

DECISION

No. 426, date 26.6.2003

**CONCERNING THE APPROVAL OF THE TECHNICAL REGULATIONS,
CONCERNING THE IMPLEMENTATION OF THE DIRECTIVES No.90/396/EEC AND
No.93/68/EEC OF THE EUROPEAN UNION CONCERNING THE PLACEMENT ON
THE MARKET, THE FREE CIRCULATION, AND THE CONFORMITY ASSESSMENT
OF THE APPLIANCES BURNING GASEOUS FUELS.**

In sustenance of the articles 17 of the law no 8464, dated 11.03.1999 “On Standardisation”, with the proposal of the Ministry of Industry and Energy, the Council of Ministers

HAS DECIDED:

The approval of the technical regulation, concerning the implementation of the directives no 90/396/EEC and no 93/68/EEC of the European Union related to the placement in the market, the free circulation, and the conformity assessment of the appliances burning gaseous fuels, based on the material attached to this decision.

This decision enters into power after its publication on the Official Journal.

Prime Minister
Fatos Nano

**CONFORMITY RELATION
CONCERNING THE IMPLEMENTATION OF THE DIRECTIVE 90/396/EEC
AMENDED BY THE DIRECTIVE 93/68/EEC “APPLIANCES BURNING GASEOUS
FUELS” IN THE ALBANIAN LEGISLATION (BASED ON THE APPROXIMATION
METHODOLOGY PREPARED BY THE MINISTRY OF JUSTICE).**

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**TECHNICAL REGULATIONS CONCERNING THE PLACEMENT INTO THE
MARKET; THE FREE CIRCULATION, AND THE CONFORMITY ASSESSMENT FOR
THE APPLIANCES BURNING GASEOUS FUELS.**

**CHAPTER I
THE IMPLEMENTATION AREA, THE PLACEMENT IN THE MARKET, AND THE
FREE CIRCULATION.**

Article 1

1. These regulations are applicable for:
 - Appliances used for cooking, heating, manufacturing of the hot water, refrigeration, illumination and cleaning, appliances that burn gaseous fuels and have, when necessary, a normal water temperature no higher than 105°C, which are called in continuance “Appliances”.Appliances include the burners of inflated air and the heat conductors equipped with the above-mentioned burners.
- The disposals of security, controlling, the sub-groups, different from the burners of inflated air from the buddies of the heat conductors equipped with the above-mentioned beneficiaries which are sold in a particular way to be used from the professionals and designated to be included in a gas appliance or assembled for constructing a gas appliance, called in continuance “Disposal”.
2. The appliances designated to be used only in industrial processes of the industrial firms are excluded from the implementation area established in paragraph 1.
3. In the meaning of these technical regulations, with “gas combustibles” is understood every combustible that in the temperature 15° C and the pressure 1 bar is in the gas state.
4. In the meaning of these technical regulations, one appliance is considered “normally used” when:
 - has been installed correct and has been undergone to the regular maintenance in accordance with the manufacturer’s instructions;
 - has been used in the normal area of changing the characteristics of gas and food pressure;
 - has been used as intended or in a foreseeable way.

Article 2

1. It is allowed the placement into the market and the operation of the appliances with gas combustibles only if, when used normally, do not jeopardize the safety of people, domestic animals or materials values.
2. The General Directorate of Hydrocarbons inform the interested distributors of the appliances with gas combustibles, about the types of gases used in the Albanian Territory and respective food pressures. In addition informs them regarding any changes in any time.

Article 3

The appliances and the disposals mentioned in Article 1 shall fulfill the principal requirements applicable for them and presented in annex 1.

Article 4

1. It cannot be limited or prohibited the placement into the market and the operation of the appliances, which are in accordance with all the dispositions of this decision, including also the conformity assessment procedures formulated in chapter II and affixing of the CE marking foreseen in article 10.

