

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)

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:

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- (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;

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- (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

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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.

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## 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

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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;

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- 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.

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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.



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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.

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## 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

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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.

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### 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.

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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

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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.

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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.

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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.



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## 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.

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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.

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## 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

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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.

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2 If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant 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:

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- 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

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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.

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#### *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



**Status:**

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