L.N. 28 of 2004

PRODUCT SAFETY ACT
(ACT NO. V OF 2001)

Appliances Burning Gaseous Fuels Regulations, 2004

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister of Finance and Economic Affairs, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and Commencement.

1.1. The title of these regulations is the Appliances Burning Gaseous Fuels Regulations, 2004.

1.2. These regulations shall come into force on the date of publication:

1.2.1. Provided that the requirements to provide information to the European Commission referred to in regulation 7.6 of these regulations shall come into force on the 1st May, 2004.

Scope.

2.1. These regulations shall apply to:

2.1.1. appliances burning gaseous fuels used for cooking, heating, hot water production, refrigeration, lighting or washing and having, where applicable, a normal water temperature not exceeding 105° hereinafter referred to as 'appliances'. Forced draught burners and heating bodies to be equipped with such burners will also be considered as appliances.

2.1.2. safety devices, controlling devices or regulating devices and sub-assemblies, other than forced draught burners and heating bodies to be equipped with such burners separately marketed for trade use and designed to be incorporated into an appliance burning gaseous fuel or assembled to constitute such an appliance, hereinafter referred to as 'fittings'.

2.2. Appliances specifically designed for use in industrial processes carried out on industrial premises are excluded from the scope defined in regulation 2.1 of these regulations.

Definitions.

3.1. In these regulations:

3.1.1. "authorised representative" means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.2. "CE marking" means marking as set out in Annex III of the Directive, which is set out in Schedule III to these regulations following the relevant procedure for certification of conformity as laid down in regulation 8 of these regulations;

3.1.3. "Community" means the European Community;

3.1.4. "gaseous fuel" means any fuel which is in a gaseous state at a temperature of 15˚C and a pressure of 1 bar;

3.1.5. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Council Directive 98/34/EC[1] of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC[2] of the European Parliament and of the Council, the reference of which has been published in the OJEU;

3.1.6. "importer" means any person who places on the Community or Maltese market and puts into service the product that is covered by regulation 2.1 of theses regulations and imported from a third country;

3.1.7. "manufacturer" means the person:

3.1.7.1 who is primarily responsible for the design and construction of the product covered by regulation 2.1 of these regulations with a view to placing it on the Community or Maltese market on his/their behalf;

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[1] OJ No. L204, 21-07-98, P.37.
[2] OJ No. L217, 05-08-98, P.18.

3.1.7.2 who is responsible for "re-building" or modifying an existing product falling under regulation 2.1 of these regulations, and who in so doing is creating an "as-new" product, with a view to placing it on the Community or Maltese market on his/their behalf;

3.1.7.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported products falling under regulation 2.1 of these regulations and coming from third countries;

3.1.8. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI, the reference of which has been published in the OJEU;

3.1.9. "normally used" means

- correctly installed and regularly serviced in accordance with the manufacturer's instructions,

- used with a normal variation in the gas quality and a normal fluctuation in the supply pressure, and

- used in accordance with its intended purposes or in a way which can be reasonably foreseen;

3.1.10. "notified body" means a body appointed by a Member State and notified to the Commission and the other Member States, assessed according to the criteria laid down in Annex V of the Directive, set out in Schedule V hereto and appointed to carry out the procedures referred to in Article 8 of the Directive and regulation 8 of these regulations;

3.1.10.1. The names of such bodies are published in the OJEU;

3.1.10.2. Maltese notified bodies wishing to operate within the scope of these regulations shall follow the procedure prescribed in the *Method for Designating Conformity Assessment Bodies Regulations, 2003;* L.N. 136 of 2003.

3.1.11. "OJEU" means Official Journal of the European Union;

3.1.12. "placing on the market" means the initial action of making available a product, falling under regulation 2.1 of these regulations, for the first time on the Community or Maltese market with a view to distribution or use in the Community or Malta;

3.1.12.1. "making available" means the transfer of the product falling under regulation 2.1 of these regulations, irrespective of the legal act on which the transfer is based (sale, loan, hire, lease, gift or ony other type of legal instrument);

3.1.13. "putting into service" means the first use of a product, falling under regulation 2.1 of these regulations, in the Community or Maltese territory by its end user;

3.1.14. "the Directive" means Council Directive 90/396/EEC[3] as amended by Council Directive 93/68/EEC[4] on the approximation of the laws of the Member States relating to appliances burning gaseous fuels.

