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NOTE

From:	General Secretariat of the Council
To:	Delegations
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Subject:	Proposal for a Regulation of the European Parliament and of the Council on appliances burning gaseous fuels - Analysis of the final compromise text with a view to agreement

Delegations find below the text as agreed during the trilogue with the representatives of the European Parliament and the European Commission on 22 September 2015. The Presidency considers that the substance of the text entirely reflects the mandate given by Coreper on 11 September 2015.

Text in **bold** reflects text changes in relation to the original Commission proposal.

The Committee is invited to endorse this text and to mandate the Presidency to inform the European Parliament that, should Parliament adopt the text of the Proposal in the exact form as set out in the Annex - subject to legal-linguistic revision- at a forthcoming plenary meeting, the Council would adopt the proposed Regulation thus amended.

REGULATION (EU) 2015/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

on appliances burning gaseous fuels

(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 Committee¹,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C 458, 19.12.2014, p. 25.

Whereas:

- (1) Directive 2009/142/EC of the European Parliament and of the Council relating to appliances burning gaseous fuels² lays down rules for the placing on the market and the putting into service of appliances burning gaseous fuels.
- (2) Directive 2009/142/EC is based on the New Approach principles, as set out in Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards³. Thus, it sets out only the essential requirements applying to appliances burning gaseous fuels, 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 on European Standardisation⁴. 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 this sector and should be maintained and even further promoted.

² 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).

³ OJ C 136, 4.6.1985, p. 1.

⁴ 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).

- (3) Experience 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 ensure thus legal certainty as regards the definitions relating to its scope, the content of the Member States' communications of their gas types and supply pressures and certain essential requirements.
- (4) *This Regulation covers appliances burning gaseous fuels ('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.*
- (5) *Appliances possessing a historic and artistic value in the meaning of Article 36 of the Treaty on the Functioning of the European Union and not put into service, as antique and other appliances serving exhibition or collection purposes, should not be considered as appliances covered by this Regulation.*

- (6) *This Regulation should apply to all forms of supply, including distance selling.*
- (7) As certain aspects of Directive 2009/142/EC should be revised and enhanced, in the interests of clarity that Directive should be repealed. 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 ensures thus a uniform implementation throughout the Union.
- (8) Decision No 768/2008/EC of the European Parliament and of the Council **■** on a common framework for the marketing of products⁵ 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.

⁵ 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). Wording modified according to BG comments.

(9) Regulation (EC) No 765/2008 of the European Parliament and of the Council ■ setting out the requirements for accreditation and market surveillance relating to the marketing of products 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.*

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(10) The scope of Directive 2009/142/EC should be maintained. 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.

(11) This Regulation should aim to ensure the functioning of the internal market of appliances ■ and of fittings as regards the 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 issued under Directive 2009/125/EC of the European Parliament and of the Council⁶ establishing a framework for ecodesign requirements.

⁶ 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).

- (13) ■ This Regulation prevents 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 ■ does not affect the possibility for Member States, when implementing other Union directives, to impose requirements which affect the energy efficiency of products, including gas appliances, as long as such measures are compatible with the Treaty *on the Functioning of the European Union*.
- (14) Directive 2009/28/EC of the European Parliament and of the Council⁷ on the promotion of the use of energy from renewable sources 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 on the energy performance of buildings⁸ 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 on energy efficiency⁹ requires Member States to take sufficient measures to progressively reduce energy consumption in different areas including in buildings.

⁷ 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).

⁸ 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).

⁹ 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 does not affect the obligation for Member States to adopt national 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 gas appliances which comply with the rational use of energy requirement of this Regulation, provided that such requirements do not constitute an unjustifiable market barrier.
- (16) *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.*
- (17) 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.

