out in paragraph 2 of this Article or conformity based on unit verification (Module G) set out in point 6 of Annex III.

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

Article 15

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I has been demonstrated.

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

3. In order to assist compliance of finished appliances with the applicable essential requirements set out in Annex I, the EU declaration of conformity for a fitting shall state the characteristics of the fitting and shall contain instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance. The EU declaration of conformity shall be in a language which can be easily understood by appliance manufacturers and market surveillance authorities, as determined by the Member State concerned.

4. Where an appliance or a fitting 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.

5. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the appliance or the fitting with the requirements laid down in this Regulation.

6. A copy of the EU declaration of conformity shall be supplied with the fitting.

Article 16

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 17***Rules and conditions for affixing the CE marking**

1. The CE marking shall be affixed visibly, legibly and indelibly to the appliance and the fitting or to their data plate as far as relevant. Where that is not possible or not warranted on account of the nature of the appliance or the fitting, it shall be affixed to the packaging and to the documents accompanying the appliance or the fitting.
2. The CE marking shall be affixed before the appliance or the fitting 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 of the appliance or of the fitting and by the last two digits of the year in which the CE marking was affixed. 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.

*Article 18***Inscriptions**

1. The inscriptions referred to in Annex IV shall be affixed visibly, legibly and indelibly to the appliance or to its data plate and, as far as relevant, to the fitting or to its data plate.
2. The inscriptions referred to in Annex IV shall be affixed before the appliance or the fitting is placed on the market.

CHAPTER IV

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES*Article 19***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 20***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 25.
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 21. 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 21

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 22

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 23

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 appliance or the fitting 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 appliances or fittings 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 appliances or the fittings which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed appliances or fittings that are necessary for the operations of the conformity assessment body or the use of such appliances or fittings 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, the marketing, installation, use or maintenance of those appliances or fittings, 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 Annex III 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 appliances or fittings 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 appliance or fitting 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 I, 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 or 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 Annex III 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 pursuant to Article 35 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 24

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 23 in so far as the applicable harmonised standards cover those requirements.

Article 25

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 23 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 Annex III.

Article 26

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 appliance/fitting or appliances/fittings 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 23.

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 23.

Article 27

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 23.

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 appliance/fitting or appliances/fittings concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate as referred to in Article 26(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 23.
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 28

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 29

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 23 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 30

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 42(2).

Article 31

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex III.
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 appliance or fitting 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 appliance or the fitting with this Regulation.

3. Where a notified body finds that the essential requirements set out in Annex I 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 an appliance or a fitting 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 32

Appeal against decisions of notified bodies

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

Article 33

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 appliances or fittings with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 34

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 35

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 a sectoral group or groups of notified bodies.

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

CHAPTER V

UNION MARKET SURVEILLANCE, CONTROL OF APPLIANCES AND FITTINGS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 36

Union market surveillance and control of appliances and fittings entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to appliances and fittings covered by this Regulation.

Article 37

Procedure at national level for dealing with appliances or fittings presenting a risk

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that an appliance or fitting covered by this Regulation presents a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the appliance or fitting 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 appliance or fitting 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 action to bring the appliance or fitting into compliance with those requirements, to withdraw the appliance or fitting 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 appliances and fittings 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 appliances or fittings being made available on their national market, to withdraw the appliance or fitting 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 appliance or fitting, the origin of the appliance or fitting, 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 appliance or fitting to meet requirements relating to the health or safety of persons or to the protection of domestic animals or property; or

(b) shortcomings in the harmonised standards referred to in Article 13 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 appliance or fitting 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 appliance or fitting from the market, are taken in respect of the appliance or fitting concerned without delay.