Applicability.

4.1. The provisions of these regulations are applicable to imported products falling under regulation 2.1 of these regulations, as well as those manufactured for the local market.

4.2. The placing on the market and the putting into service of appliances, falling under regulation 2.1 of these regulations, which comply with all the provisions of these regulations, including the conformity assessment procedures laid down in Chapter II of the Directive and regulation 8 of these regulations, and which bear the CE marking provided for in Article 10 of the Directive and regulation 6 of these regulations, shall not be prohibited, restricted or impeded.

4.3. The placing on the market of fittings as referred to in regulation 2.1 of these regulations, accompanied by a certificate as referred to in Article 8 (4) of the Directive and regulation 8.4 of these regulations shall not be prohibited, restricted or impeded.

General requirements.

5.1. Appliances referred to in regulation 2.1 of these regulations may be placed on the market and put into service only if, when normally used, they do not compromise the safety of persons, domestic animals and property.

[3] OJ No. L196, 26-07-90, P.15.
[4] OJ No. L220, 30-08-93, P.15.

5.2. Appliances and fittings as referred to in regulation 2.1 of these regulations shall satisfy the essential requirements applicable to them set out in Annex I of the Directive, which is set out in Schedule I to these regulations.

5.3. Appliances and fittings shall be presumed to comply with these regulations when they conform to:

5.3.1. the national standards applicable to them implementing the harmonised standards whose reference numbers have been published in the OJEU;

5.3.2. the national standards applicable to them relating to those areas in which no harmonised standards exist and which are regarded as complying with the essential requirements.

5.4. The Malta Standards Authority shall communicate to the Commission the texts of its national standards as referred to in regulation 5.3.2 of these regulations which it regards as complying with the essential requirements referred to in Article 3 of the Directive and regulation 5.2 of these regulations.

CE marking of conformity.

6.1. The CE marking of conformity and the inscriptions set out in Annex III of the Directive, which is set out in Schedule III to these regulations shall be affixed in a visible, easily legible and indelible form to the appliance or to a data plate attached to it.

6.1.1. The data plate shall be so designed that it cannot be re-used.

6.2. The affixing of markings on the appliances which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited.

6.2.1. Any other marking may be affixed to the appliance or to the data plate provided that the visibility and legibility of the CE marking is not hereby reduced.

6.3. Without prejudice to regulation 7 of these regulations:

6.3.1. where it is established that the CE marking has been affixed unduly, the manufacturer or his authorized representative shall be obliged to make the product comply as regards the provisions concerning the CE marking and to end the infringement under conditions imposed by the Director of Consumer Affairs;

6.3.2. where non-compliance continues, all appropriate measures shall be taken to restrict or prohibit the placing on the market of the appliance in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in regulation 7 of these regulations.

Withdrawal or restriction from market.

7.1. Where it is ascertained that normally used appliances bearing the CE marking might compromise the safety of persons, domestic animals or property, all appropriate action shall be taken to withdraw those appliances from the market and prohibit or restrict their being placed on the market.

7.2. Where an appliance which does not comply bears the CE marking, appropriate action shall be taken against whomsoever has affixed the mark.

7.3. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall be immediately informed of any such measures taken under regulations 7.1 and 7.2 above, indicating the reasons for such decision and, in particular, whether non-conformity is due to:

(a) failure to meet the essential requirements referred to in Article 3 of the Directive and regulation 5.2 of these regulations, where the appliance does not correspond to the standards referred to in Article 5(1) of the Directive and regulation 5.3 of these regulations;

(b) incorrect application of the standards referred to in Article 5(1) of the Directive and regulation 5.3 of these regulations;

(c) shortcomings in the standards referred to in Article 5 (1) of the Directive and regulation 5.3 of these regulations.

7.4. Any decision taken pursuant to these regulations which restricts the placing on the market and the putting into service of appliances shall state the exact grounds on which it is based.

7.4.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

7.5. Competent Authorities shall communicate the types of gas and corresponding supply pressures used on the Maltese territory to the Consumer and Industrial Goods Directorate of the Malta Standards Authority before the 1st May, 2004.

