DIRECTIVE 2014/32/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 26 February 2014

on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) Directive 2004/22/EC of the European Parliament and of the Council of 31 March 2004 on measuring instruments [3] has been substantially amended [4]. Since further amendments are to be made, that Directive should be recast in the interests of clarity.

(2) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products [5] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(3) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products [6] lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. Directive 2004/22/EC should be adapted to that Decision.

(4) This Directive covers measuring instruments which are new to the Union market when they are placed on the market; that is to say they are either new measuring instruments made by a manufacturer established in the Union or measuring instruments, whether new or second-hand, imported from a third country.

(5) Correct and traceable measuring instruments can be used for a variety of measurement tasks. Those responding to reasons of public interest, public health, safety and order, protection of the environment and the consumer, of levying taxes and duties and of fair trading, which directly and indirectly affect the daily life of citizens in many ways, may require the use of legally controlled measuring instruments.

(6) This Directive should apply to all forms of supply, including distance selling.

(7) Legal metrological control should not lead to barriers to the free movement of measuring instruments. The applicable provisions should be the same in all Member States and proof of conformity should be accepted throughout the Union.

(8) Legal metrological control requires conformity with specified performance requirements. The performance requirements that the measuring instruments must meet should provide a high level of protection. The conformity assessment should provide a high level of confidence.

(9) Member States should as a general rule prescribe legal metrological control. Where legal metrological control is prescribed, only measuring instruments complying with common performance requirements should be used.

(10) The principle of optionality introduced by Directive 2004/22/EC allows Member States to exercise their right to decide whether or not to prescribe the use of the measuring instruments covered by this Directive.

[1] OJ C 181, 21.6.2012, p. 105.
[2] Position of the European Parliament of 5 February 2014 (not yet published in the Official Journal) and decision of the Council of 20 February 2014.
[3] OJ L 135, 30.4.2004, p. 1.
[4] See Annex XIV, Part A.
[5] OJ L 218, 13.8.2008, p. 30.
[6] OJ L 218, 13.8.2008, p. 82.

(11) National specifications concerning the appropriate national requirements for use should not interfere with the provisions of this Directive on 'putting into use'.

(12) The performance of certain measuring instruments is particularly sensitive to the environment, in particular the electromagnetic environment. Immunity of measuring instruments to electromagnetic interference should form an integral part of this Directive and the immunity requirements of Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility [1] should therefore not apply.

(13) In order to ensure the free circulation of measuring instruments in the Union, Member States should not impede the placing on the market and/or putting into use of measuring instruments that carry the CE marking and supplementary metrology marking in accordance with the provisions of this Directive.

(14) Member States should take appropriate action to prevent non-complying measuring instruments from being placed on the market and/or put into use. Adequate cooperation between the competent authorities of the Member States is therefore necessary to ensure a Union-wide effect of this objective.

(15) Economic operators should be responsible for the compliance of measuring instruments with this Directive, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the aspects of public interest covered by this Directive, and also to guarantee fair competition on the Union market.

(16) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only measuring instruments which are in conformity with this Directive. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(17) In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(18) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

(19) It is necessary to ensure that measuring instruments from third countries entering the Union market comply with this Directive, and in particular that the appropriate conformity assessment procedures have been carried out by manufacturers with regard to those measuring instruments. Provision should therefore be made for importers to make sure that the measuring instruments they place on the market comply with the requirements of this Directive and that they do not place on the market measuring instruments which do not comply with such requirements or present a risk. Provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that marking of measuring instruments and documentation drawn up by manufacturers are available for inspection by the competent national authorities.

(20) When placing a measuring instrument on the market, every importer should indicate on the measuring instrument his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the measuring instrument does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the measuring instrument.

(21) The distributor makes a measuring instrument available on the market after it has been placed on the market by the manufacturer or the importer. The distributor should act with due care to ensure that its handling of the measuring instrument does not adversely affect the compliance of that instrument with this Directive.

(22) Any economic operator that either places a measuring instrument on the market under his own name or trade mark or modifies a measuring instrument in such a way that compliance with of this Directive may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(23) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the measuring instrument concerned.

[1] OJ L 390, 31.12.2004, p. 24.

(24) Ensuring traceability of a measuring instrument throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates market surveillance authorities' task of tracing economic operators who made non-compliant measuring instruments available on the market. When keeping the information required under this Directive for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with a measuring instrument or to whom they have supplied a measuring instrument.

(25) This Directive should be limited to the expression of essential requirements that do not impede technical progress, preferably performance requirements. In order to facilitate conformity assessment with those requirements it is necessary to provide for a presumption of conformity for measuring instruments which are in conformity with harmonised standards that are adopted in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European Standardisation [1] for the purpose of expressing detailed technical specifications of those requirements.

(26) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Directive.

(27) The technical and performance specifications of internationally agreed normative documents may also comply, in part or in full, with the essential requirements laid down by this Directive. In those cases the use of these internationally agreed normative documents should be allowed as an alternative to the use of harmonised standards and, under specific conditions, give rise to a presumption of conformity.

(28) Conformity with the essential requirements laid down by this Directive can also be provided by specifications that are not supplied by a harmonised standard or an internationally agreed normative document. The use of harmonised standards or internationally agreed normative documents should therefore be optional.

(29) In order to enable economic operators to demonstrate and the competent authorities to ensure that measuring instruments made available on the market comply with the essential requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules. However, it is necessary to adapt those modules in order to reflect specific aspects of metrological control.

(30) The conformity assessment of sub-assemblies should be carried out in accordance with this Directive. If sub-assemblies are made available on the market separately and independently of an instrument, their conformity assessment should be undertaken independently of the instrument concerned.

(31) The state of the art in measurement technology is subject to constant evolution which may lead to changes in the needs for conformity assessments. Therefore, for each category of measuring instrument and, where appropriate, sub-assemblies, there should be an appropriate procedure or a choice between different procedures of equivalent stringency.

(32) Manufacturers should draw up an EU declaration of conformity to provide information required under this Directive on the conformity of a measuring instrument with this Directive and with other relevant Union harmonisation legislation.

(33) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts should be available in a single EU declaration of conformity. In order to reduce the administrative burden on economic operators, that single EU declaration of conformity may be a dossier made up of relevant individual declarations of conformity.

(34) The CE marking and the supplementary metrology marking, indicating the conformity of a measuring instrument, are the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking and its relationship to other markings are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking and the supplementary metrology marking should be laid down in this Directive.

(35) In order to take account of differences in climatic conditions or of different levels of consumer protection that may apply at national level, it is necessary to establish environmental or accuracy classes as essential requirements.

(36) Certain conformity assessment procedures set out in this Directive require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

[1] OJ L 316, 14.11.2012, p. 12.

(37) Experience has shown that the criteria set out in Directive 2004/22/EC that conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Union. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(38) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards it should be presumed to comply with the corresponding requirements set out in this Directive.

(39) In order to ensure a consistent level of quality in the performance of conformity assessment of measuring instruments, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(40) The system set out in this Directive should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(41) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.

(42) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the measuring instruments to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also activities carried out by subcontractors and subsidiaries.

(43) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable online notification.

(44) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(45) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(46) In order to ensure legal certainty, it is necessary to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to measuring instruments covered by this Directive. This Directive should not prevent Member States from choosing the competent authorities to carry out those tasks.

(47) Member States should take all appropriate measures to ensure that measuring instruments may be placed on the market only if, when properly stored and used for their intended purpose, or under conditions of use which can be reasonably foreseen, they do not endanger the health and safety of persons. Measuring instruments should be considered as non-compliant with the essential requirements laid down in this Directive only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(48) Directive 2004/22/EC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against measuring instruments it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the view to making it more efficient and drawing on the expertise available in Member States.

(49) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to measuring instruments presenting a risk to aspects of public interest protection covered by this Directive. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an early stage in respect of such measuring instruments.

(50) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard or a normative document.

(51) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([1]).

(52) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

(53) The advisory procedure should also be used for the adoption of implementing acts with respect to the objections to the internationally agreed normative documents whose references have not yet been published in the *Official Journal of the European Union*, given that the relevant document has not yet led to the presumption of conformity with the applicable essential requirements.

(54) The examination procedure should be used for the adoption of implementing acts with respect to the objections to the internationally agreed normative documents whose references were already published in the *Official Journal of the European Union* and which a Member State or the Commission considers justified, given that such acts could have consequences on the presumption of conformity with the applicable essential requirements.

(55) The examination procedure should also be used for the adoption of implementing acts with respect to compliant measuring instruments which present a risk to the health or safety of persons or to other aspects of public interest protection.

(56) In line with established practice, the committee set up by this Directive can play a useful role in examining matters concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

(57) When matters relating to this Directive, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(58) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant measuring instruments are justified or not.

(59) In order to take into account the developments in the measurement technology, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amendments to the instrument-specific Annexes. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(60) Member States should lay down rules on penalties applicable to infringements of the provisions of national law adopted pursuant to this Directive and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(61) It is necessary to provide for reasonable transitional arrangements that allow the making available on the market and putting into use, without the need to comply with further product requirements, of measuring instruments that have already been placed on the market in accordance with Directive 2004/22/EC before the date of application of national measures transposing this Directive. Distributors should therefore be able to supply measuring instruments that have been placed on the market, namely stock that is already in the distribution chain, before the date of application of national measures transposing this Directive.

([1]) OJ L 55, 28.2.2011, p. 13.

(62) Since the objective of this Directive, namely to ensure that measuring instruments on the market fulfil the requirements providing for a high level of protection of the public interests covered by this Directive while guaranteeing the functioning of the internal market cannot be sufficiently achieved by the Member States but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(63) The obligation to transpose this Directive into national law should be confined to those provisions which represent a substantive amendment as compared to the earlier Directive. The obligation to transpose the provisions which are unchanged arises under the earlier Directive.

