



Product standards

Gas Appliances

UK Regulations

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Whilst every effort has been made to ensure that the information in this booklet is accurate, the Department of Trade and Industry cannot accept liability for any errors, omissions or misleading statements in that information, whether caused by negligence or otherwise.

Gas appliances - the new law in brief

From 6 April 1992, under the Gas Appliances (Safety) Regulations 1992, manufacturers will have the choice of following the new Community regime (described below) or of continuing to comply with existing national legislation of the Member State in which the appliance is marketed, in force on 31 December 1991.

From **1 January 1996**:

- many gas appliances made or sold in the United Kingdom, including imports, will have to:
 - satisfy safety and efficiency requirements, for example on design, construction, and materials used;
 - undergo type-examination, and some form of supervision during production, by an approved body;
 - carry the CE mark and specified information, mainly about the appliance; and
 - be accompanied by instructions and warnings in the language of the country of destination.

- some of these requirements will also apply to gas fittings.

Failure to comply with these requirements will be a criminal offence.

The same rules will apply everywhere in the Community, so appliances and fittings that comply with these requirements may be sold anywhere in the Community.

This booklet describes the Regulations in more detail. You should, however, consult the Regulations themselves for all the provisions that may be relevant.

Free movement of goods

Achieving the free movement of goods lies at the heart of the drive to create the single European market.

All European Community countries have laws on product safety and so on. Different laws can cause technical barriers to trade.

In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' to tackle this long standing problem for business.

'New Approach' Directives (that is Community laws) set out 'essential requirements' (for safety, for example), written in general terms, which must be met before products may be sold in the United Kingdom or anywhere else in the Community. European standards fill in the detail and are the main way for businesses to meet the 'essential requirements'. The Directives also say how manufacturers are to show that products meet the 'essential requirements'. Products meeting the requirements are to carry the CE mark, which should mean that they can be sold anywhere in the Community.

For the wider background and to find out more about what this means for your business, get your copy of *Keeping your product on the market* by telephoning DTI's Business in Europe Hotline on 01179 444888.

The Gas Appliances Directive is one such Directive. It has been implemented in United Kingdom law by the Gas Appliances (Safety) Regulations 1992 which came into force on 6 April 1992. The rest of this booklet describes those Regulations.

Gas Appliances (Safety) Regulations 1992 (S.I. 1992/711)

Entry into force: 6 April 1992.

Primary legislation: the Consumer Protection Act 1987 and the European Communities Act 1972.

Coverage: the Regulations apply to:

- ❑ appliances, that is gas burning appliances used for cooking, heating, water heating, refrigeration, lighting and washing with, where appropriate, a normal operating temperature not exceeding 105°C but excluding appliances which are specifically designed for use in industrial processes on industrial premises; and
- ❑ fittings, that is safety, controlling or regulating devices and subassemblies which are separately marketed for trade use and which are designed to be incorporated into an appliance.

Forced draught burners and heating bodies to be equipped with such burners are classed as appliances, not fittings.

'Gas' means any fuel which is in gaseous state at 15°C under a pressure of 1 bar.

Prohibition on supply: subject to the transitional arrangements described below, the Regulations make it an offence to supply an appliance or fitting:

- which does not satisfy the essential requirements which are applicable to them (reproduced in full at Annex A);
 - which, when normally used (as defined below), is not safe;
 - where, for appliances, the proper independent attestation procedures have not been followed or to which an EC mark has not been affixed;
 - where, for fittings, the proper independent attestation procedures have not been followed or a fitting certificate has not been issued.
- ❑ **'supply'** includes first putting into service by the manufacturer or Importer Into the United Kingdom.
 - ❑ **'normally used'** means use:
 - when correctly installed and regularly serviced in accordance with the manufacturer's instructions; and

- within the normal variations of gas quality and pressure; and
 - in accordance with its intended purpose or in a way which can reasonably be foreseen.
- 'safe' has the same meaning as in section 19(1) of the Consumer Protection Act 1987 but extended to include the risk of death or injury to domestic animals or of damage to property.