7.5.1. They shall also communicate all changes in good time.

7.6. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 7.1, 7.2 7.3, 7.4, 7.4.1, 7.5 and 7.5.1 of these regulations.

Certification of conformity.

8.1. The means of certification of conformity of series-manufactured appliances shall be:

(a) the EC type-examination as referred to in section 1 of Annex II of the Directive, which is set out in section 1 of Schedule II to these regulations, and

(b) prior to their being placed on the market, at the choice of the manufacturer:

- the EC declaration of conformity to type referred to in section 2 of Annex II of the Directive, which is set out in section 2 of Schedule II to these regulations, or

- the EC declaration of conformity to type (guarantee of production quality) referred to in section 3 of Annex II of the Directive, which is set out in section 3 of Schedule II to these regulations, or

- the EC declaration of conformity to type (guarantee of product quality) referred to in section 4 of Annex II of the Directive, which is set out in section 4 of Schedule II to these regulations, or

- EC verification as referred to in section 5 of Annex II of the Directive, which is set out in section 5 of Schedule II to these regulations.

8.2. In the case of production of an appliance as a single unit or in small quantities, EC verification by single unit, as referred to in section 6 of Annex II of the Directive, which is set out in section 6 of Schedule II to these regulations, may be chosen by the manufacturer.

8.3. After completion of the procedures referred to in regulations 8.1 (b) and 8.2 of these regulations, the CE marking of conformity shall be affixed to conforming appliances in accordance with Article 10 of the Directive and regulations 6.1 and 6.2 of these regulations.

8.4 The procedures referred to in regulation 8.1 of these regulations shall be applied in respect of fittings as referred to in Article 1 of the Directive and regulation 2.1of these regulations, with the exception of the affixing of the CE marking of conformity and, where appropriate, the drawing-up of the declaration of conformity.

8.4.1 A certificate shall be issued declaring the conformity of the fittings with the provisions of these regulations which apply to them and stating their characteristics and how they must be incorporated into an appliance or assembled to assist compliance with the essential requirements applicable to finished appliances.

8.4.2. The certificate shall be supplied with the fitting.

8.5. Where the appliances are covered by other Directives dealing with other aspects and specifying the affixing of the CE marking, the latter shall indicate that the appliances are also presumed to conform to the provisions of those other Directives.

8.5.1. However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity to the provisions only of those Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the OJEU, must be given in the documents, notices or instructions required by the Directives and accompanying such devices.

8.6. Records and correspondence relating to the means of certification of conformity shall be drawn up in the official language(s) of the Member State where the body responsible for carrying out these procedures is established or in a language accepted by it.

Revokes L.N. 52 of 1996.

9.1. The Appliances Burning Gaseous Fuels Order, 1996 are hereby being revoked.

Schedule I

Based on Annex I of the Directive

ESSENTIAL REQUIREMENTS

Preliminary remark

The obligations resulting from the essential requirements for appliances in this Schedule also apply to fittings where the corresponding risk exists.

1. GENERAL CONDITIONS

1.1. Appliances must be so designed and built as to operate safely and present no danger to persons, domestic animals or property when normally used as defined in Article 1(4) of the Directive and regulation 3.1.9 of these regulations.

1.2. When placed on the market, all appliances must:

- be accompanied by technical instructions intended for the installer,

- be accompanied by instructions for use and servicing, intended for the user,

- bear appropriate warning notices, which must also appear on the packaging.

The instructions and warning notices must be in Maltese and/or English or in any other language of the Community acceptable to the Maltese authorities.

1.2.1. The technical instructions intended for the installer must 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. In particular, the instructions must specify:

- the type of gas used,

- the gas supply pressure used,

- the flow of fresh air required:

- for the combustion air supply,

- to avoid the formation of dangerous unburned gas mixtures for appliances not fitted with the device referred to in point 3.2.3,

- the conditions for the dispersal of combustion products,

- for forced draught burners and heating bodies intended to be equipped with such burners, their characteristics, the requirements for assembly, to assist compliance with the essential requirements applicable to finished appliances and, where appropriate, the list of combinations recommended by the manufacturer.