(64) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law and the dates of application of the Directives set out in Annex XIV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER 1

GENERAL PROVISIONS

Article 1

Subject matter

This Directive establishes the requirements that measuring instruments have to satisfy with a view to their being made available on the market and/or put into use for the measuring tasks referred to in Article 3(1).

Article 2

Scope

1. This Directive applies to the measuring instruments defined in the instrument-specific Annexes III to XII (hereinafter 'instrument-specific Annexes') concerning water meters (MI-001), gas meters and volume conversion devices (MI-002), active electrical energy meters (MI-003), thermal energy meters (MI-004), measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005), automatic weighing instruments (MI-006), taximeters (MI-007), material measures (MI-008), dimensional measuring instruments (MI-009) and exhaust gas analysers (MI-010).

2. This Directive is a specific Directive in respect of requirements for electromagnetic immunity within the meaning of Article 2(3) of Directive 2014/30/EU of the European Parliament and of the Council [1]. That Directive continues to apply with regard to emission requirements.

Article 3

Optionality

1. Member States may prescribe the use of measuring instruments for measuring tasks, where they consider it justified for reasons of public interest, public health, public safety, public order, protection of the environment, protection of consumers, levying of taxes and duties and fair trading.

2. Where Member States do not prescribe such use, they shall communicate the reasons therefor to the Commission and the other Member States.

Article 4

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'measuring instrument' means any device or system with a measurement function that is covered by Article 2(1);

(2) 'sub-assembly' means a hardware device, mentioned as such in the instrument-specific annexes, that functions independently and makes up a measuring instrument together with other sub-assemblies with which it is compatible, or with a measuring instrument with which it is compatible;

(3) 'legal metrological control' means the control of the measurement tasks intended for the field of application of a measuring instrument, for reasons of public interest, public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

(4) 'normative document' means a document containing technical specifications adopted by the International Organisation of Legal Metrology;

(5) 'making available on the market' means any supply of a measuring instrument for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(6) 'placing on the market' means the first making available of a measuring instrument on the Union market;

[1] Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (see page 79 of this Official Journal).

(7) 'putting into use' means the first use of a measuring instrument intended for the end-user for the purposes for which it was intended;

(8) 'manufacturer' means any natural or legal person who manufactures a measuring instrument or has a measuring instrument designed or manufactured, and markets that measuring instrument under his name or trade mark or puts it into use for his own purposes;

(9) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(10) 'importer' means any natural or legal person established within the Union who places a measuring instrument from a third country on the Union market;

(11) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a measuring instrument available on the market;

(12) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(13) 'technical specification' means a document that prescribes technical requirements to be fulfilled by a measuring instrument;

(14) 'harmonised standard' means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(15) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) no 765/2008;

(16) 'national accreditation body' means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) no 765/2008;

(17) 'conformity assessment' means the process demonstrating whether the essential requirements of this Directive relating to a measuring instrument have been fulfilled;

(18) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(19) 'recall' means any measure aimed at achieving the return of a measuring instrument that has already been made available to the end-user;

(20) 'withdrawal' means any measure aimed at preventing a measuring instrument in the supply chain from being made available on the market;

(21) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(22) 'CE marking' means a marking by which the manufacturer indicates that the measuring instrument is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 5

Applicability to sub-assemblies

Where instrument-specific annexes lay down the essential requirements for sub-assemblies, this Directive shall apply mutatis mutandis to such sub-assemblies.

Sub-assemblies and measuring instruments may be assessed independently and separately for the purpose of establishing conformity.

Article 6

Essential requirements

A measuring instrument shall meet the essential requirements set out in Annex I and in the relevant instrument-specific Annex.

Member States may require, if it is needed for correct use of the instrument, the information referred to in point 9 of Annex I or in the relevant instrument-specific Annexes to be provided in a language which can be easily understood by end-users, as determined by the Member State in which the instrument is made available on the market.

Article 7

Making available on the market and putting into use

1. Member States shall not impede for reasons covered by this Directive the making available on the market and/or putting into use of any measuring instrument that satisfies the requirements of this Directive.

2. Member States shall take all appropriate measures to ensure that measuring instruments are made available on the market and/or put into use only if they satisfy the requirements of this Directive.

3. A Member State may require a measuring instrument to satisfy provisions governing its putting into use that are justified by local climatic conditions. In such a case, the Member State shall choose appropriate upper and lower temperature limits from Table 1 of Annex I and may specify humidity conditions (condensing or non-condensing) and whether the intended location of use is open or closed.

4. When different accuracy classes are defined for a measuring instrument:

(a) the instrument-specific Annexes under the heading 'Putting into use' may indicate the accuracy classes to be used for specific applications;

(b) in all other cases a Member State may determine the accuracy classes to be used for specific applications within the classes defined, subject to allowing the use of all accuracy classes on its territory.

For the purposes of point (a) or point (b), measuring instruments of a better accuracy class may be used if the owner so chooses.

5. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not prevent the showing of measuring instruments not in conformity with this Directive, provided that a visible sign clearly indicates their non-conformity and their non-availability for making available on the market and/or putting into use until they are brought into conformity.

CHAPTER 2

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1. When placing their measuring instruments on the market and/or putting them into use, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

2. Manufacturers shall draw up the technical documentation referred to in Article 18 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out.

Where compliance of a measuring instrument with the applicable requirements of this Directive has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking and the supplementary metrology marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the measuring instrument has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in measuring instrument design or characteristics and changes in the harmonised standards, normative documents or in other technical specifications by reference to which conformity of a measuring instrument is declared shall be adequately taken into account.

When deemed appropriate with regard to the performance of a measuring instrument, manufacturers shall carry out sample testing of measuring instruments made available on the market, investigate and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that measuring instruments which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the measuring instrument does not allow it, that the required information is provided in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I.

6. Manufacturers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on the packaging, if any, in accordance with point 9.2 of Annex I. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7. Manufacturers shall ensure that the measuring instrument which they have placed on the market is accompanied by a copy of the EU Declaration of conformity and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

8. Manufacturers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the measuring instrument with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Article 9

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the measuring instrument has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a measuring instrument;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by measuring instruments covered by their mandate.

Article 10

Obligations of importers

1. Importers shall place only compliant measuring instruments on the market.

2. Before placing a measuring instrument on the market and/or putting a measuring instrument into use importers shall ensure that the appropriate conformity assessment procedure referred to in Article 17 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the measuring instrument bears the CE marking and the supplementary metrology marking and is accompanied by a copy of the EU declaration of conformity and the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not place the measuring instrument on the market or put it into use until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate on the measuring instrument their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, in a document accompanying the measuring instrument and on its packaging, if any, in accordance with point 9.2 of Annex I. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that the measuring instrument is accompanied by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

6. When deemed appropriate with regard to the performance of a measuring instrument, importers shall carry out sample testing of measuring instruments made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming measuring instruments and measuring instrument recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a measuring instrument which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the measuring instrument presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8. Importers shall, for 10 years after the measuring instrument has been placed on the market keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have placed on the market.

Article 11

Obligations of distributors

1. When making a measuring instrument available on the market and/or putting it into use, distributors shall act with due care in relation to the requirements of this Directive.

2. Before making a measuring instrument available on the market and/or putting a measuring instrument into use distributors shall verify that the measuring instrument bears the CE marking and the supplementary metrology marking, that it is accompanied by the EU declaration of conformity, by the required documents and by instructions and information in accordance with point 9.3 of Annex I, in a language which can be easily understood by end-users in the Member State in which the measuring instrument is to be made available on the market and/or put into use, and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that a measuring instrument is not in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, he shall not make the measuring instrument available on the market or put it into use, until it has been brought into conformity. Furthermore, where the measuring instrument presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while a measuring instrument is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes.

4. Distributors who consider or have reason to believe that a measuring instrument which they have made available on the market or put into use is not in conformity with this Directive shall make sure that the corrective measures necessary to bring that measuring instrument into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the measuring instrument presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the measuring instrument available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a measuring instrument. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by measuring instruments which they have made available on the market.

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and he shall be subject to the obligations of the manufacturer under Article 8, where he places a measuring instrument on the market under his name or trade mark or modifies a measuring instrument already placed on the market in such a way that compliance with this Directive may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a measuring instrument;

(b) any economic operator to whom they have supplied a measuring instrument.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the measuring instrument and for 10 years after they have supplied the measuring instrument.

CHAPTER 3

CONFORMITY OF MEASURING INSTRUMENTS

Article 14

Presumption of conformity of measuring instruments

1. Measuring instruments which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those standards or parts thereof.

2. Measuring instruments which are in conformity with parts of normative documents, the list of which has been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes covered by those parts of normative documents.

3. A manufacturer may choose to use any technical solution that complies with the essential requirements set out in Annex I and in the relevant instrument-specific Annexes. In addition, to benefit from the presumption of conformity, the manufacturer must correctly apply solutions mentioned either in the relevant harmonised standards or in the normative documents referred to in paragraphs 1 and 2.

4. Member States shall presume compliance with the appropriate tests mentioned in point (i) of Article 18(3) if the corresponding test programme has been performed in accordance with the relevant documents mentioned in paragraphs 1, 2 and 3 and if the test results ensure compliance with the essential requirements.

Article 15

Publication of the references of normative documents

On request by a Member State or in its own initiative, the Commission shall, where appropriate:

(a) identify normative documents and, in a list, indicate the parts thereof that satisfy the requirements which they cover and which are set out in Annex I and in the relevant instrument-specific Annexes;

(b) publish the reference of the normative documents and the list referred to in point (a) in the *Official Journal of the European Union*.

Article 16

Withdrawal of the references of normative documents

1. When a Member State or the Commission considers that a normative document whose reference has been published or is intended to be published in the *Official Journal of the European Union* does not entirely satisfy the essential requirements which it covers and which are set out in Annex I and in the relevant instrument-specific Annexes, the Commission shall decide:

(a) to publish, not to publish or to publish with restriction the references to the normative documents concerned in the *Official Journal of the European Union*;

(b) to maintain, to maintain with restrictions or to withdraw the references to the normative documents concerned in or from the *Official Journal of the European Union*.

2. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

3. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 46(3).

Article 17

Conformity assessment procedures

Conformity assessment of a measuring instrument with the applicable essential requirements shall be carried out by the application, at the choice of the manufacturer, of one of the conformity assessment procedures listed in the relevant instrument-specific Annex.

The conformity assessment procedures are set out in Annex II.

Records and correspondence relating to conformity assessment procedures shall be drawn up in the official language(s) of the Member State where the notified body carrying out the conformity assessment procedures is established, or in a language accepted by that body.

Article 18

Technical documentation

1. The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall permit an assessment of its conformity with the applicable requirements of this Directive.

2. The technical documentation shall be sufficiently detailed to ensure compliance with the following requirements:

(a) the definition of the metrological characteristics;

(b) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate intended means;

(c) the integrity of the measuring instrument.

3. The technical documentation shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

(a) a general description of the measuring instrument;

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

(c) manufacturing procedures to ensure consistent production;

(d) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;

(e) descriptions and explanations necessary for the understanding of the information referred to in points (b), (c) and (d), including the operation of the measuring instrument;

(f) a list of the harmonised standards and/or normative documents referred to in Article 14, applied in full or in part, the references of which have been published in the *Official Journal of the European Union*;

(g) descriptions of the solutions adopted to meet the essential requirements where the harmonised standards and/or normative documents referred to in Article 14 have not been applied, including a list of other relevant technical specifications applied;

(h) results of design calculations, examinations, etc.;

(i) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:

— the requirements of this Directive under declared rated operating conditions and under specified environmental disturbances,

— the durability specifications for gas-, water-, thermal energy-meters as well as for liquids other than water;

(j) the EU-type examination certificates or EU design examination certificates in respect of measuring instruments containing parts identical to those in the design.

4. The manufacturer shall specify where seals and markings have been applied.

5. The manufacturer shall indicate the conditions for compatibility with interfaces and sub-assemblies, where relevant.

Article 19

EU declaration of conformity

1. The EU declaration of conformity shall state that the fulfilment of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes has been demonstrated.

2. The EU declaration of conformity shall have the model structure set out in Annex XIII, shall contain the elements specified in the relevant modules set out in Annex II and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the measuring instrument is placed or made available on the market.

3. Where a measuring instrument is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the measuring instrument with the requirements laid down in this Directive.

Article 20

Conformity marking

The conformity of a measuring instrument with this Directive shall be indicated by the presence on it of the CE marking and the supplementary metrology marking as specified in Article 21.

Article 21

General principles of the CE marking and of the supplementary metrology marking

1. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

2. The supplementary metrology marking shall consist of the capital letter 'M' and the last two digits of the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE marking.

3. The general principles set out in Article 30 of Regulation (EC) No 765/2008 shall apply, mutatis mutandis, to the supplementary metrology marking.

Article 22

Rules and conditions for affixing the CE marking and the supplementary metrology marking

1. The CE marking and the supplementary metrology marking shall be affixed visibly, legibly and indelibly to the measuring instrument or to its data plate. Where that is not possible or not warranted on account of the nature of the measuring instrument, they shall be affixed to the accompanying documents and to the packaging, if any.

2. When a measuring instrument consists of a set of devices, not being sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument's main device.

3. The CE marking and the supplementary metrology marking shall be affixed before the measuring instrument is placed on the market.

4. The CE marking and the supplementary metrology marking may be affixed to the instrument during the fabrication process, if justified.

5. The supplementary metrology marking shall immediately follow the CE marking.

The CE marking and the supplementary metrology marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase as set out in Annex II.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

The identification number of the notified body concerned shall be indelible or self destructive upon removal.

6. The CE marking, the supplementary metrology marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

7. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

CHAPTER 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 23

Notification

1. Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Directive.

2. If a Member State has not introduced national legislation for measuring tasks referred to in Article 3, it shall retain the right to notify a body for conformity assessment tasks relating to the measuring instrument concerned.

Article 24

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article 29.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 25. In addition it shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 25

Requirements relating to notifying authorities

1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5. A notifying authority shall safeguard the confidentiality of the information it obtains.

6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 26

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 27

Requirements relating to notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the measuring instrument it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of measuring instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the measuring instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed measuring instruments that are necessary for the operations of the conformity assessment body or the use of such measuring instruments for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those measuring instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

The second subparagraph does not, however, preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of measuring instruments in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out conformity assessment tasks shall have the following:

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements set out in Annex I and in the relevant instrument-specific Annexes, of the applicable harmonised standards and normative documents and of the relevant provisions of Union harmonisation legislation and of national legislation;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 28

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 27 in so far as the applicable harmonised standards cover those requirements.

Article 29

Subsidiaries of and subcontracting by notified bodies

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 27 and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annex II.

Article 30

Accredited in-house bodies

1. An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set out in point 2 (Module A2) and point 5 (Module C2) of Annex II. That body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, production, supply, installation, use or maintenance of the measuring instruments it assesses.

2. An accredited in-house body shall meet the following requirements:

(a) it shall be accredited in accordance with Regulation (EC) No 765/2008;

(b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the measuring instruments they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

(d) it shall supply its services exclusively to the undertaking of which it forms a part.

3. An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article 31

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the measuring instrument or measuring instruments for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 27.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 27.

Article 32

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 27.

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include information on the kind(s) of measuring instrument(s) for which each body has been designated and, where relevant, the instrument accuracy classes, the measuring range, the measurement technology, and any other instrument characteristic limiting the scope of the notification. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and measuring instrument or measuring instruments concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 27.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 33

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 34

Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 27, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 35

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including withdrawal of notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).

Article 36

Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annex II.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the measuring instrument with this Directive.

3. Where a notified body finds that the essential requirements set out in Annex I and in the relevant instrument-specific Annexes or corresponding harmonised standards, normative documents or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

4. Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a measuring instrument no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 37

Appeal against decisions of notified bodies

Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Article 38

Information obligation on notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of or conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive carrying out similar conformity assessment activities covering the same measuring instruments with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 39

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 40

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral or cross sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or those groups, directly or by means of designated representatives.

CHAPTER 5

UNION MARKET SURVEILLANCE, CONTROL OF MEASURING INSTRUMENTS ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 41

Union market surveillance and control of measuring instruments entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to measuring instruments.

Article 42

Procedure for dealing with measuring instruments presenting a risk at national level

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a measuring instrument covered by this Directive presents a risk to aspects of public interest protection covered by this Directive, they shall carry out an evaluation in relation to the measuring instrument concerned covering all relevant requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the measuring instrument does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the measuring instrument into compliance with those requirements, to withdraw the measuring instrument from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the measuring instruments concerned that it has made available on the market throughout the Union.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the measuring instrument being made available on their national market, to withdraw the measuring instrument from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant measuring instrument, the origin of the measuring instrument, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

(a) failure of the measuring instrument to meet requirements relating to aspects of public interest protection laid down in this Directive; or

(b) shortcomings in the harmonised standards or normative documents referred to in Article 14 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the measuring instrument concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7. Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the measuring instrument from the market, are taken in respect of the measuring instrument concerned, without delay.

Article 43

Union safeguard procedure

1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant measuring instrument is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3. Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 42(5) of this Directive, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

4. Where the national measure is considered justified and the non-compliance of the measuring instrument is attributed to shortcomings in the normative documents referred to in point (b) of Article 42(5), the Commission shall apply the procedure provided for in Article 16.

Article 44

Compliant measuring instruments which present a risk

1. Where, having carried out an evaluation under Article 42(1), a Member State finds that although a measuring instrument is in compliance with this Directive, it presents a risk to aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the measuring instrument concerned, when placed on the market, no longer presents that risk, to withdraw the measuring instrument from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that corrective action is taken in respect of all the measuring instruments concerned that he has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the measuring instrument concerned, the origin and the supply chain of the measuring instrument, the nature of the risk involved and the nature and duration of the national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not, and where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 46(3).

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 45

Formal non-compliance

1. Without prejudice to Article 42, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(a) the CE marking or the supplementary metrology marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 22 of this Directive;

(b) the CE marking or the supplementary metrology marking has not been affixed;

(c) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Article 22 or has not been affixed;

(d) the EU declaration of conformity does not accompany the measuring instrument;

(e) the EU declaration of conformity has not been drawn up correctly;

(f) technical documentation is either not available or not complete.

(g) the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;

(h) any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the measuring instrument being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER 6

COMMITTEE AND DELEGATED ACTS

Article 46

Committee procedure

1. The Commission shall be assisted by the Committee on Measuring Instruments. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter concerning the application of this Directive raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

Article 47

Amendments of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 48 concerning the amendment of the instrument-specific Annexes, in relation to the following:

(a) maximum permissible errors (MPEs) and accuracy classes;

(b) rated operating conditions;

(c) critical change values;

(d) disturbances.

Article 48

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 47 shall be conferred on the Commission for a period of five years from 18 April 2014. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 47 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 47 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

CHAPTER 7

TRANSITIONAL AND FINAL PROVISIONS

Article 49

Penalties

Member States shall lay down rules on penalties applicable to infringements by economic operators of the provisions of national law adopted pursuant to this Directive and shall take all measures necessary to ensure that they are enforced. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Article 50

Transitional provisions

1. Member States shall not impede the making available on the market and/or the putting into use of measuring instruments covered by Directive 2004/22/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

Certificates issued under Directive 2004/22/EC shall be valid under this Directive.