Exceptions: the Regulations do **not** apply to:

- appliances and fittings which were supplied for the first time in the Community before 1 January 1992;
- second hand gas appliances (but note that second hand gas cookers continue to be subject to the Gas Cooking Appliances (Safety) Regulations 1989);
- appliances or fittings where the person placing them on the market reasonably believes that they will not be put into service in the United Kingdom or in any other Member State;
- in the transitional period from 6 April 1992 until 31 December 1995, gas appliances supplied in the United Kingdom which comply with the legislation in force at 31 December 1991, comprising:
 - the Gas Cooking Appliances (Safety) Regulations 1989;
 - the Heating Appliances (Fireguards) (Safety) Regulations 1991;
 - the general safety requirement under section 10(2) and 10(3) of the Consumer Protection Act 1987;
 - the general duties of manufacturers etc as regards articles and substances for use at work under section 6 of the Health and Safety at Work etc Act 1974.

Means of satisfying the essential requirements: the Regulations provide that an appliance or a fitting shall be presumed to satisfy the essential requirements if:

- it complies with a national standard which implements the relevant harmonised standard
- where there is no relevant harmonised standard, if it complies with a national standard which has been subjected to Community scrutiny under the procedure in Article 5(2) and has been notified by the Commission to the Member States as conforming to the essential requirements;

- ❑ **'harmonised standard' is** a standard adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) on a remit from the European Commission.

The national standards must relate to all matters relevant to the essential requirements.

Work is proceeding in CEN on the preparation of the required harmonised standards and it is expected that the full range of standards will become available within the next two years.

The reference numbers of the harmonised standards will be published by the European Commission in the *Official Journal of the European Communities* and, by the United Kingdom, in the journal *Business Briefing* published by the British Chambers of Commerce.

Attestation and certification: in order to demonstrate that the essential requirements are satisfied, the Regulations require the involvement of an independent third-party notified body in both the type-examination of new appliances or fittings and in the subsequent production monitoring.

A choice of options is available to the manufacturer, outlined in diagrammatic form in Annex B with fuller details of each procedure given separately in Annexes C to H.

In brief:

- ❑ for series manufactured appliances or fittings,
 - i) an EC type-examination certificate (see Annex C) by a notified body is required for the appliance or fitting, which must be representative of the production envisaged but may cover variants with similar risk characteristics; and
 - ii) a method of production monitoring, involving a notified body, is required to ensure conformity of the production with the 'type' and with the essential requirements. The manufacturer may choose from either:
 - (a) a system whereby sufficient random examinations and checks on the appliances or fittings are conducted by a notified body. Subject to satisfactory EC surveillance, the manufacturer may issue an EC declaration of conformity to type (see Annex D) and affix CE marking or, for fittings, issue a fitting certificate; or
 - (b) & (c) the provision of a system of quality assurance either for the product or for the production system, approved by a notified body. Subject to satisfactory EC surveillance of the system by the notified body, the manufacturer may issue an EC declaration of conformity (guarantee of product or production quality) - see

Annexes E & F - and affix CE marking or, for fittings, issue a fitting certificate; or

- (d) EC verification of conformity (see Annex G) by a notified body of each individual appliance or fitting, or of a statistical sample of a batch. If satisfied, the notified body will issue an EC certificate of conformity and CE marking will be affixed by the notified body or the manufacturer, as appropriate, or for fittings, a fitting certificate will be issued.

- for the production of individual appliances, or of small numbers, type-examination would not be required but each appliance would be subject to EC unit verification (see Annex H) involving detailed examinations and checks by a notified body. If satisfied, the notified body will issue an EC certificate of conformity and will affix CE marking.

Notified bodies: are independent product certification and/or quality assurance bodies designated by Member States, in the case of the United Kingdom by the Secretary of State for Trade and Industry, and notified to the European Commission.

The European Commission is to publish a list of notified bodies and their distinguishing numbers in the *Official Journal of the European Communities*: information about notified bodies is also available from the DTI contact on page 11.

Notified bodies have varied skills and qualifications, and the Regulations allow manufacturers to commission different notified bodies to undertake the different aspects of product type-examination and production monitoring, depending on their specialist capabilities. This is to enable specialists in product certification and/or quality assurance to contribute in their respective fields. Individual notified bodies may also have limitations on the range of appliances covered.

Applications for product certification or production monitoring may be made to any notified body designated by any Member State.

CE Marking and other information

Appliances which have been properly attested must bear the CE mark on the appliance (or on a data plate securely affixed to the appliance). CE marking also indicates that the appliance complies with any other relevant Directives.