Article 38

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 37(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 appliance or fitting 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 appliance or fitting is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 37(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 39

Compliant appliances or fittings which present a risk

1. Where, having carried out an evaluation under Article 37(1), a Member State finds that although an appliance or fitting is in compliance with this Regulation, it presents a risk to the health or safety of persons or to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the appliance or fitting concerned, when placed on the market, no longer presents that risk, to withdraw the appliance or fitting 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 appliances or fittings 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 appliance or fitting concerned, the origin and the supply chain of the appliance or fitting, 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 42(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 42(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 40

Formal non-compliance

1. Without prejudice to Article 37, 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 17 of this Regulation;
- (b) the CE marking has not been affixed;
- (c) the inscriptions referred to in Annex IV have not been affixed or have been affixed in violation of Article 18;
- (d) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;
- (e) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;
- (f) a copy of the EU declaration of conformity does not accompany the fitting;

- (g) the technical documentation is either not available or not complete;
- (h) the information referred to in Article 7(6) or Article 9(3) is absent, false or incomplete;
- (i) any other administrative requirement provided for in Article 7 or Article 9 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 appliance or fitting being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VI

DELEGATED ACTS AND COMMITTEE PROCEDURE

Article 41

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 4(2) shall be conferred on the Commission for a period of five years from 21 April 2018. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3. The delegation of power referred to in Article 4(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 4(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 42

Committee procedure

1. The Commission shall be assisted by the Committee on appliances. 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.

CHAPTER VII

TRANSITIONAL AND FINAL PROVISIONS

Article 43

Penalties

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

The penalties provided for shall be effective, proportionate and dissuasive.

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 44

Transitional provisions

1. Member States shall not impede the making available on the market or the putting into service of appliances covered by Directive 2009/142/EC which are in conformity with that Directive and which were placed on the market before 21 April 2018.

2. Member States shall not impede the making available on the market of fittings covered by Directive 2009/142/EC which are in conformity with that Directive and which were placed on the market before 21 April 2018.

Article 45

Repeal

Directive 2009/142/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 VI.

Article 46

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 4, 19 to 35 and 42 and Annex II, which shall apply from 21 October 2016;
- (b) Article 43(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

ANNEX I

ESSENTIAL REQUIREMENTS

PRELIMINARY OBSERVATIONS:

1. The essential requirements laid down in this Regulation are compulsory.
2. The essential requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture as well as technical and economic considerations which are consistent with a high degree of energy efficiency and of health and safety protection.

1. GENERAL REQUIREMENTS

- 1.1. Appliances shall be so designed and constructed as to operate safely and present no danger to persons, domestic animals or property, when normally used.

Fittings shall be so designed and constructed as to fulfil correctly their intended purpose when incorporated into an appliance or assembled to constitute an appliance.

- 1.2. The manufacturer is under an obligation to analyse the risks in order to identify those which apply to his appliance or fitting. He shall then design and construct it taking into account its risk assessment.

- 1.3. In selecting the most appropriate solutions, the manufacturer shall apply the principles set out below, in the following order:

- (a) eliminate or reduce risks as far as possible (inherently safe design and construction);
- (b) take the necessary protection measures in relation to risks that cannot be eliminated;
- (c) inform users of the residual risks due to any shortcomings of the protection measures adopted and indicate whether any particular precautions are required.

- 1.4. When designing and constructing the appliance, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the appliance, but also the reasonably foreseeable uses.

- 1.5. All appliances shall:

- (a) be accompanied by instructions for installation intended for the installer;
- (b) be accompanied by instructions for use and servicing, intended for the user;
- (c) bear appropriate warning notices, which shall also appear on the packaging.

- 1.6.1. The instructions for installation intended for the installer shall contain all the instructions for installation, adjustment and servicing required to ensure that those operations are correctly performed so that the appliance may be used safely.

The instructions for installation intended for the installer shall include also information on the technical specifications of the interface between the appliance and its installation environment allowing its correct connection to the gas supply network, the supply of auxiliary energy, the combustion air supply and the flue gas evacuation system.

- 1.6.2. The instructions for use and servicing intended for the user shall contain all the information required for safe use and in particular shall draw the user's attention to any restrictions on use.

The manufacturers shall note in the instructions where additional care is needed or where it would be advisable that any of the above work be carried out by a professional. This shall be without prejudice to national requirements to that effect.

The manufacturer of the appliance shall include in the instructions accompanying the appliance all necessary information for adjustment, operation and maintenance of the fittings as part of the finished appliance, as appropriate.