- (18) The provisions of this Regulation do 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 their correct installation, use and maintenance, *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.*
- (19) The provisions of this Regulation do 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 provisions do not impose design requirements on appliances ■ .
- (20) As this Regulation does not cover such risks caused by appliances ■ in case of incorrect installation, maintenance or use, Member States are encouraged to take measures to ensure that 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.*

- (21) 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 and 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.
- (22) 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 ensure thus a sufficient information of economic operators, Member States should communicate to the other Member States and to the Commission the gas types and supply pressures used *on* their territory and any changes thereof in good time.
- (23) 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.

- (24) When determining the gas families and gas groups used on their territory, Member States are encouraged to take into account the on-going standardisation work concerning gas qualities and ensure thus across the Union, a coherent and coordinated approach towards harmonisation of the gaseous fuels via standardisation.
- (25) When in accordance with Directive 2009/73/EC of the European Parliament and of the Council concerning common rules for the internal market in natural gas¹⁰ and the on-going standardisation work of CEN on the 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 to timely update their communication of gas types in case the quality of the supplied gas does not remain within the already communicated quality range.
- (26) 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 in the gas distribution network.

¹⁰ 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).

- (27) 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.
- (28) Appliances ■ covered by this Regulation and complying with its provisions 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.
- (29) 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.
- (30) The essential ■ requirements should be observed in order to ensure that appliances ■ are safe when normally used at the desired performance level.

- (31) 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, safety protection and rational use of energy.
- (32) 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.
- (33) 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.

- (34) 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.
- (35) 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.
- (36) ***This Regulation does not apply to any natural person who manufactures an appliance on a non-professional basis and uses it exclusively for his own purposes.***
- (37) In order to facilitate the 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.

- (38) 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.
- (39) 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.

- (40) 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 product.
- (41) 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.
- (42) 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.

- (43) 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 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 fitting or to whom they have supplied an appliance or fitting.*
- (44) 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 ■ or 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 ■ .

- (45) 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.
- (46) In order to enable economic operators to demonstrate and the competent *national* authorities to ensure that appliances ■ or 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.
- (47) 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.

(48) 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.*



(49) 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 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.*

- (50) 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 such an appliance. With a view to simplification and in order to avoid any confusion and misunderstanding for manufacturers in the implementation of their obligations, it is considered justified that fittings should also bear the CE marking. Exceptions should be provided for in cases where the size or nature of the fitting does not allow the CE marking to be affixed to it.*
- (51) 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.*
- (52) 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.

- (53) 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.
- (54) 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.
- (55) 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.
- (56) 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.

- (57) 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.
- (58) 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.

- (59) 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.
- (60) 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.
- (61) 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.

- (62) In the interests of competitiveness, it is crucial that conformity assessment 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 conformity assessment bodies.
- (63) *Interested parties should have the right to appeal against the result of an 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.*
- (64) *Directive 2009/142/EC already provides for a safeguard procedure which is necessary to allow the possibility for 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) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred to the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules for the Commission's exercise of implementing powers¹¹.

¹¹ 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 the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (68) 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.
- (69) *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.*
- (70) ■ 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 ■ the content ■ of the Member State communications on the gas supply conditions on their territory.
- (71) 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.
- (72) *The examination procedure should 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.*

- (73) *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.*
- (74) *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.*
- (75) *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.*
- (76) *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.*

- (77) 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 *products* that have already been placed on the market in accordance with Directive 2009/142/EC *before the date for application of this Regulation. Distributors should therefore be able to supply products that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of this Regulation.*
- (78) Member States should lay down rules on penalties applicable to infringements to this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.

- (79) Since the objective of this Regulation, namely to ensure that appliances *and fittings* on the 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.
- (80) Directive 2009/142/EC should therefore be repealed.

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Scope

1. This Regulation shall apply to appliances and fittings.
2. For the purposes of this Regulation, an appliance shall be 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 defined by Member States in their communication pursuant to Article 4;*

(c) it is used in accordance with its intended purpose or in a way which can be reasonably foreseen.