CE marking shall be in a visible, easily legible and indelible form and consists of the symbol CE as shown below, followed by the last two digits of the year in which the mark was affixed and the identification symbol (the distinguishing number) of the notified body that has carried out the random checks, EC surveillance or EC verification.



The manufacturer shall affix the mark if the procedures of EC declaration of conformity to type or EC declaration of conformity to type (guarantee of product or production quality) have been used. Otherwise the notified body shall affix the mark.

The European Commission has proposed a measure on the use and protection of the CE mark. If adopted, such a measure may necessitate amendments to the provisions in the Regulations relating to CE marking.

The appliance or the data plate shall also carry the following information:

- the name, or an identifiable trade mark, of the manufacturer, if established in the Community;
- if not so established, the name of his authorised representative established in the Community;
- the trade name of the appliance;
- the type of electrical supply used, if applicable;
- the appliance category.

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

The CE mark should not be affixed to fittings: they are required to be accompanied by a fitting certificate.

Fitting certificate: this is the equivalent, for fittings, of affixing the CE mark to appliances. It is a declaration that the fitting conforms with the provisions of the Directive which apply to it. It must accompany the fitting and shall also describe:

- the characteristics of the fitting; and
- the manner in which the fitting is to be incorporated in the appliance, or assembled with other fittings, in order to comply with the essential requirements.

One certificate may relate to a number of identical fittings.

Free circulation: under the Gas Appliances Directive Member States may not impede the supply or taking into service of appliances which satisfy the relevant essential requirements of the Directive. Nor may they impede the placing on the market of fittings accompanied by the relevant fitting certificate.

Safeguard procedure: Member States are required to take all appropriate measures to remove from the market unsafe appliances bearing CE marking. They must then immediately inform the European Commission what they have done and why. The Commission will consult the parties concerned as soon as possible and, if it finds the action justified, immediately so inform all the Member States.

Enforcement: the Regulations will be enforced:

- for consumer products, by trading standards departments of local authorities in Great Britain and by district councils in Northern Ireland;
- for goods for use at work, by the Health and Safety Executive in Great Britain and by the Department of Economic Development in Northern Ireland.

Penalties: any person contravening the Regulations is guilty of an offence and is liable, on summary conviction, to imprisonment for a term not exceeding six months or a fine not exceeding level 5 on the standard scale (presently £2,000, but increasing to £5,000 with effect from 1 October 1992) or both. Where the contravention applies to injury or impairment to the health or safety of any domestic animal, or damage to any property, the maximum term of imprisonment is limited to three months.

Availability of national standards: the British Standards, and other national standards, can be obtained from BSI Sales at 389 Chiswick High Road, Chiswick, London W4 4AL (0181-996 9000).

Availability of text of the Regulations: the Gas Appliances (Safety) Regulations 1992 (S. I. 1992/711) are available from HMSO and its agents.

Availability of text of Directive: the complete text of the Gas Appliances Directive (Directive 90/396/EEC) has been published in the *Official Journal of the European Communities* (No L196 of 26.7.90, pages 15-29). Copies of this text are generally available from European Information Centres and European Documentation Centres located throughout the United Kingdom, who may provide them for a modest charge. To locate your nearest Centre, consult the DTI Business in Europe booklet *Contacts*, available through the Business in Europe Hotline on 01179 444888.

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Essential requirements

PRELIMINARY REMARK

The obligations resulting from the essential requirements for appliances in this Annex 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. For the purposes of the Regulations, an appliance is said to be 'normally used' when it is:

- 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 purpose or in a way which can be reasonably foreseen.

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 the official language or languages of the Member State of destination.

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 and to avoid the formation of dangerous unburned gas mixtures for appliances not fitted with the device referred to in 3.2.3, below;

- 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 for 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 normally used, no instability, distortion, breakage or wear likely to impair its 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 minimise 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⁽¹⁾ shall be equivalent to fulfilment of this requirement.
- 3.1.8 All pressurised parts of an appliance must withstand the mechanical and thermal stresses to which they are subjected without any deformations affecting safety occurring.
- 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.
- 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.

⁽¹⁾ Implemented in United Kingdom law as the Low Voltage Electrical Equipment (Safety) Regulations 1989.

Member States may define on their territory adequate space ventilation conditions for the installation of such appliances, bearing in mind the features peculiar to them. (The United Kingdom has not defined any space ventilation conditions of the nature mentioned).