2. It cannot be limited or prohibited the placement into the market of the disposals mentioned in article 1, supplied with a certificate based on paragraph 4 of article 8.

Article 5

1. It is presumed in accordance with the principal requirements of article 3 that the appliances and the disposals that are in accordance with:

- a) the respective Albanian standards and that adopt the international standards ISO and the harmonized European standards. The General Directorate of Standardization publishes the references to these standards.
- b) With the respective Albanian standards, when I the sector covered by these standards do not exist the harmonized standards.

Article 6

In the cases when the appliances normally operated may jeopardize the safety of people, domestic animals, or the material values, the Ministry of Industry and Energetic undertakes the necessary measures for the withdraw of these appliances from the market or for prohibiting or limiting their replacement into the market.

CHAPTER II THE CONFORMITY ASSESSMENT PROCEDURES.

Article 7

1. The conformity assessment procedures for the appliances manufactured in series include the following:

- a) Examination of the type foreseen in annex II point 1:
- b) Before the placement into the market, based on the manufacturer's choice;
 - declaration of conformity with the type, foreseen in annex II point 2;
 - declaration of conformity with the type (guarantee of the manufacturing quality) foreseen in annex II point 3;
 - declaration of conformity with the type (guarantee of the manufacturing quality) foreseen in annex II point 4;
 - verification foreseen in annex II point 5.
- c) The conformity assessment procedures in annex II shall be implemented in order to guarantee the fulfillment of the principal requirements of article 3 and to enable the entrance of the suppliers of the appliances locally manufactured or with origin from the territory of the member states of OBT. The entrance means the rights of the suppliers for the conformity assessment including the possibility for performing the activity of the conformity assessment to the manufacturer as well as the possibility of receiving the conformity marking.

2. In the cases of appliances manufactured as a single exemplar or in small quantities, the manufacturer may perform the verification of the single exemplar foreseen in the annex II point 6.

3. After the termination of the procedures in paragraph 1 letter (b) and paragraph 2, related to the adequate appliances manufactured from the member states of the European Union or from manufacturers that have stabilized representatives in the community, shall be affixed the CE marking based on the regulations established in article 9.

4. For the disposals foreseen in article 1 shall be implemented the procedures of paragraph 1, excluding the affixing the CE marking and according to the situation, the compilation of the conformity declaration. It shall be released a certificate that declares the conformity of the

5. For the disposals foreseen in article 1 shall be implemented the procedures of paragraph 1, excluding the affixing the CE marking and according to the situation, the compilation of the conformity declaration. It shall be released a certificate that declares the conformity of the

disposals with the respective requirements and establishes the characteristics of the disposals. This certificate demonstrates also the conditions for the inclusion in the appliances and the assembling, which contribute in fulfilling the principal requirements to be applied in the finished appliances. The certificate shall be given together with the disposal.

5.a) Where the appliances are subject to other directives covering other aspects and which also provide for the affixing of the CE marking, the latter shall indicate that the appliances in question are also presumed to conform to the requirements of those other directives.

b) However, where one or more of these directives allow the manufactures, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate the conformity only with the dispositions of the directives applied by the manufacturer. In this case, the particulars of the directives applied as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the Directives and accompanying such appliances.

6. The files and the correspondence related to the means of conformity certification shall be formulated in the language of the country where it has been established the organization charged with the implementation of these procedures or in a language accepted by this organism.

Article 8

1. The Ministry of Industry and Energetic shall approve the organisms that perform the conformity assessment. When the notified organisms of the member states of the European Union are in charge of the procedures referred to in the article 7, the list of these organisms and their identification numbers are published from the commission in the Official Journal of the European Union.

2. For evaluating the organisms to be approved, there shall be applied the criteria established in annex V. The organisms that fulfill the criteria established in the harmonized standards are presumed to fulfill the criteria established in annex V.

3. When the approved organisms do not longer fulfill the criteria of paragraph 2, the approval shall be revoked.

CHAPTER III CONFORMITY MARKING CE.