- 1.6.3. The warning notices on the appliance and its packaging shall clearly state the type of gas to be used, the gas supply pressure, the appliance category and any restrictions on use, in particular the restriction whereby the appliance shall be installed only in areas where there is sufficient ventilation so as to ensure that the risks presented by it are minimised.
- 1.7. The instructions for incorporation of the fitting into an appliance or its assembly in order to constitute an appliance and for its adjustment, operation and maintenance shall be provided with the fittings concerned as part of the EU declaration of conformity.

2. MATERIALS

Materials for appliances or fittings shall be appropriate for their intended purpose and shall withstand the mechanical, chemical and thermal conditions to which they will foreseeably be subjected.

3. DESIGN AND CONSTRUCTION

The obligations arising for appliances from the essential requirements set out in this point apply also to fittings, as far as relevant.

3.1. General

- 3.1.1. Appliances shall be so designed and constructed that, when normally used, no instability, distortion, breakage or wear likely to impair their safety may occur.
- 3.1.2. Condensation produced at the start-up and/or during use shall not affect the safety of appliances.
- 3.1.3. Appliances shall be so designed and constructed as to minimise the risk of explosion in the event of a fire of external origin.
- 3.1.4. Appliances shall be so designed and constructed that water and inappropriate air penetration into the gas circuit does not occur.
- 3.1.5. In the event of a normal fluctuation of auxiliary energy, appliances shall continue to operate safely.
- 3.1.6. Abnormal fluctuation or failure of auxiliary energy or its restoration shall not lead to an unsafe situation.
- 3.1.7. Appliances shall be so designed and constructed as to obviate any gas-related risks due to hazards of electrical origin. As far as relevant, the results of the conformity assessment in relation to the safety requirements of Directive 2014/53/EU of the European Parliament and of the Council ⁽¹⁾ or the safety objectives of Directive 2014/35/EU of the European Parliament and of the Council ⁽²⁾ shall be taken into account.
- 3.1.8. Appliances shall be so designed and constructed as to obviate any gas-related risks due to hazards originating from electromagnetic phenomena. As far as relevant, the results of the conformity assessment in relation to the electromagnetic compatibility requirements of Directive 2014/53/EU or Directive 2014/30/EU of the European Parliament and of the Council ⁽³⁾ shall be taken into account.
- 3.1.9. All pressurised parts of an appliance shall withstand the mechanical and thermal stresses to which they are subjected without any deformation affecting safety.
- 3.1.10. Appliances shall be so designed and constructed that failure of a safety, controlling or regulating device may not lead to an unsafe situation.

⁽¹⁾ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

⁽²⁾ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

⁽³⁾ Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79).

3.1.11. If an appliance is equipped with safety and controlling devices, the functioning of the safety devices shall not be overruled by that of the controlling devices.

3.1.12. All parts of appliances which are set or adjusted at the stage of manufacture and which should not be manipulated by the user or the installer shall be appropriately protected.

3.1.13. Levers and other controlling and setting devices shall be clearly marked and give appropriate instructions so as to prevent any error in operation/use. Their design shall be such as to preclude accidental operation.

3.2. Unburned gas release

3.2.1. Appliances shall be so designed and constructed that the gas leakage rate is not dangerous.

3.2.2. Appliances shall be so designed and constructed that gas release at any state of operation is limited in order to avoid a dangerous accumulation of unburned gas in the appliance.

3.2.3. Appliances intended to be used in indoor spaces and rooms shall be so designed and constructed as to prevent the release of unburned gas in all situations which could lead to a dangerous accumulation of unburned gas in such spaces and rooms.

3.2.4. Appliances designed and constructed to burn gas containing carbon monoxide or other toxic components shall not present a danger to the health of persons and domestic animals exposed.

3.3. Ignition

Appliances shall be so designed and constructed that, when normally used, ignition and re-ignition is smooth and cross-lighting is assured.

3.4. Combustion

3.4.1. Appliances shall be so designed and constructed that, when normally used, the combustion process is stable and combustion products do not contain unacceptable concentrations of substances harmful to health.