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

1.2.3. The warning notices on the appliance and its packaging must clearly state the type of gas used, the gas supply pressure and any restrictions on use, in particular the restriction whereby the appliance must be installed only in areas where there is sufficient ventilation.

1.3. Fittings intended to be part of an appliance must be so designed and built as to fulfil correctly their intended purpose when incorporated in accordance with the instructions for installation.

The instructions for installation, adjustment, operation and maintenance must be provided with the fittings concerned.

2. MATERIALS

2.1. Materials must be appropriate for their intended purpose and must withstand the technical, chemical and thermal conditions to which they will foreseeably be subjected.

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

3. DESIGN AND CONSTRUCTION

3.1. *General*

3.1.1. Appliances must be so constructed that, when used normally, no instability, distortion, breakage or wear likely to impair their safety can occur.

3.1.2. Condensation produced at the start-up and/or during use must not affect the safety of appliances.

3.1.3. Appliances must be so designed and constructed as to minimize the risk of explosion in the event of a fire of external origin.

3.1.4. Appliances must be so 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 must continue to operate safely.

3.1.6. Abnormal fluctuation or failure of auxiliary energy or its restoration must not lead to an unsafe situation.

3.1.7. Appliances must be so designed and constructed as to obviate hazards of electrical origin. In the area in which it applies, compliance with the safety objectives in respect of electrical hazards laid down in Directive 73/23/EEC[5], as implemented in Malta by the Low Voltage Electrical Equipment Regulations, 2002, shall be equivalent to fulfilment of this requirement. L.N. 367 of 2002.

3.1.8. All pressurised parts of an appliance must withstand the mechanical and thermal stresses to which they are subjected without any deformation affecting safety.

3.1.9. Appliances must be so designed and constructed that failure of a safety, controlling or regulating device may not lead to an unsafe situation.

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

3.1.11. 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 must be appropriately protected.

3.1.12. Levers and other controlling and setting devices must be clearly marked and give appropriate instructions so as to prevent any error in handling. Their design must be such as to preclude accidental manipulation.

3.2. *Unburned gas release*

3.2.1. Appliances must be so constructed that the gas leakage rate is not dangerous.

3.2.2. Appliances must be so constructed that gas release during ignition and re-ignition and after flame extinction is limited in order to avoid a dangerous accumulation of unburned gas in the appliance.

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[5] OJ No L 77, 26-03-73, P.29.

3.2.3. Appliances intended to be used in indoor spaces and rooms must be fitted with a special device which avoids a dangerous accumulation of unburned gas in such spaces or rooms.

Appliances which are not fitted with such devices must be used only in areas where there is sufficient ventilation to avoid a dangerous accumulation of unburned gas.

Large-scale kitchen appliances and appliances powered by gas containing toxic components must be equipped with the aforesaid device.

3.3. *Ignition*

Appliances must be so constructed that, when used normally:

- ignition and re-ignition is smooth,
- cross-lighting is assured.

3.4. *Combustion*

3.4.1. Appliances must be so constructed that, when used normally, flame stability is assured and combustion products do not contain unacceptable concentrations of substances harmful to health.

3.4.2. Appliances must be so 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 must be so constructed that in abnormal draught conditions there is no release of combustion products in a dangerous quantity in the room concerned.

3.4.4. Independent flueless domestic heating appliances and flueless instantaneous water heaters must not cause, in the room or space concerned, a carbon monoxide concentration likely to present a danger to the health of persons exposed, bearing in mind the foreseeable duration of their exposure.

3.5. *Rational use of Energy*

Appliances must be so 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 placed in close proximity to the floor or other surfaces must not reach temperatures which present a danger in the surrounding area.

3.6.2. The surface temperature of knobs and levers of appliances intended to be manipulated must not present a danger to the user.

3.6.3. The surface temperatures of external parts of appliances intended for domestic use, with the exception of surfaces or parts which are associated with the transmission of heat, must not under operating conditions present a danger to the user and in particular to children, for whom an appropriate reaction time must be taken into account.

3.7. *Foodstuffs and water used for sanitary purposes*

Without prejudice to the Community rules in this area, materials and components used in the construction of an appliance, which may come into contact with food or water used for sanitary purposes, must not impair their quality.