Article 9

1. The conformity marking CE, as well as the file of the characteristics shown in annex III shall be affixed in a visible way in order to be easily legible and in an indelible form on the appliances or on an identification label affixed to the appliances. The identification label shall be formulated in a way that it cannot be reused.

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. Any other marking may be affixed to the appliances or the identification label provided that the visibility and legibility of the EC marking is not thereby reduced.

Article 10

Without prejudice to Article 6:

- Where competent organism establishes that the CE marking has been affixed unduly, the manufacturer or his authorized representative established within the EU shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the competent organism;

- Where non-conformity continues, the competent organism must take all appropriate measures to restrict or prohibit the placing on the market of the appliances in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in Article 6.

CHAPTER IV LAST DISPOSITION.

Article 11

Any decision taken pursuant to this decision, which involves restrictions on the placing of on the market or operation of the appliances, shall state the exact motivations on which it is based. It shall be notified with the extreme attention to the party concerned, who shall at the same time be informed of the legal measures available to him under the laws in force and of the time limits applying to the filing of the complaints.

Article 12

The custom declaration and the custom clearance of the appliances of gas combustibles in article 1 shall be performed after the verification of the documentation foreseen in point 1.2 of annex I confirmed from the control organisms, approved in accordance with the requirements of Article 8, as well as the origin conformity certificate.

ANNEX I
PRINCIPAL REQUIREMENTS.
Preliminary remarks.

The obligations derived from the requirements presented in this annex concerning the appliances shall be implemented also for the disposals when a respective risk exists.

1. General conditions.

1.1 Every appliance shall be designed and manufactured in safe conditions and shall no present risks for people, domestic animals and material values, when are normally used based on the definitions of article 1, paragraph 4 of this decision.

1.2 The appliances placed into the market shall:

- be equipped with the technical instructions formulated for the installer;
- be equipped with the instructions concerning the usage and the maintenance prepared for the manufacturer;
- contain itself as well as its packaging the eventual warnings; the instructions and the warnings shall be formulated in the Albanian language.

1.2.1 The technical instruction formulated for the installer shall contain all the instructions concerning the installations, the adjustment and maintenance, enabling in this way the correct performance of these tasks and the safe usage of the appliances. The instructions shall specify in a particular way:

- the type of gas used;
- the pressure used for the alimentation;
- the ventilated required for the premises;
- the alimentation with air for the combustion;
- for preventing the creating of the mixtures with dangerous content of unburned gas in the appliances, which do not have the disposal of the point 3.2.3 of this annex;
- the elimination conditions for the combustor products;
- for burners with inflated air and conductors of the heat exchange designated to be furnished with the above-mentioned combustibles, their characteristics, and the assemblage conditions which contribute in respecting the principal requirements for the finished appliances and, if necessary, the list of the combinations recommended by the manufacturer.

1.2.2 The usage and maintenance instructions, formulated for the user, shall contain all the necessary information for a safe usage and shall also attract the user's attention concerning the restriction in the usage area.

1.2.3 The warnings showed on the appliances and on the packaging shall denote in a clear way the type of gas, the alimentation pressure and the eventual restrictions concerning the usage, especially the restriction based on which the appliances shall be installed only in properly ventilated premises.

1.3 Every disposal designated to be used in appliances shall be designed and manufactured in order to function properly for the designated usage, if assembled in accordance with the technical instructions related to the installation.

The instructions concerning the installation, arrangements, functioning and maintenance shall be supplied together with the disposal.

2. The materials.

2.1 The materials shall be appropriate for the designated usage and shall resist to the mechanical, chemical and thermal strains foreseen to be undergo.

2.2 The material characteristics important to the safety shall be guaranteed by the manufacturer or the supplier of the appliances.