3.4.2. Appliances shall be so designed and constructed that, when normally used, there will be no accidental release of combustion products.

3.4.3. Appliances connected to a flue for the dispersal of combustion products shall be so designed and constructed that in abnormal draught conditions there is no release of combustion products in a dangerous quantity into the indoor spaces or rooms concerned.

3.4.4. Appliances shall be so designed and constructed that, when normally used, they do not cause a concentration of carbon monoxide or other substances harmful to health, such as they would be likely to present a danger to the health of persons and domestic animals exposed.

3.5. Rational use of energy

Appliances shall be so designed and constructed as to ensure rational use of energy, reflecting the state of the art and taking into account safety aspects.

3.6. Temperature

3.6.1. Parts of appliances which are intended to be installed or placed in close proximity to surfaces shall not reach temperatures which present a danger.

3.6.2. The surface temperature of parts of appliances intended to be handled during normal use shall not present a danger to the user.

- 3.6.3. The surface temperatures of external parts of appliances, with the exception of surfaces or parts which are associated with the transmission of heat, shall not under operating conditions present a danger to the health and safety of persons exposed and in particular to children and elderly people, for whom an appropriate reaction time shall be taken into account.
- 3.7. Contact with food and water intended for human consumption
- Without prejudice to Regulations (EC) No 1935/2004 ⁽¹⁾ and (EU) No 305/2011 ⁽²⁾ of the European Parliament and of the Council, materials and parts used in the construction of an appliance which may come into contact with food or water intended for human consumption as defined in Article 2 of Council Directive 98/83/EC ⁽³⁾, shall not impair quality of the food or water.
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⁽¹⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

⁽²⁾ Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

⁽³⁾ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

ANNEX II

CONTENT OF THE MEMBER STATES COMMUNICATIONS OF THE GAS SUPPLY CONDITIONS

1. The communications of the Member States to the Commission and the other Member States provided for in Article 4 shall have the following content:
 - (a) (i) gross calorific value (GCV) in MJ/m³ minimum/maximum;
 - (ii) Wobbe index in MJ/m³ minimum/maximum.
 - (b) Gas composition by volume in % of the total content:
 - C₁ to C₅ content in % (sum) minimum/maximum;
 - N₂ + CO₂ content in % minimum/maximum;
 - CO content in % minimum/maximum;
 - unsaturated HC content in % minimum/maximum;
 - hydrogen content in % minimum/maximum.
 - (c) Information on toxic components contained in the gaseous fuel.That communication shall also include either of the following:
 - (a) supply pressure at the inlet of appliances in mbar: nominal/minimum/maximum;
 - (b) (i) supply pressure at the point of delivery in mbar: nominal/minimum/maximum;
 - (ii) admissible pressure loss in the end-user gas installation in mbar: nominal/minimum/maximum.
 2. The reference conditions for Wobbe index and gross calorific value shall be the following:
 - (a) combustion reference temperature: 15 °C;
 - (b) volume measurement reference temperature: 15 °C;
 - (c) volume measurement reference pressure: 1 013,25 mbar.
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ANNEX III

CONFORMITY ASSESSMENT PROCEDURES FOR APPLIANCES AND FITTINGS

1. MODULE B: EU TYPE-EXAMINATION — PRODUCTION TYPE

- 1.1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an appliance or a fitting and verifies and attests that the technical design of the appliance or the fitting meets the requirements of this Regulation that apply to it.
- 1.2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the appliance or the fitting through examination of the technical documentation and supporting evidence referred to in point 1.3, plus examination of a specimen, representative of the production envisaged, of the complete appliance or fitting (production type).
- 1.3. The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.
 - 1.3.1. The application shall include the following:
 - (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. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting. The technical documentation shall contain, wherever applicable, at least the following elements:
 - (1) a general description of the appliance or the fitting;
 - (2) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (3) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
 - (4) a list of the harmonised standards 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;
 - (5) results of design calculations made, examinations carried out, etc.;
 - (6) test reports;
 - (7) instructions for installation and use of the appliance;
 - (8) the EU declaration of conformity of the fitting containing the instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance;
 - (d) the specimens representative of the production envisaged. The notified body may request further specimens where needed for carrying out the test programme;
 - (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

1.3.2. Where appropriate, the manufacturer shall also submit to the notified body the following documents:

- (a) the EU type-examination certificate and the EU declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance or the fitting;
- (c) any other document making it possible for the notified body to improve its assessment.