Schedule II

Based on Annex II of the Directive

PROCEDURE FOR CERTIFICATION OF CONFORMITY

1. EC TYPE-EXAMINATION

1.1. The EC type-examination is that part of the procedure by which a notified body checks and certifies that an appliance, representative of the production envisaged, meets the provisions of these regulations which apply to it.

1.2. The application for type-examination must be lodged by the manufacturer or his authorized representative with a single notified body.

1.2.1. The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address,

- a written declaration that the application has not been lodged with any other notified body,

- the design documentation, as described in Annex IV of the Directive, which is set out in Schedule IV to these regulations.

1.2.2. The manufacturer must place at the disposal of the notified body an appliance, representative of the production envisaged, hereinafter called 'type'. The notified body may request further samples of the type if needed for the test programme.

The type may additionally cover variants of the product provided that those variants do not have different characteristics with respect to types of risk.

1.3. The notified body must:

1.3.1. examine the design documentation and verify that the type has been manufactured in conformity with the design documentation and identify the elements which have been designed in accordance with the applicable provisions of the standards referred to in Article 5 of the Directive and regulation 5.3 of these regulations and the essential requirements of these regulations;

1.3.2. perform, or have performed, the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the standards referred to in Article 5 of the Directive and regulation 5.3 of these regulations have not been applied;

1.3.3. perform, or have performed, the appropriate examinations and/or tests to check whether the applicable standards have effectively been applied where the manufacturer has chosen to do so, thereby assuring conformity with the essential requirements.

1.4. Where the type satisfies the provisions of these regulations, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions, if any, for its validity and the necessary data for identification of the approved type and, if relevant, descriptions of its functioning. Relevant technical elements such as drawings and diagrams must be annexed to the certificate.

1.5. The notified body must inform the other notified bodies forthwith of the issuing of the EC type-examination certificate and any additions to the said type as referred to in point 1.7. They may obtain a copy of the EC type-examination certificate and/or its additions and on a reasoned request may obtain a copy of the Annexes to the certificate and the reports on the examinations and tests carried out.

1.6. A notified body which refuses to issue or withdraws an EC type-examination certificate must inform the Member State which notified it and the other notified bodies accordingly, giving the reasons for its decision.

1.7. The applicant must keep the notified body that has issued the EC type-examination certificate informed of all modifications to the approved type which might affect conformity with the essential requirements.

Modifications to the approved type must receive additional approval from the notified body that issued the EC type-examination certificate where such changes affect conformity with the essential requirements or the prescribed conditions for use of the appliance. This additional approval is to be given in the form of an addition to the original EC type-examination certificate.

2. **EC DECLARATION OF CONFORMITY TO TYPE**

2.1. The EC declaration of conformity to type is that part of the procedure whereby the manufacturer declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of these regulations which apply to them. The manufacturer or his authorized representative established within the Community shall affix the CE marking on each appliance and draw up a written certificate of conformity. The declaration of conformity may cover one or more appliances and must be kept by the manufacturer. The CE marking must be followed by the identification number of the notified body responsible for the random checks set out in point 2.3.

2.2. The manufacturer must take all necessary measures to ensure that the manufacturing process, including final product inspection and testing, results in homogeneity of production and conformity of the appliances with the type as described in the EC type-examination certificate and with the requirements of these regulations which apply to them. A notified body, chosen by the manufacturer, must carry out random checks on the appliances as set out in point 2.3.

2.3. On-site checks of appliances must be undertaken at random by the notified body at intervals of one year or less. An adequate number of appliances must be examined and appropriate tests as set out in the applicable standards referred to in Article 5 of the Directive and regulation 5.3 of these regulations, or equivalent tests must be carried out in order to ensure conformity with the corresponding essential requirements of these regulations. The notified body shall in each case determine whether these tests need to be carried out in full or in part. Where one or more appliances are rejected, the notified body shall take the appropriate measures to prevent the marketing thereof.

3. **EC DECLARATION OF CONFORMITY TO TYPE (guarantee of production quality)**

3.1. The EC declaration of conformity to type (guarantee of production quality) is the procedure whereby a manufacturer who fulfils the obligations in point 3.2 declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of these regulations which applies to them. The manufacturer or his authorized representative must affix the CE marking to each appliance and draw up a written declaration of conformity. The CE marking must be followed by the identification number of the notified body responsible for EC surveillance.

