ANNEX II

MODULE A:INTERNAL PRODUCTION CONTROL

1. ‘Internal production control’ is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument’s conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

4. **Conformity marking and EU declaration of conformity**

4.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual measuring instrument that satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for an instrument model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the measuring instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

5. **Authorised representative**

The manufacturer’s obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

1. Internal production control plus supervised instrument checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility

that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured instruments with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

4. **Instrument checks**

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the instrument, taking into account, inter alia, the technological complexity of the instruments and the quantity of production. An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard, and/or normative document, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Directive. In the absence of a relevant harmonised standard or normative document, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.

In those cases where a relevant number of instruments in the sample do not conform to an acceptable quality level, the accredited in-house body or notified body shall take appropriate measures.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. **Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual instrument that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for an instrument model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a

batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. **Authorised representative**

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility provided that they are specified in the mandate.

MODULE B: EU- TYPE EXAMINATION

1. 'EU-type examination' is the part of a conformity assessment procedure in which a notified body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of this Directive that apply to it.

2. EU-type examination may be carried out in either of the following manners:

(a) examination of a specimen, representative of the production envisaged, of the complete measuring instrument (production type),

(b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);

(c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

The notified body decides on the appropriate manner and the specimens required.

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation as described in Article 18. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The application shall in addition contain, wherever applicable:

(d) the specimens, representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the instrument:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and normative documents, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;

4.5. agree with the manufacturer on the location where the examinations and tests will be carried out.

For the other parts of the measuring instrument:

4.6. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the measuring instrument.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis, the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of this Directive, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined type to be evaluated and to allow for in-service control. In particular, to allow the conformity of

manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:

— the metrological characteristics of the type of instrument;

— measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

— information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;

— if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;

— in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

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

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

8. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of this Directive or the conditions for validity of that certificate Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.

10. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

11. The manufacturer’s authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 8 and 10, provided that they are specified in the mandate.

MODULE C: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Conformity marking and EU declaration of conformity**

3.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

3.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it was drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

4. **Authorised representative**

The manufacturer’s obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS

1. Conformity to type based on internal production control plus supervised instrument checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the type

described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Instrument checks**

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the instrument, taking into account, inter alia, the technological complexity of the measuring instruments and the quantity of production. An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the harmonised standards, and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instrument with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.

Where a sample does not conform to an acceptable quality level, the accredited in-house body or notified body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the instrument performs within acceptable limits, with a view to ensuring conformity of the instrument.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. **Conformity marking and EU declaration of conformity**

4.1. The manufacturer shall affix the CE marking, and the supplementary metrology marking set out in this Directive to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

4.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) a written declaration that the same application has not been lodged with any other notified body,

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure that the measuring instruments are in conformity with the type described in the EU-type examination certificate and comply with the requirements of this Directive that apply to them.

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

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point (e) of point 3.1, to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

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

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual measuring instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports from the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

4. **Manufacturing**

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the measuring instruments concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. **Quality system**

5.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

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

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during, and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument

technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. **Surveillance under the responsibility of the notified body**

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

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation referred to in point 2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. **Conformity marking and EU declaration of conformity**

7.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.

7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 5.1;

(b) the information relating to the change referred to in point 5.5, as approved;

(c) the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE E: CONFORMITY TO TYPE BASED ON INSTRUMENT QUALITY ASSURANCE

1. Conformity to type based on instrument quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring instruments concerned as specified in point 3 and shall be subject to surveillance, as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure compliance of the measuring instruments with the type described in the EU-type examination certificate and with the applicable requirements 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 policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(d) the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point (e) of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

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

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 3.1;

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING

1. Quality assurance of final instrument inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

4. **Manufacturing**

The manufacturer shall operate an approved quality system for final product inspection and testing of the measuring instruments concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. **Quality system**

5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) all relevant information for the instrument category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(d) the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer's premises.

The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. **Surveillance under the responsibility of the notified body**

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

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the technical documentation referred to in point 2;

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. **Conformity marking and EU declaration of conformity**

7.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.

7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

8. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation referred to in point 5.1,

(b) the information relating to the change referred to in point 5.5, as approved;

(c) the decisions and reports from the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

10. **Authorised representative**

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Verification**

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the instruments with the type as described in the EU-type examination certificate and the appropriate requirements of this Directive.

The examinations and tests to verify the conformity of the measuring instruments with the appropriate requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 4, or by examination and testing of the measuring instruments on a statistical basis as specified in point 5.

4. **Verification of conformity by examination and testing of every instrument**

4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the instrument has been placed on the market.

5. **Statistical verification of conformity**

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this

Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

5.4. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for those measuring instruments from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. **Conformity marking and EU declaration of conformity**

6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual instrument that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

If y the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the measuring instruments.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the measuring instruments during the manufacturing process.

