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PROPOSAL

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 258 final - Annexes 1 to VII
Subject:	ANNEXES to the Proposal for a Regulation of the European Parliament and of the Council on appliances burning gaseous fuels

Delegations will find attached document COM(2014) 258 final - Annexes 1 to VII.

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ANNEXES 1 to 7

ANNEXES

to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on appliances burning gaseous fuels

{SWD(2014) 150 final}
{SWD(2014) 151 final}

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 at the desired performance level.

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 analysis.

1.3. In selecting the most appropriate solutions, the manufacturer of an appliance or a fitting 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. When placed on the market, all appliances shall:

(a) be accompanied by technical instructions 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.

The instructions and warning notices shall be in a language which can be understood by consumers and other end-users as determined by the Member State concerned.

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

The instructions for installation 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 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 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 or assembly, adjustment, operation and maintenance shall be provided with the fittings concerned as part of the Fitting conformity certificate.

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.

2.2. The properties of materials that are important for safety shall be guaranteed by the manufacturer or by the supplier of the material.

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 1999/5/EC of the European Parliament and of the Council[1] on radio equipment or the safety objectives of Directive 2006/95/EC of the European Parliament and of the Council relating to electrical equipment designed for use within certain voltage limits[2] shall be taken into account.

3.1.8. Appliances must 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 1999/5/EC or Directive 2004/108/EC of the European Parliament and of the Council relating to electromagnetic compatibility[3] shall be taken into account.

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

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1 Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p.10).

2 Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 374, 27.12.2006, p.10).

3 Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p.24).

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

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

3.2.3. Appliances intended to be used in indoor spaces and rooms shall be so designed and constructed 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 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 room**s** concerned.

3.4.4. Appliances shall be so designed and constructed that, when used normally, they do not cause a concentration of 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 must 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 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 Council[4] on materials and articles intended to come into contact with food and Regulation (EU) No 305/2011 of the European Parliament and of the Council[5] 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 consumption[6], shall not impair quality of the food or water.

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;

– $N_2 + CO_2$ 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;

[4] 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).

[5] 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).

[6] 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).

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.

1.2. EU-type examination is 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 and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Regulation where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(5) results of design calculations made, examinations carried out, etc.;

(6) test reports;

(7) the specimens representative of the production envisaged. The notified body may request further specimens where needed for carrying out the test programme;

(8) 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 and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

(9) instructions for installation and use of the appliance.

(10) the Fitting conformity certificate containing the instructions on how the fitting should be incorporated into an appliance or assembled to constitute such an appliance.

1.3.2. Where appropriate, the design documentation shall contain the following elements:

(a) the EU type-examination certificate and the Fitting conformity certificate 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 and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

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 and/or technical specifications, 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 and/or technical specifications have not been applied, the solutions adopted by the manufacturer 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 towards 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 and, if relevant, descriptions of its functioning. The certificate may have one or more annexes attached.

The 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.

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 authorities and the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has issued.

The notified body which refuses to issue or withdraws, suspends or otherwise restricts an EU type-examination certificate shall inform its notifying authorities and the other notified bodies accordingly, giving the reasons for its decision.

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 the 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 APPLIANCE OR FITTING CHECKS AT RANDOM INTERVALS

2.1. Conformity to type based on internal production control plus supervised appliance or fitting checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2.2 and 2.3 and point 2.4 or 2.5, 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.

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.

2.3. Appliance or fitting checks

A notified body, chosen by the manufacturer, shall carry out appliance or fitting 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 technical specifications, or equivalent tests, 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 to prevent the placing on the market of the concerned appliances or fittings.

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 and the inscriptions provided for in Annex IV to each individual appliance 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 an appliance model 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 appliance 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. Fitting conformity certificate

2.5.1. The manufacturer shall affix the inscriptions provided for in point 3 of Annex IV to each individual fitting that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

2.5.2. The manufacturer shall draw up a written Fitting conformity certificate for a fitting model and keep it at the disposal of the national authorities for 10 years after the fitting has been placed on the market. The Fitting conformity certificate shall identify the fitting model for which it has been drawn up and shall accompany the fitting.

2.6. Authorised representative

The manufacturer's obligations set out in point 2.4 or 2.5 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 point 3.2 and points 3.5 or 3.6, 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 instrument 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 appliance 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 appliance 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 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant appliance or fitting field and the appliance or fitting 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 appliance or fitting 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 the inscriptions provided for in Annex IV, and, under the responsibility of the notified body referred to in point 3.3.1, the latter's identification number to each individual appliance 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 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 appliance 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. Fitting conformity certificate

3.6.1. The manufacturer shall affix the inscriptions provided for in point 3 of Annex IV and, under the responsibility of the notified body referred to in point 3.3.1, the latter's identification number to each individual fitting that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

3.6.2. The manufacturer shall draw up a written Fitting conformity certificate for a fitting and keep it at the disposal of the national authorities for 10 years after the fitting has been placed on the market. The Fitting conformity certificate shall identify the fitting model for which it has been drawn up and shall accompany the fitting.

3.7. 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 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.

3.8. Each notified body shall inform its notifying authorities of quality system approvals withdrawn, and shall, periodically or upon request, make available to its notifying authorities information related to quality system assessments.