3. Design and manufacturing.

3.1 General Aspects.

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

3.1.2 The condensation produced at the start-up and/or during usage shall not affect the safety of appliances.

3.1.3 Every appliance must be designed and constructed in order to minimize the risk of explosion in the event of a fire of external origin.

3.1.4 The appliances must be constructed in order 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 represent a source of risk.

3.1.7 Every appliance must be designed and constructed in order to as to prevent hazards of electrical origin. In the area in which it applies, it is presumed the compliance with the safety objectives in respect of electrical hazards laid down in Directive 73/23/EEC shall be equivalent to fulfillment of this requirement.

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

3.1.9 Every appliance must be designed and constructed in order 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 the functioning of the controlling devices.

3.1.11 All parts of appliances which are assembled 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 The levers and other controlling and setting devices must be clearly marked and give appropriate instructions in order to prevent any error in handling. Their design must be such as to prevent accidental manipulation.

3.2 Unburned gas release.

3.2.1 Every appliance must be constructed in order that the gas leakage rate is not dangerous.

3.2.2 Every appliance must be constructed in order 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 appliances.

3.2.3 Appliances intended to be used in indoor spaces and rooms must be equipped 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.

The Ministry of Industry and Energy, keeping in mind the characteristics of these appliances, may define on their territory adequate space ventilation conditions for the installation of such appliances.

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

3.3 Ignition.

Every appliance must be so constructed that, when used normally:

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

3.4 Combustion.

3.4.1 Every appliance 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 Every appliance must be so constructed that, when used normally, there will be no accidental release of combustion products.

3.4.3 Every appliance 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 respective room.

3.4.4 Independent flueless domestic heating appliances and flueless instantaneous water heaters must not cause, in the respective room or space, 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.

Every appliance must be constructed in order 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 such temperatures, which present a danger in the surrounding area.

3.6.2 The surface temperature of knobs and regulation levers of appliances intended to be manipulated must not reach such levels, which 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, under operating conditions, must not pass such temperatures that 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 respective legislative dispositions 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.

ANNEX II

PROCEDURES FOR THE CERTIFICATION OF CONFORMITY.

1. Type examination.

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

1.2 The application for type-examination must be presented by the manufacturer or his authorized representative established within the community to an approved or notified body within the community.

1.2.1 The application must include:

- the name and the 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 documentation related to the project, as described in Annex IV.

1.2.2 The manufacturer must place at the disposal of the notified body an appliance, representative of the manufacturing foreseen, hereinafter called 'type'. The controlling organism may request further samples of the type if needed for the test program.

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

1.3 The approved and the notified body.

1.3.1 The approved and the notified body examines the documentation relating to the project and verify that the type has been manufactured in conformity with the project documentation and identify the elements which have been designed in accordance with the applicable provisions of the standards referred to in article 5 and the essential requirements foreseen in this decision.

1.3.2 The approved and the notified body performs, or has 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 have not been applied.

1.3.3 The approved and the notified body performs, or has 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 If the type satisfies the provisions of this decision, the controlling organism must issue a type-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the eventual conditions for its validity and the necessary data for identification of the approved type and, if necessary, the description 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 regarding the issuing of the type-examination certificate and any additional certificates as referred to in point 17. These other notified bodies may obtain a copy of the type-examination certificate and/or the additional certificates, and on a reasoned request, may obtain a copy of the Annexes to the certificate and the reports of the examinations and tests carried out.

1.6. A notified body, which refuses to issue or withdraws a type-examination certificate must inform the EU Member State which notified the respective organism 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 type-examination certificate

informed of all modifications to the approved type, which might affect conformity with the essential requirements.

The modifications to the approved type must receive additional approval from the notified body that issued the type-examination certificate where such changes affect the conformity with the essential requirements or the prescribed conditions for usage of the appliances. This additional approval takes the form of an annex of the original type-examination certificate.

