ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

1. Module B: EU-type examination

1.1. 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.

1.2. EU-type examination may be carried out in any of the following manners:

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

— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, 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);

— assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in point 1.3, without examination of a specimen (design type).

1.3. 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. 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 technical documentation shall contain, wherever applicable, at least the following elements:

(i) a general description of the instrument;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event

of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out, etc.;

(vi) test reports;

(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 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.

1.4. The notified body shall:

For the instrument:

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

For the specimen(s):

1.4.2. 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, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3. 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, these have been applied correctly;

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

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

1.5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 1.4 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.

1.6. Where the type meets the requirements of this Directive, that apply to the instrument concerned, 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 instruments with the examined type to be evaluated and to allow for in-service control.

The EU-type examination certificate shall have a validity period of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each. In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of EU-type examination certificate may be limited to two years and extended by three years.

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.

1.7. 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. 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.

1.8. 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.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

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.

1.9. 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.

1.10. The manufacturer’s authorised representative may lodge the application referred to in point 1.3 and fulfil the obligations set out in points 1.7 and 1.9, provided that they are specified in the mandate.

2. **Module D: Conformity to type based on quality assurance of the production process**

2.1. 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 2.2 and 2.5, and ensures and declares on his sole responsibility that the 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.

2.2. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 2.3, and shall be subject to surveillance as specified in point 2.4.

2.3. *Quality system*

2.3.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the 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; and

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

2.3.2. The quality system shall ensure that the 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. 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 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, etc.;

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

2.3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 2.3.2.

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 2.3.1(e) 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.

2.3.4. 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.

2.3.5. 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 2.3.2 or whether a reassessment is necessary.

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

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

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

2.4.2. The manufacturer shall, 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, etc.

2.4.3. 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.

2.4.4. 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.

2.5. *Conformity marking and EU declaration of conformity*

2.5.1. 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 2.3.1, 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.

2.5.2. 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.

2.6. 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 2.3.1;

(b) the information relating to the change referred to in point 2.3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 2.3.5, 2.4.3 and 2.4.4.

2.7. 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.

2.8. *Authorised representative*

The manufacturer's obligations set out in points 2.3.1, 2.3.5, 2.5 and 2.6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

3. **Module D1: Quality assurance of the production process**

3.1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 3.2, 3.4 and 3.7, and ensures and declares on his sole responsibility that the instruments concerned satisfy the requirements of this Directive that apply to them.

3.2. *Technical documentation*

The manufacturer shall establish the technical documentation. 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 technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant

technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

3.3. 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.

3.4. *Manufacturing*

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the instruments concerned as specified in point 3.5, and shall be subject to surveillance as specified in point 3.6.

3.5. *Quality system*

3.5.1. The manufacturer shall lodge an application for assessment of his quality system with the notified body of his choice, for the 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 3.2.

3.5.2. The quality system shall ensure compliance of the 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 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, etc.;

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

3.5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.5.2.

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 3.2 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.

3.5.4. 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.

3.5.5. 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 3.5.2 or whether reassessment is necessary.

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

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

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

3.6.2. 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 3.2;

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

3.6.3. 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.

3.6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product 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.

3.7. *Conformity marking and EU declaration of conformity*

3.7.1. 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 3.5.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

3.7.2. 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.

3.8. 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 3.5.1;

(b) the information relating to the change referred to in point 3.5.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5.5, 3.6.3 and 3.6.4.

3.9. 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.

3.10. *Authorised representative*

The manufacturer's obligations set out in points 3.3, 3.5.1, 3.5.5, 3.7 and 3.8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

4. Module F: Conformity to type based on product verification

4.1. 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 4.2 and 4.5 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 4.3, are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

4.2. *Manufacturing*

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

4.3. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the instruments with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the instruments with the appropriate requirements shall be carried out by examination and testing of every instrument as specified in point 4.4.

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

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

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

4.4.2. 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.

4.5. *Conformity marking and EU declaration of conformity*

4.5.1. 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 4.3, 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.

4.5.2. 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.

If the notified body referred to in point 4.3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

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

4.7. *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 4.2.

5. **Module F1: Conformity based on product verification**

5.1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 5.2, 5.3 and 5.6 and ensures and declares on his sole responsibility that the instruments concerned, which have been subject to the provisions of point 5.4, are in conformity with the requirements of this Directive that apply to them.

5.2. *Technical documentation*

5.2.1. The manufacturer shall establish the technical documentation. 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 technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

5.2.2. 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.

5.3. *Manufacturing*

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

5.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the instruments with the applicable requirements of this Directive.

The examinations and tests to check the conformity with those requirements shall be carried out by examination and testing of every instrument as specified in point 5.5.

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

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

5.5.2. 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.

5.6. *Conformity marking and EU declaration of conformity*

5.6.1. 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 5.4, the latter's identification number to each individual instrument that satisfies the applicable requirements of this Directive.

5.6.2. 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.

If the notified body referred to in point 5.5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the instruments.

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

5.8. *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 5.2.1 and 5.3.

6. **Module G: Conformity based on unit verification**

6.1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 6.2, 6.3 and 6.5, and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 6.4, is in conformity with the requirements of this Directive that apply to it.

6.2. *Technical documentation*

6.2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 6.4. 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 technical documentation shall, wherever applicable, contain at least the following elements:

(a) a general description of the instrument;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the instrument;

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;

(e) results of design calculations made, examinations carried out, etc.;

(f) test reports.

6.2.2. 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.

6.3. *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.

6.4. *Verification*

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check 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 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 shall 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.

6.5. *Conformity marking and EU declaration of conformity*

6.5.1. 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 6.4, the latter's identification number to each instrument that satisfies the applicable requirements of this Directive.

6.5.2. 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.

6.6. *Authorised representative*

The manufacturer's obligations set out in points 6.2.2 and 6.5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

7. **Common provisions**

7.1. The conformity assessment according to Module D, D1, F, F1 or G may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, it shall be carried out at the place of use of the instrument.

7.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 7.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument. If a Member State has established gravity zones on its territory the expression 'at the place of use of the instrument' may be read as 'in the gravity zone of use of the instrument'.

7.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 7.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

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

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

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

7.2.3. A manufacturer who has opted for Module D or D1 in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with Module F or F1 as appropriate.

7.2.4. The CE marking and the supplementary metrology marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.