ANNEX II

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 this Directive which apply to it.

1.2. The application for type-examination must be lodged by the manufacturer or his authorised representative established within the Community 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 authorised 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.

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 and the essential requirements of this Directive;

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 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 this Directive, 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 this Directive which apply to them. The manufacturer or his authorised representative established within the Community shall affix the CE marking on 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. 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 this Directive 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 or equivalent tests must be carried out in order to ensure conformity with the corresponding essential requirements of this Directive. 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 this Directive which applies to them. The manufacturer or his authorised representative established within the Community 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.

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 this Directive 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 organisational 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 harmonised 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.

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 this Directive which apply to them. The manufacturer or his authorised representative established within the Community 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 or equivalent tests

carried out to check its conformity with the essential requirements relating to it in this Directive.

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 organisational 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 harmonised 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.

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 authorised representative established within the Community 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 this Directive that apply to them.

5.2. The manufacturer or his authorised representative established within the Community 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 this Directive that apply to them. The manufacturer or his authorised representative established within the Community 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 authorised representative established within the Community.

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 this Directive 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, 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 this Directive 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 authorised 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, 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 authorised 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 authorised representative established within the Community ensures and declares that the appliance concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised 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 this Directive.

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, is to enable conformity to the requirements of this Directive to be assessed and the design, manufacture and operation of the appliance to be understood.

The design documentation referred to in Annex IV 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 authorised representative must ensure that he is able to supply the notified body's certificates of conformity on request.