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

3.9. Authorised representative

The manufacturer's obligations set out in points 3.3.1, 3.3.5 and point 3.5 or 3.6 and point 3.7 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 APPLIANCE OR FITTING QUALITY ASSURANCE

4.1. Conformity to type based on appliance or fitting 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 or 4.6, 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 appliance or fitting 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 appliance 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 national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant appliance or fitting field and appliance or fitting 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 appliance or fitting 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 the inscriptions provided for in Annex IV and, under the responsibility of the notified body referred to in point 4.3.1, the latter's identification number to each individual appliance 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 model 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 appliance 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. Fitting conformity certificate

4.6.1. The manufacturer shall affix the inscriptions provided for in point 3 of Annex IV and, under the responsibility of the notified body referred to in point 4.3.1, the latter's identification number to each individual fitting that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

4.6.2. The manufacturer shall draw up a written Fitting conformity certificate for each fitting model and keep it at the disposal of the national authorities for 10 years after the fitting has been placed on the market. The Fitting conformity certificate shall identify the fitting model for which it has been drawn up and shall accompany the fitting.

4.7.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.

4.8. Each notified body shall inform its notifying authorities of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities 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 issued. Each notified body shall inform the other notified bodies of quality system

approvals which it has refused, suspended or withdrawn, providing the reasons for its decision.

4.9. Authorised representative

The manufacturer's obligations set out in points 4.3.1, 4.3.5 and 4.5 or 4.6 and point 4.7 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 APPLIANCE OR FITING VERIFICATION

5.1. Conformity to type based on appliance or fitting 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 point 5.6 or 5.7, 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 technical specifications, or equivalent tests, 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 this Regulation. All appliances or fittings in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure 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. 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.

5.5.4. 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 the inscriptions provided for in Annex IV and, under the responsibility of the notified body referred to in point 5.3, the latter's identification number to each individual appliance 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 model 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 appliance 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 appliances.

5.7. Fitting conformity certificate

5.7.1. The manufacturer shall affix the inscriptions provided for in point 3 of Annex IV and, under the responsibility of the notified body referred to in point 5.3, the latter's identification number to each individual fitting that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation.

5.7.2. The manufacturer shall draw up a written Fitting conformity certificate for each fitting model and keep it at the disposal of the national authorities for 10 years after the fitting has been placed on the market. The Fitting conformity certificate shall identify the fitting model for which it has been drawn up and shall accompany the fitting.

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 fittings.

5.8. 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.

5.9. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 5.2 and 5.5.1.

6. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the appliance 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 appliance’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 appliance.

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

(a) a general description of the appliance;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the appliance;

(d) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Regulation where those harmonised standards have not been 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) manuals for installation and use.

6.2.2. Where appropriate, the design documentation shall contain the following elements:

(a) the conformity certificate 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 appliance has been placed on the market.

6.3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured appliances 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 technical specifications, or equivalent tests, to check the conformity of the appliance with the applicable requirements of this Regulation, or have them carried out. In the absence of such a harmonised standard and/or technical specification 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 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 appliance, 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 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 the inscriptions provided for in Annex IV and, under the responsibility of the notified body referred to in point 6.4, the latter's identification number to each appliance 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 appliance 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.

ANNEX IV

CE MARKING AND INSCRIPTIONS

(1) The appliance or its data plate shall bear the CE marking provided for in Annex II to Regulation (EC) No 765/2008 followed by the identification number of the notified body involved in the production control phase and the last two digits of the year in which the CE marking was affixed.

(2) The appliance or its data plate shall bear the following information:

(a) The manufacturer's name, registered trade name, registered trade mark or identification symbol.

(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 gas supply pressure.

(f) The necessary information to ensure correct and safe installation, according to the nature of the appliance.

(3) The fitting or its data plate shall bear, as far as relevant, the information provided for in paragraph (2).

ANNEX V

EU DECLARATION OF CONFORMITY

The EU declaration of conformity shall contain the following elements:

(a) Appliance/appliance model (product, batch, type or serial number).

(b) Name and address of the manufacturer and, where applicable, his authorised representative.

(c) This declaration of conformity is issued under the sole responsibility of the manufacturer.

(d) Object of the declaration (identification of the appliance allowing traceability. It may, where necessary for the identification of the appliance, include an image):

(1) description of the appliance;

(2) conformity assessment procedure followed;

(3) name and address of the notified body which carried out the conformity assessment;

(4) reference to the EU-type examination certificate.

(e) The object of the declaration described above is in conformity with the relevant Union harmonisation legislation: ……. (reference to the other Union acts applied):

(f) References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:

(g) The notified body or bodies … (name, address, number) … performed … (description of intervention) … and issued the certificate(s): …

(h) Additional information:

Signed for and on behalf of: …….

(place and date of issue):

(name, function) (signature):

ANNEX VI

FITTING CONFORMITY CERTIFICATE

The Fitting conformity certificate shall contain the following elements:

(a) Fitting/fitting model (product, batch, type or serial number).

(b) Name and address of the manufacturer and, where applicable, his authorised representative.

(c) This Fitting conformity certificate is issued under the sole responsibility of the fitting manufacturer.

(d) Object of the declaration (identification of the fitting allowing traceability. It may, where necessary for the identification of the fitting, include an image):

(1) description and characteristics of the fitting;

(2) conformity assessment procedure followed;

(3) name and address of the notified body which carried out the conformity assessment;

(4) reference to the EU-type examination certificate.

(e) The object of the Fitting conformity certificate described above is in conformity with Regulation ……. On appliances burning gaseous fuels (reference to this Regulation):

(f) References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared.

(g) The notified body or bodies … (name, address, number) … performed … (description of intervention) … and issued the certificate(s): …

(h) 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.

(i) Additional information:

Signed for and on behalf of: ……;

(place and date of issue);

(name, function) and signature.

ANNEX VII

CORRELATION TABLE	
Directive 2009/142/EC	This Regulation
Article 1(1) first subparagraph	Article 1(1)
Article 1(1) second subparagraph	Article 1(3)(a)
Article 1(2)	Article 2(1), (2) and (5)
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___	Article 2(3), (4), (6) to (31)
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