1.4. The notified body shall:

For the appliance or the fitting:

1.4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the appliance or the fitting.

For the specimen(s):

1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which 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;

1.4.3. 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;

1.4.4. 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;

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

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 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.

1.6. Where the appliance or the fitting 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, the conditions (if any) for its validity, the necessary data for identification of the approved type, such as the type of gas, appliance category and gas supply pressure, 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 appliances or fittings 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 ten 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.

1.7. 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 all modifications to the approved type that may affect the conformity of the appliance or the fitting with the essential requirements of this Regulation or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.

- 1.8. 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.

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.

- 1.9. 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 10 years after the appliance or the fitting has been placed on the market.
- 1.10. The manufacturer's authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

2. MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS

- 2.1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2, 2.3 and 2.4, and ensures and declares on his sole responsibility that the appliances or the fittings 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.

2.2. Manufacturing

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

2.3. Product checks

A notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at intervals of one year or less, in order to verify the quality of the internal checks on the appliance or the fitting, taking into account, inter alia, the technological complexity of the appliances or the fittings and the quantity of production. An adequate sample of the final appliances or fittings taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to check the conformity of the appliance or the fitting with the relevant requirements of this Regulation. Where a sample does not conform to the acceptable quality level, the notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the appliance or the fitting performs within acceptable limits, with a view to ensuring conformity of the appliance or the fitting.

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

2.4. CE marking and EU declaration of conformity

2.4.1. The manufacturer shall affix the CE marking to each individual appliance or fitting that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2.4.2. The manufacturer shall draw up a written EU declaration of conformity for each appliance or fitting model and keep it at the disposal of the national authorities for 10 years after the appliance or fitting has been placed on the market. The EU declaration of conformity shall identify the appliance or fitting 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. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

2.5. Authorised representative

The manufacturer's obligations set out in point 2.4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

3.1. 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 3.2 and 3.5, and ensures and declares on his sole responsibility that the appliances or fittings 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.

3.2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the appliances or fittings concerned as specified in point 3.3, and shall be subject to surveillance as specified in point 3.4.

3.3. Quality system

3.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the appliances or fittings 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) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the appliance or the fitting 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.

3.3.2. The quality system shall ensure that the appliances or fittings are in conformity with the type described in the EU type-examination certificate 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 product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (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.

3.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.3.2.

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.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and the product technology 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 3.3.1(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 appliance or the fitting 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.

3.3.4. 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.

3.3.5. 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 3.3.2 or whether a reassessment is necessary.

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

3.4. Surveillance under the responsibility of the notified body

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

3.4.2. 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.

3.4.3. The notified body shall carry out periodic audits 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.

- 3.4.4. 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.

3.5. CE marking and EU declaration of conformity

- 3.5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
- 3.5.2. The manufacturer shall draw up a written EU declaration of conformity for each appliance or fitting model and keep it at the disposal of the national authorities for 10 years after the appliance or the fitting has been placed on the market. The EU declaration of conformity shall identify the appliance or fitting 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. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

- 3.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the national authorities:
- (a) the documentation referred to in point 3.3.1;
 - (b) the information relating to the change referred to in point 3.3.5, as approved;
 - (c) the decisions and reports of the notified body referred to in points 3.3.5, 3.4.3 and 3.4.4.
- 3.7. 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 systems 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, and, upon request, of quality system approvals which it has issued.

3.8. Authorised representative

The manufacturer's obligations set out in points 3.3.1, 3.3.5, 3.5 and 3.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE

- 4.1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 4.2 and 4.5, and ensures and declares on his sole responsibility that the appliances or fittings 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.

4.2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the appliances or fittings concerned as specified in point 4.3 and shall be subject to surveillance as specified in point 4.4.