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 are smooth;
- cross-lighting is assured.

3.4 Combustion

3.4.1 Appliances must be so constructed that, when normally used, 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 into 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.

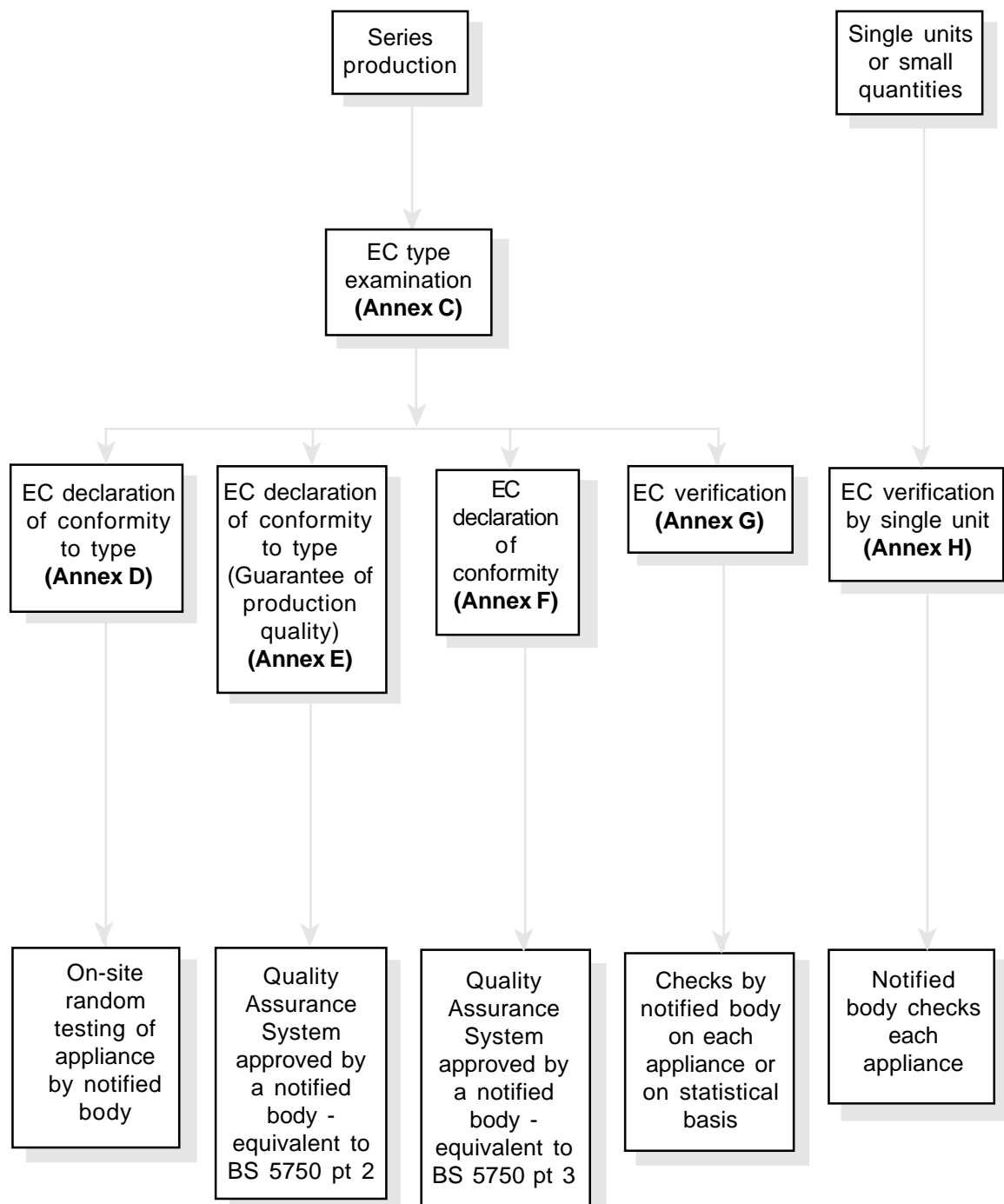
3.6 Temperatures

- 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.