2. Declaration of conformity to type.

2.1 The declaration of conformity to type is that part of the procedure whereby the manufacturer declares that the respective appliances are in conformity with the type as described in the type-examination certificate and satisfy the essential applicable requirements of this decision, which apply to them. The manufacturer or its representative, stabilized in the community, must affix the “CE” mark on every appliance and compile a written declaration of conformity. The declaration of conformity refers to one or more appliances and must be kept by the manufacturer. The CE mark must be accompanied by the identification number of the notified body responsible for the random controls foreseen in point 2.3.

2.2 The manufacturer must take all necessary measures to ensure that the manufacturing process, including the final product inspection and testing, guarantees the homogeneity of the manufacturing and the conformity of the appliances with the type as described in the type-examination certificate and comply the respective essential requirements propounded in this regulation which apply to them. An approved organism or a notified body, chosen by the manufacturer, must carry out random unannounced controls on the appliances as established in point 2.3.

2.3 At intervals of one year or less, random unannounced on-site checks of appliances must be undertaken by the approved organism or by the notified body. An adequate number of appliances must be examined and appropriate tests as set out in the applicable standards referred to in article 5 or equivalent tests must be carried out in order to ensure conformity with the respective corresponding essential requirements as established by this decision. The approved organism or the notified body shall in each case determine whether these tests need to be carried out in full or in part. If one or more appliances are rejected, the notified body shall take the appropriate measures to prevent the marketing thereof.

3. Declaration of conformity to type (guarantee of manufacturing quality).

3.1 The declaration of conformity to type (guarantee of manufacturing quality) is the procedure whereby a manufacturer who fulfils the obligations in point 3.2 declares that the respective appliances concerned are in conformity with the type as described in the type-examination certificate and satisfy the essential requirements of this decision which applies to them. The manufacturer or its authorized representative must affix the “CE” marking to every appliance designated for the European market and compiles 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 accompanied by the identification number of the notified body responsible for surveillance.

3.2 The manufacturer shall apply a quality system that ensures conformity of the appliances with the type as described in the type-examination certificate and with the essential requirements propounded in this decision, which apply to them. The manufacturer is subject to surveillance in compliance with the specification of 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 or to an approved organism of his choice for the appliances in question.

The application must include:

- the technical documentation related to the quality system,
- an undertaking to carry out the obligations arising from the quality system as approved,
- an undertaking to maintain the approved quality system unchanged in order to ensure its continuing suitability and effectiveness,
- the documentation relating to the approved type and a copy of the 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 programs, plans, manuals and records related to quality. 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 the appliances quality,
- the manufacturing processes, quality control and quality assurance technologies and systematic interventions that will be undertaken,
- 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 measures for monitoring the achievement of the required quality of the appliances 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 standards.

It must notify its decision to the manufacturer and, when the organism is notified, it must 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 respective appliances.

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 new quality concepts.

The notified body must examine the proposed modifications and decide whether the modified quality system complies with the relevant provisions or whether a 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 inform the other notified bodies about it, giving the reasons for the decision.

3.4 Surveillance.

3.4.1 The purpose of surveillance is to ensure that the manufacturer fulfils accurately 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 documentation related to the quality system,

- the records performed in the quality field, such as inspection reports and test data, calibration data, reports on qualifications of the respective staff 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 to the manufacturer a report of the control performed.

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 necessary, a test report.

3.4.5 The manufacturer keeps in disposition the organisms report in order to present it when it is requested by the state organisms.

4. Declaration of type conformity (Guarantee of product quality).

4.1 The 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 respective appliances are in conformity with the type as described in the type-examination certificate and satisfy the essential requirements propounded in this regulation which apply to them. The manufacturer must affix the CE marking to every appliance and draw up a written declaration of conformity. This declaration of conformity may cover one or more appliances and must be kept by the manufacturer. The CE marking must be accompanied by the identification number of the notified body responsible for CE 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 surveillance as specified in point 4.4.