2. The effects of Article 23 of Directive 2004/22/EC shall continue until 30 October 2016.

Article 51

Transposition

1. Member States shall adopt and publish, by 19 April 2016, the laws, regulations and administrative provisions necessary to comply with points 5 to 22 of Article 4, Articles 8 to 11, 13, 14, 19 and 21, Article 22(1), (3), (5) and (6), Articles 23 to 45, 49 and 50 and Annex II. They shall forthwith communicate the text of those measures to the Commission.

They shall apply those measures from 20 April 2016.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this Directive shall be construed as references

to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 52

Repeal

Without prejudice to Article 50, Directive 2004/22/EC as amended by the acts listed in Annex XIV, Part A, is repealed with effect from 20 April 2016 without prejudice to the obligations of the Member States relating to the time-limits for the transposition into national law and the dates of application of the Directives set out in Annex XIV, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XV.

Article 53

Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Articles 1, 2 and 3, points 1 to 4 of Article 4, Articles 5, 6, 7, 15 to 18 and 20, Article 22(2) and (4) and Annexes I and III to XII shall apply from 20 April 2016.

Article 54

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 26 February 2014.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	D. KOURKOULAS

ANNEX I

ESSENTIAL REQUIREMENTS

A measuring instrument shall provide a high level of metrological protection in order that any party affected can have confidence in the result of measurement, and shall be designed and manufactured to a high level of quality in respect of the measurement technology and security of the measurement data.

The essential requirements that shall be met by measuring instruments are set out below and are supplemented, where appropriate, by specific instrument requirements in Annexes III to XII that provide more detail on certain aspects of the general requirements.

The solutions adopted in the pursuit of the essential requirements shall take account of the intended use of the instrument and any foreseeable misuse thereof.

DEFINITIONS

Measurand	The measurand is the particular quantity subject to measurement.
Influence quantity	An influence quantity is a quantity that is not the measurand but that affects the result of measurement.
Rated Operating Conditions	The rated operating conditions are the values for the measurand and influence quantities making up the normal working conditions of an instrument.
Disturbance	An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the measuring instrument. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified.
Critical change value	The critical change value is the value at which the change in the measurement result is considered undesirable.
Material Measure	A material measure is a device intended to reproduce or supply in a permanent manner during its use one or more known values of a given quantity.
Direct sales	A trading transaction is direct sales if: — the measurement result serves as the basis for the price to pay; and — at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection; and — all the parties in the transaction accept the measurement result at that time and place.
Climatic environments	Climatic environments are the conditions in which measuring instruments may be used. To cope with climatic differences between the Member States, a range of temperature limits has been defined.
Utility	A utility is regarded as a supplier of electricity, gas, thermal energy or water.

ESSENTIAL REQUIREMENTS

1. **Allowable Errors**

1.1. Under rated operating conditions and in the absence of a disturbance, the error of measurement shall not exceed the maximum permissible error (MPE) value as laid down in the appropriate instrument-specific requirements.

Unless stated otherwise in the instrument-specific annexes, MPE is expressed as a bilateral value of the deviation from the true measurement value.

1.2. Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as laid down in the appropriate instrument-specific requirements.

Where the instrument is intended to be used in a specified permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field-amplitude modulated test shall be within MPE.

1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, power supply and other influence quantities likely to affect its accuracy, taking account of the requirements laid down in the appropriate instrument-specific annexes.

1.3.1. Climatic environments

The manufacturer shall specify the upper temperature limit and the lower temperature limit from any of the values in Table 1 unless otherwise specified in the Annexes III to XII, and indicate whether the instrument is designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Table 1

	Temperature Limits			
Upper temperature limit	30 °C	40 °C	55 °C	70 °C
Lower temperature limit	5 °C	– 10 °C	– 25 °C	– 40 °C

1.3.2. (a) Mechanical environments are classified into classes M1 to M3 as described below.

M1	This class applies to instruments used in locations with vibration and shocks of low significance, e.g. for instruments fastened to light supporting structures subject to negligible vibrations and shocks transmitted from local blasting or pile-driving activities, slamming doors, etc.
M2	This class applies to instruments used in locations with significant or high levels of vibration and shock, e.g. transmitted from machines and passing vehicles in the vicinity or adjacent to heavy machines, conveyor belts, etc.
M3	This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

(b) The following influence quantities shall be considered in relation with mechanical environments:

— vibration;

— mechanical shock.

1.3.3. (a) Electromagnetic environments are classified into classes E1, E2 or E3 as described below, unless otherwise laid down in the appropriate instrument-specific annexes.

E1	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in residential, commercial and light industrial buildings.
E2	This class applies to instruments used in locations with electromagnetic disturbances corresponding to those likely to be found in other industrial buildings.
E3	This class applies to instruments supplied by the battery of a vehicle. Such instruments shall comply with the requirements of E2 and the following additional requirements: — voltage reductions caused by energising the starter-motor circuits of internal combustion engines, — load dump transients occurring in the event of a discharged battery being disconnected while the engine is running.

(b) The following influence quantities shall be considered in relation with electromagnetic environments:

— voltage interruptions;

— short voltage reductions;

— voltage transients on supply lines and/or signal lines;

— electrostatic discharges;

— radio frequency electromagnetic fields;

— conducted radio frequency electromagnetic fields on supply lines and/or signal lines;

— surges on supply lines and/or signal lines.

1.3.4. Other influence quantities to be considered, where appropriate, are:

— voltage variation;

— mains frequency variation;

— power frequency magnetic fields;

— any other quantity likely to influence in a significant way the accuracy of the instrument.

1.4. When carrying out the tests as envisaged in this Directive, the following points shall apply:

1.4.1. Basic rules for testing and the determination of errors

Essential requirements specified in points 1.1 and 1.2 shall be verified for each relevant influence quantity. Unless otherwise specified in the appropriate instrument-specific annex, these essential requirements apply when each influence quantity is applied and its effect evaluated separately, all other influence quantities being kept relatively constant at their reference value.

Metrological tests shall be carried out during or after the application of the influence quantity, whichever condition corresponds to the normal operational status of the instrument when that influence quantity is likely to occur.

1.4.2. Ambient humidity

(a) According to the climatic operating environment in which the instrument is intended to be used either the damp heat-steady state (non-condensing) or damp heat cyclic (condensing) test may be appropriate.

(b) The damp heat cyclic test is appropriate where condensation is important or when penetration of vapour will be accelerated by the effect of breathing. In conditions where non-condensing humidity is a factor the damp-heat steady state is appropriate.

2. **Reproducibility**

The application of the same measurand in a different location or by a different user, all other conditions being the same, shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

3. **Repeatability**

The application of the same measurand under the same conditions of measurement shall result in the close agreement of successive measurements. The difference between the measurement results shall be small when compared with the MPE.

4. **Discrimination and Sensitivity**

A measuring instrument shall be sufficiently sensitive and the discrimination threshold shall be sufficiently low for the intended measurement task.

5. **Durability**

A measuring instrument shall be designed to maintain an adequate stability of its metrological characteristics over a period of time estimated by the manufacturer, provided that it is properly installed, maintained and used according to the manufacturer's instruction when in the environmental conditions for which it is intended.

6. **Reliability**

A measuring instrument shall be designed to reduce as far as possible the effect of a defect that would lead to an inaccurate measurement result, unless the presence of such a defect is obvious.

7. **Suitability**

7.1. A measuring instrument shall have no feature likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal.

7.2. A measuring instrument shall be suitable for its intended use taking account of the practical working conditions and shall not require unreasonable demands of the user in order to obtain a correct measurement result.

7.3. The errors of a utility measuring instrument at flows or currents outside the controlled range shall not be unduly biased.

7.4. Where a measuring instrument is designed for the measurement of values of the measurand that are constant over time, the measuring instrument shall be insensitive to small fluctuations of the value of the measurand, or shall take appropriate action.

7.5. A measuring instrument shall be robust and its materials of construction shall be suitable for the conditions in which it is intended to be used.

7.6. A measuring instrument shall be designed so as to allow the control of the measuring tasks after the instrument has been placed on the market and put into use. If necessary, special equipment or software for this control shall be part of the instrument. The test procedure shall be described in the operation manual.

When a measuring instrument has associated software which provides other functions besides the measuring function, the software that is critical for the metrological characteristics shall be identifiable and shall not be inadmissibly influenced by the associated software.

8. **Protection against corruption**

8.1. The metrological characteristics of a measuring instrument shall not be influenced in any inadmissible way by the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the measuring instrument.

8.2. A hardware component that is critical for metrological characteristics shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention.

8.3. Software that is critical for metrological characteristics shall be identified as such and shall be secured.

Software identification shall be easily provided by the measuring instrument.

Evidence of an intervention shall be available for a reasonable period of time.

8.4. Measurement data, software that is critical for measurement characteristics and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.

8.5. For utility measuring instruments the display of the total quantity supplied or the displays from which the total quantity supplied can be derived, whole or partial reference to which is the basis for payment, shall not be able to be reset during use.

9. **Information to be borne by and to accompany the instrument**

9.1. A measuring instrument shall bear the following inscriptions:

(a) manufacturer's name, registered trade name or registered trade mark;

(b) information in respect of its accuracy;

and, where applicable:

(c) information in respect of the conditions of use;

(d) measuring capacity;

(e) measuring range;

(f) identity marking;

(g) number of the EU-type examination certificate or the EU design examination certificate;

(h) information whether or not additional devices providing metrological results comply with the provisions of this Directive on legal metrological control.

9.2. An instrument of dimensions too small or of too sensitive a composition to allow it to bear the relevant information shall have its packaging, if any, and the accompanying documents required by the provisions of this Directive suitably marked.

9.3. The instrument shall be accompanied by information on its operation, unless the simplicity of the measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:

(a) rated operating conditions;

(b) mechanical and electromagnetic environment classes;

(c) the upper and lower temperature limit, whether condensation is possible or not, open or closed location;

(d) instructions for installation, maintenance, repairs, permissible adjustments;

(e) instructions for correct operation and any special conditions of use;

(f) conditions for compatibility with interfaces, sub-assemblies or measuring instruments.