8. **Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

MODULE F1: CONFORMITY BASED ON PRODUCT VERIFICATION

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 6.1 and 7 and ensures and declares on his sole responsibility that the measuring instruments concerned which have been subject to the provisions of point 4, are in conformity with the requirements of this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured measuring instruments with the applicable requirements of this Directive.

4. **Verification**

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to verify the conformity of the measuring instruments with the applicable requirements of this Directive.

The examinations and tests to verify the conformity with the requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 5, or by examination and testing of the measuring instruments on a statistical basis as specified in point 6.

5. **Verification of conformity by examination and testing of every instrument**

5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the relevant harmonized standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

6. **Statistical verification of conformity**

6.1. The manufacturer shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced, and shall present his measuring instruments for verification in the form of homogeneous lots.

6.2. A random sample shall be taken from each lot according to the requirements of point 6.4.

6.3. All measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

6.4. The statistical procedure shall meet the following requirements:

The statistical control will be based on attributes. The sampling system shall ensure:

(a) a level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity of less than 1 %;

(b) a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity of less than 7 %.

6.5. If a lot is accepted, all measuring instruments of the lot shall be considered approved, except for those measuring instruments from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved instrument or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

If a lot is rejected, the notified body shall take appropriate measures to prevent that lot from being placed on the market. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

7. **Conformity marking and EU declaration of conformity**

7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual measuring instrument that satisfies the applicable requirements of this Directive.

7.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a

batch or consignment rather than individual measuring instruments in those cases where a large number of instruments is delivered to a single user.

If the notified body referred to in point 5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the measuring instruments.

8. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the measuring instruments during the manufacturing process.

9. **Authorised representative**

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2, first paragraph, point 3 and point 6.1.

MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5 and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of this Directive that apply to it.

2. **Technical documentation**

The manufacturer shall establish the technical documentation as described in Article 18 and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the instrument has been placed on the market.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of this Directive.

4. **Verification**

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or normative documents, or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5. **Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with the measuring instrument.

6. **Authorised representative**

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

(b) the technical documentation, as described in Article 18, for one model of each category of measuring instruments intended to be manufactured. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument,

(c) the documentation concerning the quality system, and

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

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

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer’s premises.

The auditing team shall review the technical documentation referred to in point (b) of point 3.1 to verify the manufacturer’s ability to identify the applicable requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. **Surveillance under the responsibility of the notified body**

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

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. **Conformity marking and EU declaration of conformity**

5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Directive and, under the responsibility of the notified body referred to in point 3.1, the latter’s identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

6. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the technical documentation referred to in point 3.1,

(b) the documentation concerning the quality system referred to in point 3.1,

(c) the information relating to the change referred to in point 3.5, as approved;

(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the measuring instruments concerned satisfy the requirements of this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 3, and shall be subject to surveillance as specified in point 5.

The adequacy of the technical design of the measuring instruments shall have been examined in accordance with point 4.

3. **Quality system**

3.1. The manufacturer shall lodge an application for assessment of the quality system with the notified body of his choice for the measuring instruments concerned.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) all relevant information for the instrument category envisaged;

(c) the documentation concerning the quality system;

(d) a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the measuring instruments with the requirements of this Directive that apply to them.

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

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of this Directive. The audit shall include an assessment visit to the manufacturer’s premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer or his authorised representative of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

4. **Design examination**

4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the requirements of this Directive that apply to it.

It shall include:

(a) the name and address of the manufacturer;

(b) a written declaration that the same application has not been lodged with any other notified body;

(c) the technical documentation as described in Article 18. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of this Directive that apply to the instrument it shall issue an EU design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined design to be evaluated and to allow for in-service control. It shall allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

(a) the metrological characteristics of the design of the instrument;

(b) measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

(c) information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;

(d) if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;

(e) in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

The notified body shall establish an evaluation report in this regard and keep it at the disposal of the Member State that designated it. Without prejudice to Article 27(10), the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

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

Where the design does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

4.4. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EU design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of this Directive or the conditions for validity of the certificate. Such modifications shall require additional approval – from the notified body that issued the EU design examination certificate – in the form of an addition to the original EU design examination certificate.

4.5. Each notified body shall inform its notifying authority of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

4.6. The manufacturer shall keep a copy of the EU design examination certificate, its annexes and additions with the technical documentation at the disposal of the national authorities for 10 years after the instrument has been placed on the market.

5. **Surveillance under the responsibility of the notified body**

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

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. **Conformity marking and EU declaration of conformity**

6.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Directive, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

6.2. The manufacturer shall draw up a written EU declaration of conformity for each instrument model and keep it at the disposal of the national authorities for 10 years after the instrument has been placed on the market. The EU declaration of conformity shall identify the instrument model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

7. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the national authorities:

(a) the documentation concerning the quality system referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. **Authorised representative**

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.