ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

1. EC type-examination

1.1. EC type-examination is the procedure whereby a notified body verifies and certifies that an instrument, representative of the production envisaged, meets the requirements of this Directive.

1.2. The application for EC type-examination shall be lodged with a single notified body by the manufacturer or his authorised representative established within the Community.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition,

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

— the design documentation, as described in Annex III.

The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged, hereinafter the 'type'.

1.3. The notified body shall:

1.3.1. examine the design documentation and verify that the type has been manufactured in accordance with that documentation;

1.3.2. agree with the applicant on the location where the examinations and/or tests shall be carried out;

1.3.3. 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 harmonised standards referred to in Article 6(1) have not been applied;

1.3.4. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these standards have been applied effectively, thereby assuring conformity with the essential requirements.

1.4. Where the type complies with the provisions of this Directive, the notified body shall issue an EC type-approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. All the relevant technical elements such as drawings and layouts shall be annexed to the EC type-approval certificate.

The certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of the certificate may be limited to two years and extended by three years.

1.5. Each notified body shall periodically make available to all Member States the list of:

— applications received for EC type-examination,

— EC type-approval certificates issued,

— applications for type-certificates refused,
— additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the Member States forthwith of withdrawals of EC type-approval certificates.

Each Member State shall make this information available to the bodies which it has notified.

1.6. The other notified bodies may receive a copy of the certificates together with the annexes to them.

1.7. The applicant shall keep the notified body that has issued the EC type-approval certificate informed of any modification to the approved type.

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

2. EC declaration of type conformity (guarantee of production quality)

2.1. The EC declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer who satisfies the obligations of point 2.2 declares that the instruments concerned are, where applicable, in conformity with the type as described in the EC type-approval certificate and that they satisfy the requirements of this Directive.

The manufacturer or his authorised representative established within the Community shall affix the ‘CE’ conformity marking to each instrument and the inscriptions provided for in Annex IV and shall draw up a written declaration of conformity.

The ‘CE’ conformity marking shall be accompanied by the identification number of the notified body responsible for the EC surveillance referred to in point 2.4.

2.2. The manufacturer shall have adequately implemented a quality system as specified in point 2.3 and shall be subject to EC surveillance as specified in point 2.4.

2.3. Quality system

2.3.1. The manufacturer shall lodge an application for approval of his quality system with a notified body.

The application shall include:
— an undertaking to carry out the obligations arising from the approved quality system,
— an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

The manufacturer shall make available to the notified body all relevant information, in particular the quality system’s documentation and the design documentation of the instrument.

2.3.2. The quality system shall ensure conformity of the instruments with the type as described in the EC type-approval certificate and with the requirement(s) of this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written rules, procedures and instructions. This

quality system documentation shall ensure a proper understanding of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

— the manufacturing process, the quality control and assurance techniques and the systematic measures 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 means to monitor the achievement of the required product quality and the effective operation of the quality system.

2.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonised standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and, in the event of refusal, the justification for the decision.

2.3.4. The manufacturer or his authorised representative shall keep the notified body that has approved the quality system informed of any updating of the quality assurance system in relation to changes brought about by, e.g. new technologies and new quality concepts.

2.3.5. Any notified body that withdraws approval of a quality system shall so inform the other notified bodies.

2.4. EC surveillance

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

2.4.2. The manufacturer shall grant the notified body access for inspection purposes to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the design documentation,

— the quality records, e.g. the inspection reports and tests and calibration data, reports on the qualifications of the personnel concerned, etc.

The notified body shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report.

In addition, the notified body may carry out unscheduled visits to the manufacturer. During such visits, the notified body may carry out full or partial audits. It shall provide the manufacturer with a report on the visit, and, where appropriate, an audit report.

2.4.3. The notified body shall ensure that the manufacturer maintains and applies the approved quality system.

3. EC verification

3.1. EC verification is the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the instruments which have been checked in accordance with point 3.3 are, where applicable, in conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of this Directive.

3.2. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments, where applicable, with the type as described in the EC type-examination certificate and with the requirements of this Directive which apply to them. The manufacturer or his authorised representative established within the Community shall affix the 'CE' conformity marking to each instrument and draw up a written declaration of conformity.

3.3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of this Directive by examination and testing of every instrument, as specified in point 3.5.

3.4. For instruments not subject to EC type-approval, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body should the latter so request.

3.5. Verification by checking and testing of each instrument

3.5.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant harmonised standards referred to in Article 6(1), or equivalent tests, shall be carried out in order to verify their conformity, where applicable, with the type as described in the EC type-examination certificate and the requirements of this Directive.

3.5.2. The notified body shall affix, or cause to be affixed, its identification number on each instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity relating to the tests carried out.

3.5.3. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

4. EC unit verification

4.1. EC unit verification is the procedure whereby the manufacturer or his authorised representative established within the Community ensures and declares that the instrument, generally designed for a specific application, which has been issued with the certificate referred to in point 4.2 conforms to the requirements of this Directive that apply to it. The manufacturer or his authorised representative shall affix the 'CE' conformity marking to the instrument and shall draw up a written declaration of conformity.

4.2. The notified body shall examine the instrument and carry out the appropriate tests, as set out in the relevant harmonised standard(s) referred to in Article 6(1), or equivalent tests, in order to ensure its conformity with the relevant requirements of this Directive.

The notified body shall affix, or cause to be affixed, its identification number to the instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity concerning the tests carried out.

4.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex III, is to enable conformity with the requirements of this Directive

to be assessed and the design, manufacture and operation of the instrument to be understood. It must be accessible to the notified body.

4.4. The manufacturer or his authorised representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

5. Common provisions

5.1. The EC declaration of type conformity (guarantee of production quality), the EC verification, and the EC unit verification may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, they shall be carried out at the place of use of the instrument.

5.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 5.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

5.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 5.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

5.2.2. The party which has carried out the first stage of the procedure shall issue for each of the instruments a certificate containing the data necessary for identification of the instrument and specifying the examinations and tests that have been carried out.

The party which carries out the second stage of the procedure shall carry out those examinations and tests that have not yet been carried out.

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

5.2.3. A manufacturer who has opted for the EC declaration of type conformity (guarantee of production quality) in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with EC verification.

5.2.4. The 'CE' conformity marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.