3. This Regulation shall not apply to:

(a) appliances specifically designed for use in industrial processes carried out on industrial premises.;

(b) appliances specifically designed for use on aircrafts and railways.;

(c) appliances specifically designed for research purposes for temporary use in laboratories.

For the purposes of this paragraph, an appliance shall be 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 shall not apply or shall cease to apply to such appliances or fittings in respect of those aspects.

5. The rational use of energy essential requirement in point 3.5 of Annex I to this Regulation shall 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 for Member States to provide for 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 Treaty on the Functioning of the European Union.***

Article 2

Definitions

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

- (1) ‘appliances’ means appliances burning gaseous fuels used for cooking, refrigeration, air-conditioning, space heating, hot water production, lighting *or* washing, as 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 such 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 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 its commercial use;

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- (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 index within that of the 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) 'making available on the market ■' means any supply of appliances *or 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;

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- (14) 'energy efficiency' means the ratio of output of performance of an appliance, to input of energy;
- (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 such an appliance or fitting designed or manufactured, and markets that product 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 harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012;
- (24) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- (25) 'national accreditation body' means national accreditation body as defined in Article 2(11) 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 satisfy the requirements of 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 such appliances.

Article 4
Gas supply conditions

1. 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 before ...¹² and **■** 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 42 concerning modifications to the content **■** of the communications of the Member States of the gas supply conditions *in* 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. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 41(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.

¹² OJ: Insert date: 18 months after entry into force of this Regulation.

Article 5
Essential requirements

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

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 by the manufacturer. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons and domestic animals and protection of 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 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 the appliance 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 or 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 and, 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, amongst others, 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, as 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 the 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 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) respectively.

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, amongst others, 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, amongst others, 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 their 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 nonconforming 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 the 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 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 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** is accompanied by **a copy of the EU declaration of conformity** containing, amongst others, 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, 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 their/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 fitting* presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the appliance *or fitting* available 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 the appliance or the fitting 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 paragraphs 2 or 3.
2. The conformity of series-manufactured appliances and fittings with the requirements of this Regulation shall be certified through EU-type examination (Module B – production type) set out in point 1 of Annex III, combined with either 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 case of an appliance or a fitting produced as a single unit or in small quantities, the manufacturer may choose, the modules set out in paragraph 2 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 the official language(s) 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 and shall contain the elements specified in the relevant conformity assessment procedures 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 with the essential requirements applicable to finished appliances set out in Annex I, the EU declaration of conformity for a fitting shall state the characteristics of the fitting and it shall contain instructions on how the fitting should be incorporated into an appliance or assembled to constitute such 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 acts 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, the CE marking 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 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 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 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, as appropriate, restrict, suspend or withdraw the notification, 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 41(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 the provisions of 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 conformity 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 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 or those group or 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 for dealing with appliances or fittings presenting a risk at national level

- 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 actions 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 appliance's or fitting's 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 41(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 41(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 on the appliance or the fitting in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation or it has not been affixed;*
 - (b) *the inscriptions referred to in Annex IV have not been affixed or have been affixed in violation of Article 17;*
 - (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 EU declaration of conformity does not accompany the fitting;*
- (f) *the technical documentation is either not available or not complete.*
- (g) *the information referred to in Article 7(6) or Article 9(3) is absent, false or incomplete;*
- (h) *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
COMMITTEE PROCEDURE AND DELEGATED ACTS

Article 41
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.



Article 42

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 delegation of power *to adopt delegated acts* referred to in *Article 4 (2)* shall be conferred *on the Commission* for a period of five years from ...¹³. *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.

¹³ *OJ: Insert date of application of this Regulation.*

3. The delegation of powers 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.

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.

The Member States shall notify those provisions to the Commission by ...¹⁴ 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.*

¹⁴ OJ: Insert date: *one* month prior to the date of application of this Regulation.

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 ...¹⁵.
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 ...¹⁶.

¹⁵ OJ: Insert date: two years after entry into force of this Regulation.

¹⁶ OJ: Insert date: two years after entry into force of this Regulation.