4.3 The quality system.

4.3.1 Under this procedure, the manufacturer must present 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 documentation related to the quality system,
- an undertaking to carry out the obligations arising from the approved quality system,
- an undertaking to maintain unchanged the approved quality system to ensure its continuing suitability and effectiveness,
- the documentation relating to the approved type and a copy of the type-examination certificate.

4.3.2 As part of the quality system, every appliance must be examined and must undergo through appropriate tests as laid down in the applicable standards referred to in article 5 or equivalent tests carried out to check its conformity with the essential requirements relating to it in this regulation.

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 programs, plans, manuals and records relating to quality.

The documentation related to the quality system 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 the appliances quality,
- the checks and tests to be carried out after manufacture,
- the method of verifying the effective functioning of the quality system.

4.3.3 The notified body shall examine and evaluate the quality system in order 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 about 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 or of the approved organism as well as the reasoned assessment decision concerning the respective appliances.

4.3.4 The manufacturer must keep the notified body which approved the quality system informed about any adaptation of the quality system made necessary, e.g. by new technologies and by new 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 about its decision. The notification must contain the conclusions of the inspection and the reasoned assessment decision.

4.3.5 A notified body, which withdraws the approval of a quality system, must inform the other notified bodies about its action and give respective reasons for its decision.

4.4 The surveillance.

4.4.1 The purpose of the surveillance is to ensure that the manufacturer accurately 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 documentation related to the quality system,
- the quality registrations such as inspection reports and test data, calibration data, report on qualifications of the concerning staff, etc.

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

4.4.4 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 necessary, a test report.

4.4.5 The manufacturer must keep in disposition the notified body's report so that he/she may present it when is requested by the state organisms.

5. The Verification.

5.1. The verification is that part of the procedure through which the manufacturer or its authorized representative stabilized in the community makes sure and declares that the appliances that fulfill the dispositions of point 3, are in accordance with the type described in type-examination certificate and satisfy the requirements of this law which apply to them.

5.2 The manufacturer or its authorized representative stabilized in the community must undertake all the necessary measures so that the manufacturing process ensures the conformity with the type described in type-examination certificate and with requirements of this decision that apply to them.

The manufacturer or its authorized representative stabilized in the community must affix the "CE" marking in every appliance designated for the community market and must draw out a conformity declaration. The conformity declaration may cover one or more appliances and it must be kept by the manufacturer or by its authorized representative established in the community.

5.3 The approved organism or the notified body must carry out the necessary examinations and tests in order to check the conformity of the appliances with the requirements of this decision by examining and testing every appliance as specified in point 5.4 or by examining and testing every appliance on statistical bases, as specified in point 5.5, based on the manufacture's choice.

5.4 The verification by checking and testing every appliance.

5.4.1 Every appliance, one by one, must be examined and appropriately tested as defined in the relevant standards referred to in article 5 or equivalent tests must be carried out in order to check its conformity with the type described by the type-examination certificate and with relevant essential requirements of this decision that apply to them.

5.4.2 The notified body must affix or must have affixed the CE marking on every approved appliance and draw up a written certificate of conformity relating to the tests performed. The certificate may cover one or more appliances.

5.4.3 The manufacturer or its authorized representative must ensure that are able to present, on request, the conformity certificate of the notified organism.

5.5 The statistical verification.

5.5.1 The manufacturer must submit his manufactured appliances in the form of homogeneous batches and take all necessary measures to ensure that the manufacturing process results in the homogeneity of each batch manufactured.

5.5.2 The statistical control must be performed as follows:

The appliances must be subject to statistical control by attributes. They should be grouped into identifiable batches consisting of units of a single model, which are manufactured under the same conditions. The batch must be examined at random intervals. The appliances constituting a sample are examined individually and appropriate tests as laid down in the applicable standards referred to in article 5 or equivalent tests are carried out in order to determine whether the batch should be accepted or rejected.