9.4. Groups of identical measuring instruments used in the same location or used for utility measurements do not necessarily require individual instruction manuals.

9.5. Unless specified otherwise in an instrument-specific annex, the scale interval for a measured value shall be in the form 1×10^n, 2×10^n, or 5×10^n, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.

9.6. A material measure shall be marked with a nominal value or a scale, accompanied by the unit of measurement used.

9.7. The units of measurement used and their symbols shall be in accordance with the provisions of Union legislation on units of measurement and their symbols.

9.8. All marks and inscriptions required under any requirement shall be clear, non-erasable, unambiguous and non-transferable.

10. **Indication of result**

10.1. Indication of the result shall be by means of a display or hard copy.

10.2. The indication of any result shall be clear and unambiguous and accompanied by such marks and inscriptions necessary to inform the user of the significance of the result. Easy reading of the presented result shall be permitted under normal conditions of use. Additional indications may be shown provided they cannot be confused with the metrologically controlled indications.

10.3. In the case of hard copy the print or record shall also be easily legible and non-erasable.

10.4. A measuring instrument for direct sales trading transactions shall be designed to present the measurement result to both parties in the transaction when installed as intended. When critical in case of direct sales, any ticket provided to the consumer by an ancillary device not complying with the appropriate requirements of this Directive shall bear appropriate restrictive information.

10.5. Whether or not a measuring instrument intended for utility measurement purposes can be remotely read it shall in any case be fitted with a metrologically controlled display accessible without tools to the consumer. The reading of this display is the measurement result that serves as the basis for the price to pay.

11. **Further processing of data to conclude the trading transaction**

11.1. A measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when:

(a) the measurement is non-repeatable; and

(b) the measuring instrument is normally intended for use in the absence of one of the trading parties.

11.2. Additionally, a durable proof of the measurement result and the information to identify the transaction shall be available on request at the time the measurement is concluded.

12. **Conformity evaluation**

A measuring instrument shall be designed so as to allow ready evaluation of its conformity with the appropriate requirements of this Directive.

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.

ANNEX III

WATER METERS (MI-001)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to water meters intended for the measurement of volumes of clean, cold or heated water in residential, commercial and light industrial use.

DEFINITIONS

Water Meter	An instrument designed to measure, memorise and display the volume at metering conditions of water passing through the measurement transducer.
Minimum Flowrate (Q_1)	The lowest flowrate at which the water meter provides indications that satisfy the requirements concerning the maximum permissible errors (MPEs.)
Transitional Flowrate (Q_2)	The transitional flowrate is the flowrate value occurring between the permanent and minimum flowrates, at which the flowrate range is divided into two zones, the 'upper zone' and the 'lower zone'. Each zone has a characteristic MPE.
Permanent Flowrate (Q_3)	The highest flowrate at which the water meter operates in a satisfactory manner under normal conditions of use, i.e. under steady or intermittent flow conditions.
Overload Flowrate (Q_4)	The overload flowrate is the highest flowrate at which the meter operates in a satisfactory manner for a short period of time without deteriorating.

SPECIFIC REQUIREMENTS

Rated Operating Conditions

The manufacturer shall specify the rated operating conditions for the instrument, in particular:

1. The flowrate range of the water.

   The values for the flowrate range shall fulfil the following conditions:

   $Q_3/Q_1 \geq 10$

   $Q_2/Q_1 = 1{,}6$

   $Q_4/Q_3 = 1{,}25$

2. The temperature range of the water.

   The values for the temperature range shall fulfil the following conditions:

   0,1 °C to at least 30 °C, or

   30 °C to at least 90 °C.

   The meter may be designed to operate over both ranges.

3. The relative pressure range of the water, the range being 0,3 bar to at least 10 bar at Q_3.

4. For the power supply: the nominal value of the AC voltage supply and/or the limits of DC supply.

MPE

5. The MPE, positive or negative, on volumes delivered at flowrates between the transitional flowrate (Q_2) (included) and the overload flowrate (Q_4) is:

   2 % for water having a temperature ≤ 30 °C,

3 % for water having a temperature > 30 °C.

The meter shall not exploit the MPE or systematically favour any party.

6. The MPE, positive or negative, on volumes delivered at flowrates between the minimum flowrate (Q_1) and the transitional flowrate (Q_2) (excluded) is 5 % for water having any temperature.

The meter shall not exploit the MPE or systematically favour any party.

Permissible Effect of Disturbances

7.1. *Electromagnetic immunity*

7.1.1. The effect of an electromagnetic disturbance on a water meter shall be such that:

— the change in the measurement result is no greater than the critical change value as defined in point 7.1.3, or

— the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

7.1.2. After undergoing an electromagnetic disturbance the water meter shall:

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present just before the disturbance.

7.1.3. The critical change value is the smaller of the two following values:

— the volume corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;

— the volume corresponding to the MPE on the volume corresponding to one minute at flowrate Q_3.

7.2. *Durability*

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

7.2.1. The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed:

— 3 % of the metered volume between Q_1 included and Q_2 excluded;

— 1,5 % of the metered volume between Q_2 included and Q_4 included.

7.2.2. The error of indication for the volume metered after the durability test shall not exceed:

— ± 6 % of the metered volume between Q_1 included and Q_2 excluded;

— ± 2,5 % of the metered volume between Q_2 included and Q_4 included for water meters intended to meter water with a temperature between 0,1 °C and 30 °C,

— ± 3,5 % of the metered volume between Q_2 included and Q_4 included for water meters intended to meter water with a temperature between 30 °C and 90 °C.

Suitability

8.1. The meter shall be able to be installed to operate in any position unless clearly marked otherwise.

8.2. The manufacturer shall specify whether the meter is designed to measure reverse flow. In such a case, the reverse flow volume shall either be subtracted from the cumulated volume or shall be separately recorded. The same MPE shall apply to both forward and reverse flow.

Water meters not designed to measure reverse flow shall either prevent reverse flow or shall withstand an accidental reverse flow without any deterioration or change in metrological properties.

Units of Measurement

9. Metered volume shall be displayed in cubic metres.

Putting into Use

10. The Member State shall ensure that the requirements under points 1, 2 and 3 are determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX IV

GAS METERS AND VOLUME CONVERSION DEVICES (MI-002)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to gas meters and volume conversion devices defined below, intended for residential, commercial and light industrial use.

DEFINITIONS

Gas meter	An instrument designed to measure, memorise and display the quantity of fuel gas (volume or mass) that has passed it.
Conversion device	A device fitted to a gas meter that automatically converts the quantity measured at metering conditions into a quantity at base conditions.
Minimum flowrate (Q_{min})	The lowest flowrate at which the gas meter provides indications that satisfy the requirements regarding maximum permissible error (MPE).
Maximum flowrate (Q_{max})	The highest flowrate at which the gas meter provides indications that satisfy the requirements regarding MPE.
Transitional flowrate (Q_t)	The transitional flowrate is the flowrate occurring between the maximum and minimum flowrates at which the flowrate range is divided into two zones, the 'upper zone' and the 'lower zone'. Each zone has a characteristic MPE.
Overload Flowrate (Q_r)	The overload flowrate is the highest flowrate at which the meter operates for a short period of time without deteriorating.
Base conditions	The specified conditions to which the measured quantity of fluid is converted.

PART I

SPECIFIC REQUIREMENTS

GAS METERS

1. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions of the gas meter, taking into account:

1.1. The flowrate range of the gas shall fulfil at least the following conditions:

Class	Q_{max}/Q_{min}	Q_{max}/Q_t	Q_r/Q_{max}
1,5	≥ 150	≥ 10	1,2
1,0	≥ 20	≥ 5	1,2

1.2. The temperature range of the gas, with a minimum range of 40 °C.

1.3. *The fuel/gas related conditions*

The gas meter shall be designed for the range of gases and supply pressures of the country of destination. In particular the manufacturer shall indicate:

— the gas family or group;

— the maximum operating pressure.

1.4. A minimum temperature range of 50 °C for the climatic environment.

1.5. The nominal value of the AC voltage supply and/or the limits of DC supply.

2. **Maximum permissible error (MPEs)**

2.1. Gas meter indicating the volume at metering conditions or mass

Table 1

Class	1,5	1,0
$Q_{min} \leq Q < Q_t$	3 %	2 %
$Q_t \leq Q \leq Q_{max}$	1,5 %	1 %

The gas meter shall not exploit the MPEs or systematically favour any party.

2.2. For a gas meter with temperature conversion, which only indicates the converted volume, the MPE of the meter is increased by 0,5 % in a range of 30 °C extending symmetrically around the temperature specified by the manufacturer that lies between 15 °C and 25 °C. Outside this range, an additional increase of 0,5 % is permitted in each interval of 10 °C.

3. **Permissible effect of disturbances**

3.1. *Electromagnetic immunity*

3.1.1. The effect of an electromagnetic disturbance on a gas meter or volume conversion device shall be such that:

— the change in the measurement result is no greater than the critical change value as defined in point 3.1.3, or

— the indication of the measurement result is such that it cannot be interpreted as a valid result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

3.1.2. After undergoing a disturbance, the gas meter shall:

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present just before the disturbance.

3.1.3. The critical change value is the smaller of the two following values:

— the quantity corresponding to half of the magnitude of the MPE in the upper zone on the measured volume;

— the quantity corresponding to the MPE on the quantity corresponding to one minute at maximum flowrate.

3.2. *Effect of upstream-downstream flow disturbances*

Under installation conditions specified by the manufacturer, the effect of the flow disturbances shall not exceed one third of the MPE.

4. **Durability**

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

4.1. *Class 1,5 $3*

4.1.1. The variation of the measurement result after the durability test when compared with the initial measurement result for the flow rates in the range Q_t to Q_{max}- shall not exceed the measurement result by more than 2 %.