Article 45

Repeal

Directive 2009/142/EC is repealed from ...¹⁷.

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

Article 46

Entry into force and date of 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.

¹⁷ OJ: Insert date: two years after entry into force of this Regulation.

2. It shall apply from ...¹⁸.
3. By way of derogation from paragraph 2:
 - (a) Articles 4, 19 to 35 *and Article 41 and Annex II* shall apply from ...¹⁹.
 - (b) *Article 44(1) shall apply from ...*²⁰.

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

Done at ...,

For the European Parliament
The President

For the Council
The President

¹⁸ OJ: Insert date: two years after entry into force of this Regulation.

¹⁹ OJ: Insert date: six months after entry into force of this Regulation.

²⁰ ***OJ: Insert date: 1 year and 11 months after entry into force of this Regulation.***

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 of technical and economic considerations which are consistent with a high degree of energy efficiency, 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 such 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 foreseen 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 such 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

- 2.1. 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 used normally, 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 Council²¹ or the safety objectives of Directive **2014/35/EU** of the European Parliament and of the Council²² 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 Council²³ shall be taken into account.

²¹ ***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).***

²² ***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).***

²³ ***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).***

- 3.1.9. All pressurized 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.
- 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 designed and constructed 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 used normally, 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 used normally, 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 used normally 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 used normally, 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 Regulation (EC) No 1935/2004 of the European Parliament and of the Council²⁴ on materials and articles intended to come into contact with food and Regulation (EU) No 305/2011 of the European Parliament and of the Council²⁵ on construction products, 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 on the quality of water intended for human consumption²⁶, shall not impair quality of the food or water.

²⁴ 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/EC (OJ L 338, 13.11.2004, p. 4).

²⁵ 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).

²⁶ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.98, 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 Number 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 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: 1013,25 mbar.

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 safety requirements of this Regulation **■** . 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 such 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 elements:

- (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, 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, 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.

■

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. and
- (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 and
- (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 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.
- 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.

- 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 the following:

- (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 out 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.

4.4.4. 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.

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 all of the following:

- (a) the documentation referred to in point 4.3.1;
- (b) 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 or withdrawn, **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 the provisions of 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 according to 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 percentage of non-conformity 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's 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.

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 *product* concerned, which has been subject to the provisions of 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 documentation shall make it possible to assess the *product's* conformity with the relevant requirements, 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 *product*.

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

- (a) a general description of the *product*;
- (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 *product*;
- (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 elements:

- (a) 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;
- (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 *product* 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 *products* 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 *products* 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 *product*, 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 *product* 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 *product* 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 has been placed on the market. The EU declaration of conformity shall identify the *product* 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.

6.6. 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.

■ 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 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 paragraph (1).

ANNEX V

EU DECLARATION OF CONFORMITY (No. XXXX)²⁷

- (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. It may, where necessary for the identification of the appliance *or the fitting*, include an image):

■ description of the appliance *or the fitting*;

■
- (5) The object of the declaration described above 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:

²⁷ *It is optional for the manufacturer to assign a number to the Declaration of Conformity.*

(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 such 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):

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ANNEX VI

<i>CORRELATION TABLE</i>	
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(2)	Article 2(1), (2) and (5)
Article 1(3)	Article 1(2)
—	Article 2(3), (4), (6) to (31)
Article 2(1)	Article 3(1)
—	Article 3(2)
Article 2(2)	Article 4(1)
—	Article 4(2)
Article 3	Article 5
Article 4	Article 6
—	Article 7
—	Article 8
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—	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) to (4)	Article 14(1) to (5)
Article 8(5)	—
—	Article 14(6)
Article 8(6)	Article 14(7)
—	Article 15
—	Article 16
Article 9	—
Article 10(1)	Article 17(1)
Article 10(2)	—
Article 11	—

Article 12	—
—	Article 17(2) to (5)
—	Article 19
—	Article 20
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