3.2. The manufacturer shall apply a quality system that ensures conformity of the appliances with the type as described in the EC type-examination certificate and with the essential requirements of these regulations which apply to them. The manufacturer is subject to EC surveillance as specified in point 3.4.

3.3. *Quality system*

3.3.1. The manufacturer must lodge an application for approval of his quality system with a notified body of his choice for the appliances in question.

The application must include:

- the quality system documentation,

- an undertaking to carry out the obligations arising from the quality system as approved,

- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness,

- documentation relating to the approved type and a copy of the EC type-examination certificate.

3.3.2. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and logical manner in the form of measures, procedures and written instructions. This quality system documentation must permit a uniform interpretation of the quality programmes, plans, manuals and records. It shall contain, in particular, an adequate description of:

- the quality objectives, the organizational structure and responsibilities of management and of their powers with regard to appliance quality,

- the manufacturing processes, quality control and quality assurance techniques and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out,

- the method of monitoring attainment of the required appliance quality and the effective operation of the quality system.

3.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 3.3.2. It will presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It must notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the notified body and the reasoned assessment decision in respect of the appliances concerned.

3.3.4. The manufacturer must keep the notified body that has approved the quality system informed of any updating of the quality system in relation to changes brought about by, for example, new technologies and quality concepts.

The notified body must examine the proposed modifications and decide whether the modified quality system complies with the relevant provisions or whether reappraisal is necessary. It must notify the manufacturer of its decision. The notification must include the conclusions of the inspection and the reasoned assessment decision.

3.3.5. A notified body that withdraws approval of a quality system must so inform the other notified bodies, giving the reasons for the decision.

3.4. *EC surveillance*

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

3.4.2. The manufacturer must allow the notified body access for inspection purposes to the place of manufacture, inspection, testing and storage and must provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records, such as inspection reports and test data, calibration data, reports on qualifications of the staff concerned, etc.

3.4.3. The notified body must carry out a check at least once every two years to ensure that the manufacturer is maintaining and applying the approved quality system and must supply a report of the check to the manufacturer.

3.4.4. Furthermore, the notified body may make unannounced visits to the manufacturer. During these visits, the notified body may carry out tests on appliances or have them carried out. It must supply the manufacturer with an inspection report and, if appropriate, a test report.

3.4.5. The manufacturer may supply the notified body's report on request.

4. **EC DECLARATION OF TYPE CONFORMITY (guarantee of product quality)**

4.1. The EC declaration of type conformity (guarantee of product quality) is that part of the procedure whereby a manufacturer who fulfils the obligations in point 4.2 declares that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the essential requirements of these regulations which apply to them. The manufacturer or his authorized representative must affix the CE marking to each appliance and draw up a written declaration of conformity. This declaration may cover one or more appliances and must be kept by the manufacturer. The CE marking must be followed by the identification number of the notified body responsible for EC surveillance.

4.2. The manufacturer shall apply an approved quality system for the final inspection of the appliances and the tests, as specified in point 4.3, and is subject to EC surveillance as specified in point 4.4.

4.3. *Quality system*

4.3.1 Under this procedure, the manufacturer must lodge an application for approval of his quality system with a notified body of his choice for the appliances in question.

The application must include:

- the quality system documentation,

- an undertaking to carry out the obligations arising from the quality system as approved,

- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness,

- the documentation relating to the approved type and a copy of the EC type-examination certificate.

4.3.2. As part of the quality system, each appliance must be examined and appropriate tests as laid down in the applicable standard(s) referred to in Article 5 of the Directive and regulation 5.3 of these regulations, or equivalent tests carried out to check its conformity with the essential requirements relating to it in these regulations.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and logical manner in the form of measures, procedures and written instructions. This quality system documentation must permit a uniform interpretation of the quality programmes, plans, manuals and records.

The quality system documentation shall contain, in particular, an adequate description of:

- the quality objectives, the organizational structure and responsibilities of management and of their powers with regard to appliance quality,

- the checks and tests to be carried out after manufacture,

- the method of verifying the effective operation of the quality system.

4.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 4.3.2. It will presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard. It must notify the manufacturer of its decision and inform the other notified bodies thereof. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the notified body and the reasoned assessment decision for the appliances concerned.