4.1.2. The error of indication after the durability test shall not exceed twice the MPE in point 2.

4.2. *Class 1,0 $3*

4.2.1. The variation of the measurement result after the durability test when compared with the initial measurement result shall not exceed one-third of the MPE in point 2.

4.2.2. The error of indication after the durability test shall not exceed the MPE in point 2.

5. **Suitability**

5.1. A gas meter powered from the mains (AC or DC) shall be provided with an emergency power supply device or other means to ensure, during a failure of the principal power source, that all measuring functions are safeguarded.

5.2. A dedicated power source shall have a lifetime of at least five years. After 90 % of its lifetime an appropriate warning shall be shown.

5.3. An indicating device shall have a sufficient number of digits to ensure that the quantity passed during 8 000 hours at Q_{max} does not return the digits to their initial values.

5.4. The gas meter shall be able to be installed to operate in any position declared by the manufacturer in its installation instruction.

5.5. The gas meter shall have a test element, which shall enable tests to be carried out in a reasonable time.

5.6. The gas meter shall respect the MPE in any flow direction or only in one flow direction clearly marked.

6. **Units**

Metered quantity shall be displayed in cubic metre, or in kilogram.

PART II

SPECIFIC REQUIREMENTS

VOLUME CONVERSION DEVICES

A volume conversion device constitutes a sub-assembly when it is together with a measuring instrument with which it is compatible.

For a volume conversion device, the essential requirements for the gas meter shall apply, if applicable. In addition, the following requirements shall apply:

7. **Base conditions for converted quantities**

The manufacturer shall specify the base conditions for converted quantities.

8. **MPE**

— 0,5 % at ambient temperature 20 °C ± 3 °C, ambient humidity 60 % ± 15 %, nominal values for power supply;

— 0,7 % for temperature conversion devices at rated operating conditions;

— 1 % for other conversion devices at rated operating conditions.

Note:

The error of the gas meter is not taken into account.

The volume conversion device shall not exploit the MPEs or systematically favour any party.

9. **Suitability**

9.1. An electronic conversion device shall be capable of detecting when it is operating outside the operating range(s) stated by the manufacturer for parameters that are relevant for measurement accuracy. In such a case, the conversion device must stop integrating the converted quantity, and may totalise separately the converted quantity for the time it is operating outside the operating range(s).

9.2. An electronic conversion device shall be capable to display all relevant data for the measurement without additional equipment.

PART III

PUTTING INTO USE AND CONFORMITY ASSESSMENT

Putting into use

10. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 1,5 $3, and by Class 1,0 $3 which have a Q_{max}/Q_{min} ratio equal or greater than 150.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class 1,5 USD 3.

(c) As regards the requirements under points 1.2 and 1.3, Member States shall ensure that the properties be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are

B + F or B + D or H1.

ANNEX V

ACTIVE ELECTRICAL ENERGY METERS (MI-003)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to active electrical energy meters intended for residential, commercial and light industrial use.

Note:

Electrical energy meters may be used in combination with external instrument transformers, depending upon the measurement technique applied. However, this Annex covers only electrical energy meters but not instrument transformers.

DEFINITIONS

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit.

I	=	the electrical current flowing through the meter;
I_n	=	the specified reference current for which the transformer operated meter has been designed;
I_{st}	=	the lowest declared value of I at which the meter registers active electrical energy at unity power factor (polyphase meters with balanced load);
I_{min}	=	the value of I above which the error lies within maximum permissible errors (MPEs) (polyphase meters with balanced load);
I_{tr}	=	the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter;
I_{max}	=	the maximum value of I for which the error lies within the MPEs;
U	=	the voltage of the electricity supplied to the meter;
U_n	=	the specified reference voltage;
f	=	the frequency of the voltage supplied to the meter;
f_n	=	the specified reference frequency;
PF	=	power factor = $\cos\varphi$ = the cosine of the phase difference φ between I and U.

SPECIFIC REQUIREMENTS

1. **Accuracy**

The manufacturer shall specify the class index of the meter. The class indices are defined as: Class A, B and C.

2. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions of the meter; in particular:

The values of f_n, U_n, I_n, I_{st}, I_{min}, I_{tr} and I_{max} that apply to the meter. For the current values specified, the meter shall satisfy the conditions given in Table 1;

Table 1

	Class A	Class B	Class C
For direct-connected meters			
I_{st}	$\leq 0{,}05 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$
I_{min}	$\leq 0{,}5 \cdot I_{tr}$	$\leq 0{,}5 \cdot I_{tr}$	$\leq 0{,}3 \cdot I_{tr}$
I_{max}	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$
For transformer-operated meters			
I_{st}	$\leq 0{,}06 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$	$\leq 0{,}02 \cdot I_{tr}$

	Class A	Class B	Class C
I_{min}	$\leq 0{,}4 \cdot I_{tr}$	$\leq 0{,}2 \cdot I_{tr}$ (1)	$\leq 0{,}2 \cdot I_{tr}$
I_n	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$
I_{max}	$\geq 1{,}2 \cdot I_n$	$\geq 1{,}2 \cdot I_n$	$\geq 1{,}2 \cdot I_n$

(1) For Class B electromechanical meters $I_{min} \leq 0{,}4 \cdot I_{tr}$ shall apply.

The voltage, frequency and power factor ranges within which the meter shall satisfy the MPE requirements are specified in Table 2. These ranges shall recognise the typical characteristics of electricity supplied by public distribution systems.

The voltage and frequency ranges shall be at least:

$$0{,}9 \cdot U_n \leq U \leq 1{,}1 \cdot U_n$$

$$0{,}98 \cdot f_n \leq f \leq 1{,}02 \cdot f_n$$

power factor range at least from $\cos\varphi = 0{,}5$ inductive to $\cos\varphi = 0{,}8$ capacitive.

3. **MPEs**

The effects of the various measurands and influence quantities (a, b, c,…) are evaluated separately, all other measurands and influence quantities being kept relatively constant at their reference values. The error of measurement, that shall not exceed the MPE stated in Table 2, is calculated as:

Error of measurement $= \sqrt{(a^2 + b^2 + c^2 \ldots)}$

When the meter is operating under varying-load current, the percentage errors shall not exceed the limits given in Table 2.

Table 2

MPEs in percent at rated operating conditions and defined load current levels and operating temperature

	Operating temperatures			Operating temperatures			Operating temperatures			Operating temperatures		
	+ 5 °C … + 30 °C			– 10 °C … + 5 °C or + 30 °C … + 40 °C			– 25 °C … – 10 °C or + 40 °C … + 55 °C			– 40 °C … – 25 °C or + 55 °C … + 70 °C		
Meter class	A	B	C	A	B	C	A	B	C	A	B	C
Single phase meter; polyphase meter if operating with balanced loads												
$I_{min} \leq I < I_{tr}$	3,5	2	1	5	2,5	1,3	7	3,5	1,7	9	4	2
$I_{tr} \leq I \leq I_{max}$	3,5	2	0,7	4,5	2,5	1	7	3,5	1,3	9	4	1,5
Polyphase meter if operating with single phase load												
$I_{tr} \leq I \leq I_{max}$, see exception below	4	2,5	1	5	3	1,3	7	4	1,7	9	4,5	2
For electromechanical polyphase meters the current range for single-phase load is limited to $5I_{tr} \leq I \leq I_{max}$												

When a meter operates in different temperature ranges the relevant MPE values shall apply.

The meter shall not exploit the MPEs or systematically favour any party.

4. **Permissible effect of disturbances**

4.1. *General*

As electrical energy meters are directly connected to the mains supply and as mains current is also one of the measurands, a special electromagnetic environment is used for electricity meters.

The meter shall comply with the electromagnetic environment E2 and the additional requirements in points 4.2 and 4.3.

The electromagnetic environment and permissible effects reflect the situation that there are disturbances of long duration which shall not affect the accuracy beyond the critical change values and transient disturbances, which may cause a temporary degradation or loss of function or performance but from which the meter shall recover and shall not affect the accuracy beyond the critical change values.

When there is a foreseeable high risk due to lightning or where overhead supply networks are predominant, the metrological characteristics of the meter shall be protected.

4.2. *Effect of disturbances of long duration*

Table 3

Critical change values for disturbances of long duration

Disturbance	Critical change values in percent for meters of class		
	A	B	C
Reversed phase sequence	1,5	1,5	0,3
Voltage unbalance (only applicable to polyphase meters)	4	2	1
Harmonic contents in the current circuits [1]	1	0,8	0,5
DC and harmonics in the current circuit [1]	6	3	1,5
Fast transient bursts	6	4	2
Magnetic fields; HF (radiated RF) electromagnetic field; Conducted disturbances introduced by radio-frequency fields; and Oscillatory waves immunity	3	2	1

[1] In the case of electromechanical electricity meters, no critical change values are defined for harmonic contents in the current circuits and for DC and harmonics in the current circuit.

4.3. *Permissible effect of transient electromagnetic phenomena*

4.3.1. The effect of an electromagnetic disturbance on an electrical energy meter shall be such that during and immediately after a disturbance:

— any output intended for testing the accuracy of the meter does not produce pulses or signals corresponding to an energy of more than the critical change value,

and in reasonable time after the disturbance the meter shall:

— recover to operate within the MPE limits, and

— have all measurement functions safeguarded, and

— allow recovery of all measurement data present prior to the disturbance, and

— not indicate a change in the registered energy of more than the critical change value.

The critical change value in kWh is $m \cdot U_n \cdot I_{max} \cdot 10^{-6}$

(m being the number of measuring elements of the meter, U_n in Volts and I_{max} in Amps).

4.3.2. For overcurrent the critical change value is 1,5 %.

5. **Suitability**

5.1. Below the rated operating voltage the positive error of the meter shall not exceed 10 %.

5.2. The display of the total energy shall have a sufficient number of digits to ensure that when the meter is operated for 4 000 hours at full load ($I = I_{max}$, $U = U_n$ and PF = 1) the indication does not return to its initial value and shall not be able to be reset during use.