4.3. Quality system

- 4.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the appliances or fittings 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) a written declaration that the same application has not been lodged with any other notified body;
- (c) all relevant information for the product category envisaged;
- (d) the documentation concerning the quality system; and
- (e) the technical documentation of the approved type and a copy of the EU type-examination certificate.

4.3.2. The quality system shall ensure compliance of the appliances or the fittings with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

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 product quality;
- (b) the examinations and tests that will be carried out after manufacture;
- (c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- (d) the means of monitoring the effective operation of the quality system.

4.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 4.3.2.

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.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology 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 4.3.1(e), in order 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 appliance or the fitting 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.

4.3.4. 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.

4.3.5. 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 4.3.2 or whether a reassessment is necessary.

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

4.4. Surveillance under the responsibility of the notified body

- 4.4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.4.2. 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.
- 4.4.3. The notified body shall carry out periodic audits 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.
- 4.4.4. 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.

4.5. CE marking and EU declaration of conformity

- 4.5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4.3.1, the latter's identification number to each individual appliance or fitting that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
- 4.5.2. The manufacturer shall draw up a written EU declaration of conformity for each appliance or fitting model and keep it at the disposal of the national authorities for 10 years after the appliance or the fitting has been placed on the market. The EU declaration of conformity shall identify the appliance or fitting 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. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

- 4.6. The manufacturer shall, for a period ending at least 10 years after the appliance or the fitting has been placed on the market, keep at the disposal of the national authorities:
- (a) the documentation referred to in point 4.3.1;
 - (b) the information relating to the change referred to in point 4.3.5, as approved;
 - (c) the decisions and reports of the notified body referred to in points 4.3.5, 4.4.3 and 4.4.4.

- 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, and, upon request, of quality system approvals which it has issued.

4.8. Authorised representative

The manufacturer's obligations set out in points 4.3.1, 4.3.5, 4.5 and 4.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

5. MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

- 5.1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.5.1 and 5.6, and ensures and declares on his sole responsibility that the appliances or fittings concerned, which have been subject to point 5.3, are in conformity with the type described in the EU type-examination certificate and satisfy the requirements of this Regulation that apply to them.

5.2. Manufacturing

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

5.3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, or have them carried out, in order to check the conformity of the appliances or fittings 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 appliances or fittings with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every appliance or fitting as specified in point 5.4 or by examination and testing of the appliances or fittings on a statistical basis as specified in point 5.5.

5.4. Verification of conformity by examination and testing of every appliance or fitting

- 5.4.1. All appliances or fittings 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.

- 5.4.2. 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 appliance or fitting, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the appliance or the fitting has been placed on the market.

5.5. Statistical verification of conformity

- 5.5.1. 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 appliances or fittings for verification in the form of homogeneous lots.

- 5.5.2. A random sample shall be taken from each lot in accordance with the requirements of point 5.5.3. All appliances or fittings in a 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 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.

5.5.3. The notified body shall apply a sampling system with the following characteristics:

- a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of between 0,5 % and 1,5 %,
- a limit quality corresponding to a probability of acceptance of 5 % with a non-conformity percentage of between 5 % and 10 %.

5.5.4. If a lot is accepted, all appliances or fittings of the lot shall be considered approved, except for those appliances or fittings 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 appliance or fitting, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the appliance or the fitting has been placed on the market.

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

5.6. CE marking and EU declaration of conformity

5.6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.3, the latter's identification number to each individual appliance or fitting that is in conformity with the approved type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

5.6.2. The manufacturer shall draw up a written EU declaration of conformity for each appliance or fitting model and keep it at the disposal of the national authorities, for 10 years after the appliance or the fitting has been placed on the market. The EU declaration of conformity shall identify the appliance or fitting 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. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

If the notified body referred to in point 5.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the appliance or the fitting.

5.7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the appliances or the fittings during the manufacturing process.

5.8. 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 manufacturer's obligations set out in points 5.2 and 5.5.1.

6. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the appliance or the fitting concerned, which has been subject to point 6.4, is in conformity with the requirements of this Regulation that apply to it.