4.3.4. The manufacturer must keep the notified body which approved the quality system informed of any adaptation of the quality system made necessary, e.g. by new technology and quality concepts.

The notified body must examine the proposed changes and decide whether the amended quality system satisfies the relevant provisions or whether a reassessment is necessary. It must notify the manufacturer of its decision. The notification must contain the conclusions of the inspection and the reasoned assessment decision.

4.3.5. A notified body which withdraws approval of a quality system must inform the other notified bodies that it has done so and give reasons for its decision.

4.4. *EC surveillance*

4.4.1. The purpose of EC surveillance is to ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.4.2. The manufacturer must allow the notified body access for inspection to the place of inspection, testing and storage and must provide it with all necessary information, in particular:

- the quality system documentation,

- the quality files such as inspection reports and test data, calibration data, report on qualifications of the staff concerned, etc.

4.4.3. The notified body must carry out a check at least once every two years to ensure that the manufacturer is maintaining and applying the approved quality system and must supply a report on the check to the manufacturer.

4.4.4. Furthermore, the notified body may make unannounced visits to the manufacturer. During these visits, the body may carry out tests on appliances or have them carried out. It must supply the manufacturer with an inspection report and, if appropriate, a test report.

4.4.5. The manufacturer may supply the notified body's report on request.

5. **EC VERIFICATION**

5.1. EC verification is the procedure whereby the manufacturer or his authorized representative ensures and declares that the appliances subject to the provisions of point 3 are in conformity to the type as described in the EC type-examination certification and satisfy the requirements of these regulations that apply to them.

5.2. The manufacturer or his authorized representative must take all measures necessary in order that the manufacturing process ensures conformity of the appliances to the type as described in the EC type-examination certification and to the requirements of these regulations that apply to them. The manufacturer or his authorized representative must affix the CE marking to each appliance and draw up a written declaration of conformity. The declaration of conformity may cover one or more appliances and must be kept by the manufacturer or his authorized representative.

5.3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the appliance to the requirements of these regulations by examination and testing of every appliance, as specified in point 5.4, or by examination and testing of appliances on a statistical basis, as specified in point 5.5, at the choice of the manufacturer.

5.4. *Verification by checking and testing of each appliance*

5.4.1. All appliances must be individually examined and appropriate tests, as set out in the relevant standard(s) referred to in Article 5 of the Directive and regulation 5.3 of these regulations, or equivalent tests, must be carried out in order to verify their conformity with the type as described in the EC type-examination certificate and the requirements of these regulations that apply to them.

5.4.2. The notified body must affix, or cause to be affixed, its identification number on each appliance and draw up a written certificate of conformity relating to the tests carried out. The certificate of conformity may cover one or more appliances.

5.4.3. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

5.5. *Statistical verification*

5.5.1. Manufacturers must present the appliances manufactured in the form of uniform batches and must take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

5.5.2. Statistical control is as follows:

Appliances are subject to statistical control by attributes. They should be grouped into identifiable batches consisting of units of a single model manufactured under the same conditions. A batch is examined at random intervals. The appliances constituting a sample are examined individually and appropriate tests, as laid down in the respective standard(s) referred to in Article 5 of the Directive and regulation 5.3 of these regulations, or equivalent tests are carried out to determine whether the batch is to be accepted or rejected.

A sampling system with the following characteristics is applied:

- 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 %.

5.5.3. Where batches are accepted, the notified body must affix, or cause to be affixed, its identification number to each appliance and draw up a written certificate of conformity relating to the tests carried out. All appliances in the batch may be placed on the market except for those products from the sample which were found not to be in conformity.

Where a batch is rejected, the notified body must take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the notified body may suspend the statistical verification. The manufacturer may, under the responsibility of the notified body, affix the latter's identification number during the manufacturing process.

5.5.4. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

6. **EC UNIT VERIFICATION**

6.1. EC unit verification is the procedure whereby the manufacturer or his authorized representative ensures and declares that the appliance concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of these regulations that apply to it. The manufacturer or his authorized representative must affix the CE marking to the appliance and draw up a written declaration of conformity which he must keep.