Certification Routes



EC type-examination

Applications for EC type-examination are to be made by the manufacturer or his authorised representative established within the Community to a single approved body in respect of a prototype appliance. They are to include: the name and address of the manufacturer and, if used, that of the authorised representative; a written declaration that the application has not been lodged with any other notified body; and the design documentation, as set out in Annex J. The manufacturer must place at the disposal of the notified body an appliance, representative of the production envisaged, and any further samples requested by the notified body. The prototype may additionally cover variants of the product provided that those variants do not have different characteristics with respect to types of risk.

The notified body will examine the design documentation and verify that the prototype has been manufactured in conformity with it and perform, or have performed, the appropriate examinations and/or tests to check conformity with the essential requirements. If the manufacturer has chosen not to apply specified standards, the notified body is to check that the solutions adopted by the manufacturer meet the essential requirements.

If the prototype satisfies the relevant provisions, the notified body will draw up an EC type-examination certificate, notify the applicant to this effect and also inform all other notified bodies. That certificate will contain the findings of the examination, indicate any conditions attaching to its issue and incorporate the descriptions and drawings necessary for the identification of the approved appliance or fitting.

Any notified body which refuses to issue, or withdraws, an EC type-examination certificate shall give the reasons for its decision and shall give the applicant the opportunity of making representations within a reasonable time as to why it should not be refused or withdrawn. It will inform all other notified bodies of its decision.

The applicant is to ensure that the notified body that has issued the EC type-examination certificate is kept informed of all modifications to the approved prototype which might affect conformity with the essential requirements.

The applicant must obtain additional approval from the notified body, in the form of an addition to the original EC type-examination certificate, where such changes affect conformity with the essential requirements or the prescribed conditions for use of the appliance.

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

EC declaration of conformity to type

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 typeexamination certificate and with the requirements of the Regulations which apply to them. The manufacturer is to draw up and retain a written declaration of conformity, which may cover one or more appliances or fittings. CE marking is then to be affixed to each appliance and must be accompanied by the identification symbol (the distinguishing number) of the notified body chosen by the manufacturer to carry out EC surveillance.

EC surveillance comprises random on-site checks of appliances undertaken by the notified body at intervals of one year or less. An adequate number of appliances must be examined and appropriate tests must be carried out in order to ensure conformity with the corresponding requirements of the Regulations. It will be the responsibility of the notified body to 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 appropriate measures to prevent their being placed on the market.

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

EC declaration of conformity to type (Guarantee of production quality)

The manufacturer must have correctly applied a quality system for the production process that ensures conformity of the appliances with the type as described in the EC type-examination certificate and with the requirements of the Regulations which apply to them. The manufacturer must draw up and retain a written declaration of conformity, which may cover one or more appliances. CE marking must be affixed to each appliance and be accompanied by the identification symbol (the distinguishing number) of the notified body responsible for EC surveillance.

QUALITY SYSTEM

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

- 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 quality system documentation;
- the design documentation relating to the approved type and a copy of the EC type-examination certificate.

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

- the quality objectives, the organisational structure and responsibilities of management and of their powers with regard to product 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.

The notified body must examine and evaluate the quality system to determine whether it satisfies these requirements and will presume conformity in the case of quality systems that implement the corresponding European standard. It must notify its decision to the manufacturer and inform all other notified bodies. The notification to the manufacturer must contain the conclusions of the examination, the name and address of the approved body and the reasoned assessment decision in respect of the appliances concerned.

The manufacturer must keep the notified body informed of any updating of the quality system in relation to changes brought about by, for example, new technologies and quality concepts. The approved body must examine the proposed modifications and decide whether the modified quality system complies with the relevant provisions or whether re-appraisal is necessary. It must notify the manufacturer of the conclusions of the inspection and the reasoned assessment decision.

A notified body that intends to refuse or withdraw approval of a quality system must give the reasons for its decision and provide the opportunity for the applicant to make representation as to why it should not be refused or withdrawn. It must notify all other approved bodies of its decision

EC SURVEILLANCE

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

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 on the staff concerned, etc.

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

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

EC declaration of conformity (Guarantee of production quality)

The manufacturer must apply an approved quality system for the final inspection of the appliances and the specified tests and declare that the appliances concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Regulations which apply to them. The manufacturer must draw up and retain a written declaration of conformity, which may cover one or more appliances. The CE mark must then be affixed to each appliance and be accompanied by the identification symbol (the distinguishing number) of the approved body responsible for EC surveillance.