5.3. In the event of loss of electricity in the circuit, the amounts of electrical energy measured shall remain available for reading during a period of at least 4 months.

5.4. *Running with no load*

When the voltage is applied with no current flowing in the current circuit (current circuit shall be open circuit), the meter shall not register energy at any voltage between $0{,}8 \cdot U_n$ and $1{,}1\ U_n$.

5.5. *Starting*

The meter shall start and continue to register at U_n, PF = 1 (polyphase meter with balanced loads) and a current which is equal to I_{st}.

6. **Units**

The electrical energy measured shall be displayed in kilowatt-hours or in megawatt-hours.

7. **Putting into use**

(a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class A meter. For specified purposes the Member State is authorised to require any Class B meter.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it shall allow such measurement to be performed by any Class B meter. For specified purposes the Member State is authorised to require any Class C meter.

(c) The Member State shall ensure that the current range be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX VI

THERMAL ENERGY METERS (MI-004)

The relevant requirements of Annex I, the specific requirements and the conformity assessment procedures listed in this Annex, apply to thermal energy meters defined below, intended for residential, commercial and light industrial use.

DEFINITIONS

A thermal energy meter is an instrument designed to measure the thermal energy which, in a thermal energy exchange circuit, is given up by a liquid called the thermal energy-conveying liquid.

A thermal energy meter is either a complete instrument or a combined instrument consisting of the sub-assemblies, flow sensor, temperature sensor pair, and calculator, as defined in Article 4(2), or a combination thereof

ϑ	=	the temperature of the thermal energy-conveying liquid;
ϑ_{in}	=	the value of ϑ at the inlet of the thermal energy exchange circuit;
ϑ_{out}	=	the value of ϑ at the outlet of the thermal energy exchange circuit;
$\Delta\vartheta$	=	the temperature difference ϑ_{in} — ϑo_{ut} with $\Delta_{\vartheta} \geq 0$;
ϑ_{max}	=	the upper limit of ϑ for the thermal energy meter to function correctly within the MPEs;
ϑ_{min}	=	the lower limit of ϑ for the thermal energy meter to function correctly within the MPEs;
$\Delta\vartheta_{max}$	=	the upper limit of $\Delta\vartheta$ for the thermal energy meter to function correctly within the MPEs;
$\Delta\vartheta_{min}$	=	the lower limit of $\Delta\vartheta$ for the thermal energy meter to function correctly within the MPEs;
q	=	the flow rate of the thermal energy conveying liquid;
q_s	=	the highest value of q that is permitted for short periods of time for the thermal energy meter to function correctly;
q_p	=	the highest value of q that is permitted permanently for the thermal energy meter to function correctly;
q_i	=	the lowest value of q that is permitted for the thermal energy meter to function correctly;
P	=	the thermal power of the thermal energy exchange;
P_s	=	the upper limit of P that is permitted for the thermal energy meter to function correctly.

SPECIFIC REQUIREMENTS

1. **Rated operating conditions**

The values of the rated operating conditions shall be specified by the manufacturer as follows:

1.1. For the temperature of the liquid: ϑ_{max}, ϑ_{min},

— for the temperature differences: $\Delta\vartheta_{max}$, $\Delta\vartheta_{min}$,

subject to the following restrictions: $\Delta\vartheta_{max}/\Delta\vartheta_{min} \geq 10$; $\Delta\vartheta_{min}$ = 3 K or 5 K or 10 K.

1.2. For the pressure of the liquid: The maximum positive internal pressure that the thermal energy meter can withstand permanently at the upper limit of the temperature.

1.3. For the flow rates of the liquid: q_s, q_p, q_i, where the values of q_p and q_i are subject to the following restriction: $q_p/q_i \geq 10$.

1.4. For the thermal power: P_s.

2. **Accuracy classes**

The following accuracy classes are defined for thermal energy meters: 1, 2, 3.

3. **MPEs applicable to complete thermal energy meters**

The maximum permissible relative errors applicable to a complete thermal energy meter, expressed in percent of the true value for each accuracy class, are:

— For class 1: $E = E_f + E_t + E_c$, with E_f, E_t, E_c according to points 7.1 to 7.3.

— For class 2: $E = E_f + E_t + E_c$, with E_f, E_t, E_c according to points 7.1 to 7.3.

— For class 3: $E = E_f + E_t + E_c$, with E_f, E_t, E_c according to points 7.1 to 7.3.

The complete thermal energy meter shall not exploit the MPEs or systematically favour any party.

4. **Permissible influences of electromagnetic disturbances**

4.1. The instrument shall not be influenced by static magnetic fields and by electromagnetic fields at mains frequency.

4.2. The influence of an electromagnetic disturbance shall be such that the change in the measurement result is not greater than the critical change value as laid down in requirement 4.3 or the indication of the measurement result is such that it cannot be interpreted as a valid result.

4.3. The critical change value for a complete thermal energy meter is equal to the absolute value of the MPE applicable to that thermal energy meter (see point (3).

5. **Durability**

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criteria shall be satisfied:

5.1. Flow sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the critical change value.

5.2. Temperature sensors: The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed 0,1 °C.

6. **Inscriptions on a thermal energy meter**

— Accuracy class

— Limits of flow rate

— Limits of temperature

— Limits of temperature difference

— Place of the flow sensor installation: flow or return

— Indication of the direction of flow

7. **Sub-assemblies**

The provisions for sub-assemblies may apply to sub-assemblies manufactured by the same or different manufacturers. Where a thermal energy meter consists of sub-assemblies, the essential requirements for the thermal energy meter apply to the sub-assemblies as relevant. In addition, the following apply:

7.1. The relative MPE of the flow sensor, expressed in %, for accuracy classes:

— Class 1: $E_f = (1 + 0{,}01\ q_p/q)$, but not more than 5 %,

— Class 2: $E_f = (2 + 0{,}02\ q_p/q)$, but not more than 5 %,

— Class 3: $E_f = (3 + 0{,}05\ q_p/q)$, but not more than 5 %,

where the error E_f relates the indicated value to the true value of the relationship between flow sensor output signal and the mass or the volume.

7.2. The relative MPE of the temperature sensor pair, expressed in %:

— $E_t = (0{,}5 + 3 \cdot \Delta\vartheta_{min}/\Delta\vartheta)$,

where the error E_t relates the indicated value to the true value of the relationship between temperature sensor pair output and temperature difference.

7.3. The relative MPE of the calculator, expressed in %:

— $E_c = (0{,}5 + \Delta\vartheta_{min}/\Delta\vartheta)$,

where the error E_c relates the value of the thermal energy indicated to the true value of the thermal energy.

7.4. The critical change value for a sub-assembly of a thermal energy meter is equal to the respective absolute value of the MPE applicable to the sub-assembly (see points 7.1, 7.2 or 7.3).

7.5. Inscriptions on the sub-assemblies

Flow sensor:	Accuracy class
	Limits of flow rate
	Limits of temperature
	Nominal meter factor (e.g. litres/pulse) or corresponding output signal
	Indication of the direction of flow
Temperature sensor pair:	Type identification (e.g. P_t 100)
	Limits of temperature
	Limits of temperature difference
Calculator:	Type of temperature sensors — Limits of temperature — Limits of temperature difference — Required nominal meter factor (e.g. litres/pulse) or corresponding input signal coming from the flow sensor — Place of the flow sensor installation: flow or return

PUTTING INTO USE

8. (a) Where a Member State imposes measurement of residential use, it shall allow such measurement to be performed by means of any Class 3 meter.

(b) Where a Member State imposes measurement of commercial and/or light industrial use, it is authorised to require any Class 2 meter.

(c) As regards the requirements under points 1.1 to 1.4, Member States shall ensure that the properties be determined by the utility or the person legally designated for installing the meter, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX VII

MEASURING SYSTEMS FOR THE CONTINUOUS AND DYNAMIC MEASUREMENT OF QUANTITIES OF LIQUIDS OTHER THAN WATER (MI-005)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to measuring systems intended for the continuous and dynamic measurement of quantities (volumes or masses) of liquids other than water. If appropriate, the terms 'volume, and L' in this Annex can be read as: 'mass and kg'.

DEFINITIONS

Meter	An instrument designed to measure continuously, memorise and display the quantity at metering conditions of liquid flowing through the measurement transducer in a closed, fully charged conduit.
Calculator	A part of a meter that receives the output signals from the measurement transducer(s) and possibly, from associated measuring instruments and displays the measurement results.
Associated measuring instrument	An instrument connected to the calculator for measuring certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.
Conversion Device	A part of the calculator which by taking account of the characteristics of the liquid (temperature, density, etc.) measured using associated measuring instruments, or stored in a memory, automatically converts: — the volume of the liquid measured at metering conditions into a volume at base conditions and/or into mass, or — the mass of the liquid measured at metering conditions into a volume at metering conditions and/or into a volume at base conditions Note: A conversion device includes the relevant associated measuring instruments.
Base conditions	The specified conditions to which the measured quantity of liquid at metering conditions is converted.
Measuring System	A system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.
Fuel dispenser	A measuring system intended for the refuelling of motor vehicles, small boats and small aircraft.
Self-service arrangement	An arrangement that allows the customer to use a measuring system for the purpose of obtaining liquid for his own use.
Self-service device	A specific device that is part of a self-service arrangement and which allows one of more measuring systems to perform in this self-service arrangement.
Minimum measured quantity (MMQ)	The smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.
Direct indication	The indication, either volume or mass, corresponding to the measure and that the meter is physically capable of measuring. Note: The direct indication may be converted into another quantity using a conversion device.
Interruptible/non-interruptible	A measuring system is considered as interruptible/non-interruptible when the liquid flow can/cannot be stopped easily and rapidly.
Flowrate range	The range between the minimum flowrate (Q_{min}) and maximum flowrate (Q_{max}).