A sampling plan with the following operating characteristics is applied:

- a standard quality level corresponding to a 95 percent probability of acceptance with a percentage of non-conformity between 0,5 and 1,5 percent,
- a limit quality corresponding to a 95 percent probability of acceptance with a percentage of non-conformity between 5 and 10 percent.

5.5.3 If a batch is accepted, the notified body must affix or have affixed its identification number and draw up a written certificate of conformity related to the tests performed. All the appliances of 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. If the batches are frequently rejected, the notified body may suspend the statistical verification.

The manufacturer, under the responsibility of the notified body, may affix the identification number of this notified body during the manufacturing process.

5.5.4 The manufacturer or its authorized representative must ensure that he/she is able to present the conformity certificate of the notified body on request.

6. The verification of a single product.

6.1 The verification of a single product is that procedure through which the manufacturer or its authorized representative stabilized in the community makes sure and declares that the appliances supplied with certificate as referred to in point 2, is conform the requirements of this decision that

apply to it. The manufacturer or its authorized representative draws up a written certificate of conformity, which he/she must keep and must affix the “CE” marking on the appliances designated for the community market.

6.2 The approved organism or the notified body must examine the appliances and must carry out appropriate tests, by taking account of the design documentation carried out in order to ensure the conformity of the appliances with the essential requirements of this decision.

The approved organism or the notified body must affix or must have affixed the identification number of the body on the approved appliances and must draw up a written conformity certificate related to the tests performed.

6.3 The purpose of the technical documentation, related to the project of supplying the appliances referred to in annex IV, is to ensure the assessment of conformity with the requirements of this decision and that the project, the manufacturing and the functioning of the appliances be clear. The documentation related to the project, as referred to in annex IV must be made available for the organization.

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

6.5 The manufacturer or its authorized representative must ensure that are able to present on request the conformity certificate of the approved organism or of the notified body.

ANNEX III

THE CONFORMITY “CE” MARKING AND THE INSCRIPTIONS.

1. The conformity “CE” marking consists of the symbol CE as shown below:

The CE marking must be followed by the identification number of the notified organism that has been engaged during the phase of the manufacturing control.

2. The appliances or their data plate must bear the EC marking together with the following inscriptions:

- the manufacturer's name or identification symbol,
- the trade name of the appliances,
- the type of electrical supply used, if applicable,
- the appliances category,
- the two last digits of the year in which the “CE” marking was affixed.

Additional information about the installation may be provided in accordance with the nature of the appliances.

3. In the “CE” decreases or increase, it must respect the dimensions of the scaled design given above. The various components of the “CE” marking should generally have the same vertical dimension, which cannot be smaller than 5 mm.

ANNEX IV
THE DOCUMENTATION RELATED TO THE PROJECT.

The documentation related to the project must contain the following information, if these are necessary for the approved organism or the notified body:

- a general description of the appliances,
- the general project, conceptual designs and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding the above designs and schemes, including the instructions related to the function of the appliances,
- a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements in the cases when the standards referred to in Article 5 have not been applied,
- reports related to the performed tests,
- manuals for installation and use.

Where necessary, the documentation related to the project must contain the following elements:

- attestations relating to the equipments incorporated in the appliances,
- attestations and certificates relating to the methods of manufacture and/or inspection and/or monitoring of the appliances,
- any other document making it possible for the notified body to improve its assessment.

ANNEX V
MINIMUM CRITERIA FOR ASSESSMENT OF NOTIFIED BODIES.

The approved organisms designated by the Ministry of Industry and Energy and the notified bodies designated by the EU Member States must fulfill the following minimum conditions:

- availability of personnel and of the necessary means and appliances,
- technical competence and professional integrity of personnel,
- independence in carrying out tests, preparing reports, issuing certificates and performing the surveillance provided for in this Directive, 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.

Fulfillment of the conditions in the first two indents must be periodically verified by the Ministry of Industry and Energetic with organisms determined with laws and by-laws.