QUALITY SYSTEM

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:

- 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 quality system documentation;
- the design documentation relating to the approved type; and
- a copy of the EC type-examination certificate.

As part of the quality system, each appliance must be examined and appropriate tests, as laid down in the specified standard(s) or equivalent tests, carried out to check its conformity with the essential requirements relating to it in these Regulations.

All elements, requirements and provisions adopted by the manufacturer must be indicated in a systematically kept document setting out measures, procedures and written instructions. This quality system document must permit a uniform interpretation of programmes, manual plans and quality files and must contain, in particular, an adequate description of:

- the quality objectives, the organisational structure and responsibilities of management and of their powers with regard to product quality;

- the checks and tests to be carried out after manufacture;
- the method of verifying the effective operation of the quality system.

The notified body must evaluate the quality system to determine whether it satisfies these provisions and will presume conformity in the case of quality systems that implement the corresponding harmonised standard. It must notify the manufacturer of its decision and inform all other notified bodies of this fact. 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.

The manufacturer must keep the notified body informed of any adaptation of the quality system made necessary, eg 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 re-assessment is necessary. It must notify the manufacturer of the conclusions of the inspection and the reasoned assessment decision.

A notified body which intends to refuse or withdraw approval of a quality system must give reasons for its decision and provide the opportunity for the applicant to make representations as to why it should not be refused or withdrawn. It must notify all other notified bodies of its decision.

EC SURVEILLANCE

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

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, reports on qualifications of the staff concerned, etc.

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

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

EC verification

EC verification is the procedure whereby a notified body checks and certifies that the appliances are in conformity with the type as described in the EC type-approval certificate and satisfy the requirements of the Regulations which apply to them. At the choice of the manufacturer, it may be carried out by checking and testing each appliance, or by checking and testing the appliance on a statistical basis.

VERIFICATION BY CHECKING AND TESTING EACH APPLIANCE

Each appliance must be examined and appropriate tests as defined in the specified standards, or equivalent tests, must be carried out in order to check its conformity with the relevant requirements of the Directive. The notified body must affix its identification symbol and the CE mark on each approved appliance and draw up a written certificate of conformity. That certificate covers one or more appliances and is kept by the manufacturer.

STATISTICAL VERIFICATION

The manufacturer must submit his appliances in the form of homogeneous batches and take all necessary measures to ensure that the manufacturing process results in the homogeneity of each product batch. Where appropriate, the manufacturer may affix CE marking on each appliance during the manufacturing process. It must be accompanied by the identification symbol (the distinguishing number) of the notified body responsible for the statistical verification.

Appliances must be subject to statistical control by attributes and should therefore be grouped into identifiable batches consisting of units of a single model which are manufactured under essentially the same conditions. At random intervals a batch is examined. The appliances constituting a sample are examined individually and appropriate tests, as laid down in the specified standard(s), or equivalent tests, are carried out to determine whether the batch is to be accepted or rejected.

A sampling plan with the following operating characteristics is applied:

- a standard quality level corresponding to a 95% probability of acceptance with a percentage of non-conformity between 0.5% and 1.5%;
- a limit quality corresponding to a 5% probability of acceptance with a percentage of non-conformity between 5% and 10%.

If a batch is accepted, the notified body must draw up a written certificate of conformity which is kept by the manufacturer. All the appliances in the batch may be placed on the market, except those in the sample which have been identified as not conforming. If a batch is rejected, the competent notified

body must take the appropriate measures to prevent its being placed on the market. Should batches be rejected frequently, the notified body may suspend statistical verification.

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

EC verification by unit

EC verification by unit is the procedure whereby a notified body checks and certifies that an appliance is in conformity with the requirements of the Regulations which apply to it. The notified body must affix CE marking on the appliance and draw up a written certificate of conformity which is kept by the manufacturer.

The design documentation referred to in Annex J must be made available to the notified body.

The appliance must be examined and appropriate tests carried out, taking account of the design documentation, in order to ensure conformity of the appliance with the requirements of the Regulations. If deemed necessary by the notified body, this work may be conducted after installation of the appliance.

Correspondence shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.

Design documentation

The design documentation must contain the following information, insofar 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 specified standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the specified standards 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.

Records and correspondence relating to the means of certification of conformity shall be conducted in the official language(s) of the Member State in which these procedures are carried out or in a language accepted by the notified body.