6.2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 6.4. The technical documentation shall make it possible to assess the appliance's or fitting's conformity with the applicable requirements of this Regulation, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the appliance or the fitting.

6.2.1. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the appliance or the fitting;
- (b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance or the fitting;
- (d) a list of the harmonised standards 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;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports;
- (g) instructions for installation and use, for appliances;
- (h) instructions for incorporation into an appliance or for assembly, for fittings.

6.2.2. Where appropriate, the manufacturer shall also submit to the notified body the following documents:

- (a) the EU type-examination certificate and the EU declaration of conformity relating to the fittings incorporated into the appliance;
- (b) attestations and certificates relating to the methods of manufacture and inspection and monitoring of the appliance or the fitting;
- (c) any other document making it possible for the notified body to improve its assessment.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the appliance or the fitting has been placed on the market.

6.3. Manufacturing

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

6.4. Verification

A notified body chosen by the manufacturer shall carry out 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 appliances or fittings 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.

If deemed necessary by the notified body, the examinations and tests may be carried out after the incorporation of the fitting, the assembly or the installation of the appliance.

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 appliances or fittings, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the appliance or the fitting has been placed on the market.

6.5. CE marking and EU declaration of conformity

6.5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each appliance or fitting that satisfies the applicable requirements of this Regulation.

6.5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the appliance or the fitting has been placed on the market. The EU declaration of conformity shall identify the appliance or the fitting 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. A copy of the EU declaration of conformity of the fitting shall accompany the fitting or, where applicable, the batch or consignment.

6.6. Authorised representative

The manufacturer's obligations set out in points 6.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX IV

INSCRIPTIONS

1. In addition to the CE marking referred to in Article 16, the appliance or its data plate shall bear the following information:
 - (a) the manufacturer's name, registered trade name or registered trade mark;
 - (b) the appliance type, batch or serial number of the appliance or other element allowing its identification;
 - (c) the type of electrical supply used, where applicable;
 - (d) the appliance category marking;
 - (e) the nominal supply pressure for the appliance;
 - (f) the necessary information to ensure correct and safe installation, according to the nature of the appliance.
 2. The fitting or its data plate shall bear, as far as relevant, the information provided for in point 1.
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ANNEX V

EU DECLARATION OF CONFORMITY No ... ⁽¹⁾

1. Appliance or fitting /appliance or fitting 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 appliance or fitting allowing traceability; where necessary for the identification of the appliance or the fitting, an image may be included): description of the appliance or the fitting.
 5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: ... (reference to the other Union acts applied).
 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. In the case of fittings, instructions on how the fitting should be incorporated into an appliance or assembled to constitute an appliance in order to assist compliance with the essential requirements applicable to finished appliances.
 9. Additional information:
- Signed for and on behalf of: ...
- (place and date of issue):
- (name, function) (signature):
- _____

⁽¹⁾ It is optional for the manufacturer to assign a number to the declaration of conformity.

ANNEX VI

CORRELATION TABLE

Directive 2009/142/EC	This Regulation
Article 1(1) first subparagraph	Article 1(1)
Article 1(1) second subparagraph	Article 1(3)(a)
—	Article 1(3)(b) and (c)
—	Article 1(4) to (6)
Article 1(2)	Article 2, points 1, 2 and 6
Article 1(3)	Article 1(2)
—	Article 2, points 3, 4, 5, 7 to 31
Article 2(1)	Article 3(1)
—	Article 3(2) and (3)
Article 2(2)	Article 4(1) and (4)
—	Article 4(2) and (3)
Article 3	Article 5
Article 4	Article 6(1) and (2)
—	Article 6(3)
—	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
—	Article 13
Article 5(1)(a)	—
Article 5(1)(b)	—
Article 5(2)	—
Article 6	—
Article 7	—
Article 8(1), (2) and (4)	Article 14(1) to (3)
Article 8(3) and (5)	—
Article 8(6)	Article 14(4)
—	Article 15
—	Article 16
Article 9	—
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—	Article 17
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Article 12	—
—	Article 18
—	Article 19
—	Article 20

Directive 2009/142/EC	This Regulation
—	Article 21
—	Article 22
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
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