6.2. The notified body must examine the appliance and carry out the appropriate tests, taking account of the design documentation in order to ensure its conformity with the essential requirements of these regulations.

The notified body must affix, or cause to be affixed, its identification number to the approved appliance and must draw up a written certificate of conformity concerning the tests carried out.

6.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex IV of the Directive, which is set out in Schedule IV to these regulations, is to enable conformity to the requirements of these regulations to be assessed and the design, manufacture and operation of the appliance to be understood.

The design documentation referred to in Annex IV of the Directive, which is set out in Schedule IV hereto must be made available to the notified body.

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

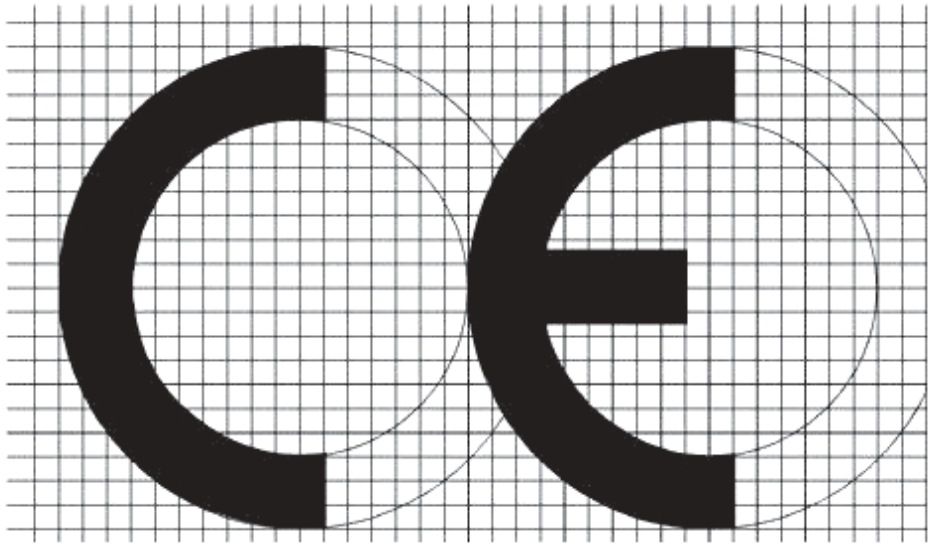
6.5. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

Schedule III

Annex III of the Directive

CE CONFORMITY MARKING AND INSCRIPTIONS

1 The CE conformity marking consists of the initials "CE" as shown below:



The CE marking must be followed by the identification number of the notified body involved in the production control phase.

2 The appliance or its data plate must bear the CE marking together with the following inscriptions:

- the manufacturer's name or identification symbol,

- the trade name of the appliance,

- the type of electrical supply used, if applicable,

- the appliance category,

- the last two digits of the year in which the CE marking was affixed.

Information needed for installation purposes may be added according to the nature of the appliance.

3 If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

Schedule IV

Annex IV of the Directive

DESIGN DOCUMENTATION

The design documentation must contain the following information, in so far as is required by the notified body for assessment:

- a general description of the appliance,

- conceptual designs and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for the understanding of the above, including the operation of the appliances,

- a list of the standards referred to in Article 5 of the Directive and regulation 5.3 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 5 of the Directive and regulation 5.3 of these regulations have not been applied,

- test reports,

- manuals for installation and use.

Where appropriate, the design documentation must contain the following elements:

- attestations relating to the equipment incorporated in the appliance,

- attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliance,

- any other document making it possible for the notified body to improve its assessment.

Schedule V

Annex V of the Directive

MINIMUM CRITERIA FOR ASSESSMENT OF NOTIFIED BODIES

The notified bodies designated by the Member States must fulfil the following minimum conditions:

- availability of personnel and of the necessary means and equipment,

- technical competence and professional integrity of personnel,

- independence in carrying out tests, preparing reports, issuing certificates and performing the surveillance provided for in these regulations, of management and technical staff in relation to all circles, groups or persons directly or indirectly involved in the field of the appliances,

- maintenance of professional secrecy by staff,

- possession of civil liability insurance unless that liability is covered by the State under national law.

Fulfilment of the conditions in the first two indents must be periodically verified by the competent authorities of the Member States or by bodies designated by the Member States.