SPECIFIC REQUIREMENTS

1. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions for the instrument, in particular;

1.1. *The flowrate range*

The flowrate range is subject to the following conditions:

(i) the flowrate range of a measuring system shall be within the flowrate range of each of its elements, in particular the meter.

(ii) meter and measuring system:

Table 1

Specific measuring system	Characteristic of liquid	Minimum ratio of Q_{max}: Q_{min}
Fuel dispensers	Not Liquefied gases	10: 1
	Liquefied gases	5: 1
Measuring system	Cryogenic liquids	5: 1
Measuring systems on pipeline and systems for loading ships	All liquids	Suitable for use
All other measuring systems	All liquids	4: 1

1.2. The properties of the liquid to be measured by the instrument by specifying the name or type of the liquid or its relevant characteristics, for example:

— Temperature range;

— Pressure range;

— Density range;

— Viscosity range.

1.3. The nominal value of the AC voltage supply and/or limits of the DC voltage supply.

1.4. The base conditions for converted values.

Note:

Point 1.4 is without prejudice to the Member States' obligations to require use of a temperature of either 15 °C in accordance with Article 12(2) of Council Directive 2003/96/EC of 27 October 2003 restructuring the Community framework for the taxation of energy products and electricity [1].

2. **Accuracy classification and maximum permissible errors (MPEs)**

2.1. For quantities equal to or greater than 2 litres the MPE on indications is:

Table 2

	Accuracy Class				
	0,3	0,5	1,0	1,5	2,5
Measuring systems (A)	0,3 %	0,5 %	1,0 %	1,5 %	2,5 %
Meters (B)	0,2 %	0,3 %	0,6 %	1,0 %	1,5 %

[1] OJ L 283, 31.10.2003, p. 51.

2.2. For quantities less than two litres the MPE on indications is:

Table 3

Measured volume V	MPE
V < 0,1 l	4 × value in Table 2, applied to 0,1 L
0,1 l ≤ V < 0,2 l	4 × value in Table 2
0,2 l ≤ V < 0,4 l	2 × value in Table 2, applied to 0,4 L
0,4 l ≤ V < 1 l	2 × value in Table 2
1 l ≤ V < 2 l	Value in Table 2, applied to 2 L

2.3. However, no matter what the measured quantity may be, the magnitude of the MPE is given by the greater of the following two values:

— the absolute value of the MPE given in Table 2 or Table 3,

— the absolute value of the MPE for the minimum measured quantity (E_{min}).

2.4.1. For minimum measured quantities greater than or equal to 2 litres the following conditions apply:

Condition 1

E_{min} shall fulfil the condition: $E_{min} \geq 2$ R, where R is the smallest scale interval of the indication device.

Condition 2

E_{min} is given by the formula: $E_{min} = (2MMQ) \times (A/100)$, where:

— MMQ is the minimum measured quantity,

— A is the numerical value specified in line A of Table 2.

2.4.2. For minimum measured quantities of less than two litres, the above mentioned condition 1 applies and E_{min} is twice the value specified in Table 3, and related to line A of Table 2.

2.5. *Converted indication*

In the case of a converted indication the MPEs are as in line A of Table 2.

2.6. *Conversion devices*

MPEs on converted indications due to a conversion device are equal to ± (A — B), A and B being the values specified in Table 2.

Parts of conversion devices that can be tested separately

(a) Calculator

MPEs on quantities of liquid indications applicable to calculation, positive or negative, are equal to one-tenth of the MPEs as defined in line A of Table 2.

(b) Associated measuring instruments

Associated measuring instruments shall have an accuracy at least as good as the values in Table 4:

Table 4

MPE on Measurements	Accuracy classes of the measuring system				
	0,3	0,5	1,0	1,5	2,5
Temperature	± 0,3 °C	± 0,5 °C			± 1,0 °C

MPE on Measurements	Accuracy classes of the measuring system				
	0,3	0,5	1,0	1,5	2,5
Pressure	Less than 1 MPa: ± 50 kPa From 1 to 4 MPa: ± 5 % Over 4 MPa: ± 200 kPa				
Density	± 1 kg/m^3		± 2 kg/m^3		± 5 kg/m^3

These values apply to the indication of the characteristic quantities of the liquid displayed by the conversion device.

(c) Accuracy for calculating function

The MPE for the calculation of each characteristic quantity of the liquid, positive or negative, is equal to two fifths of the value fixed in (b).

2.7. The requirement (a) in point 2.6 applies to any calculation, not only conversion.

2.8. The measuring system shall not exploit the MPEs or systematically favour any party.

3. **Maximum permissible effect of disturbances**

3.1. The effect of an electromagnetic disturbance on a measuring system shall be one of the following:

— the change in the measurement result is not greater than the critical change value as defined in point 3.2, or

— the indication of the measurement result shows a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result. Furthermore, in the case of an interruptible system, this can also mean the impossibility to perform any measurement, or

— the change in the measurement result is greater than the critical change value, in which case the measuring system shall permit the retrieval of the measuring result just before the critical change value occurred and cut off the flow.

3.2. The critical change value is the greater of MPE/5 for a particular measured quantity or E_{min}.

4. **Durability**

After an appropriate test, taking into account the period of time estimated by the manufacturer, has been performed, the following criterion shall be satisfied:

The variation of the measurement result after the durability test, when compared with the initial measurement result, shall not exceed the value for meters specified in line B of table 2.

5. **Suitability**

5.1. For any measured quantity relating to the same measurement, the indications provided by various devices shall not deviate one from another by more than one scale interval where devices have the same scale interval. In the case where the devices have different scale intervals, the deviation shall not be more than that of the greatest scale interval.

However, in the case of a self-service arrangement the scale intervals of the main indicating device on the measuring system and the scale intervals of the self-service device shall be the same and results of measurement shall not deviate one from another.

5.2. It shall not be possible to divert the measured quantity in normal conditions of use unless it is readily apparent.

5.3. Any percentage of air or gas not easily detectable in the liquid shall not lead to a variation of error greater than:

— 0,5 % for liquids other than potable liquids and for liquids of a viscosity not exceeding 1 mPa.s, or

— 1 % for potable liquids and for liquids of a viscosity exceeding 1 mPa.s.

However, the allowed variation shall never be smaller than 1 % of MMQ. This value applies in the case of air or gas pockets.

5.4. *Instruments for direct sales*

5.4.1. A measuring system for direct sales shall be provided with means for resetting the display to zero.

It shall not be possible to divert the measured quantity.

5.4.2. The display of the quantity on which the transaction is based shall be permanent until all parties in the transaction have accepted the measurement result.

5.4.3. Measuring systems for direct sales shall be interruptible.

5.4.4. Any percentage of air or gas in the liquid shall not lead to a variation of error greater than the values specified in point 5.3.

5.5. *Fuel Dispensers*

5.5.1. Displays on fuel dispensers shall not be capable of being reset to zero during a measurement.

5.5.2. The start of a new measurement shall be inhibited until the display has been reset to zero.

5.5.3. Where a measuring system is fitted with a price display, the difference between the indicated price and the price calculated from the unit price and the indicated quantity shall not exceed the price corresponding to E_{min}. However this difference need not be less than the smallest monetary value.

6. **Power supply failure**

A measuring system shall either be provided with an emergency power supply device that will safeguard all measuring functions during the failure of the main power supply device or be equipped with means to save and display the data present in order to permit the conclusion of the transaction in progress and with means to stop the flow at the moment of the failure of the main power supply device.

7. **Putting into use**

Table 5

Accuracy Class	Types of Measuring system
0,3	Measuring systems on pipeline
0,5	All measuring systems if not differently stated elsewhere in this Table, in particular: — fuel dispensers (not for liquefied gases), — measuring systems on road tankers for liquids of low viscosity (< 20 mPa.s) — measuring systems for (un)loading ships and rail and road tankers ([1]) — measuring systems for milk — measuring systems for refuelling aircraft
1,0	Measuring systems for liquefied gases under pressure measured at a temperature equal to or above – 10 °C
	Measuring systems normally in class 0,3 or 0,5 but used for liquids — whose temperature is less than – 10 °C or greater than 50 °C — whose dynamic viscosity is higher than 1 000 mPa.s — whose maximum volumetric flowrate is not higher than 20 L/h
1,5	Measuring systems for liquefied carbon dioxide
	Measuring systems for liquefied gases under pressure measured at a temperature below – 10 °C (other than cryogenic liquids)
2,5	measuring systems for cryogenic liquids (temperature below – 153 °C)

([1]) However, Member States may require measuring systems of accuracy class 0,3 or 0,5 when used for the levying of duties on mineral oils when (un)loading ships and rail and road tankers.
Note: However, the manufacturer may specify a better accuracy for a certain type of measuring system.

8. **Units of measurement**

The metered quantity shall be displayed in millilitres, cubic centimetres, litres, cubic metres, grams, kilograms or tonnes.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1 or G.

ANNEX VIII

AUTOMATIC WEIGHING INSTRUMENTS (MI-006)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in Chapter I of this Annex, apply to automatic weighing instruments defined below, intended to determine the mass of a body by using the action of gravity on that body.

DEFINITIONS

Automatic weighing instrument	An instrument that determines the mass of a product without the intervention of an operator and follows a predetermined programme of automatic processes characteristic of the instrument.
Automatic catchweigher	An automatic weighing instrument that determines the mass of pre-assembled discrete loads (for example prepackages) or single loads of loose material.
Automatic checkweigher	An automatic catchweigher that subdivides articles of different mass into two or more subgroups according to the value of the difference of their mass and a nominal set-point.
Weight labeller	An automatic catchweigher that labels individual articles with the weight value.
Weight/price labeller	An automatic catchweigher that labels individual articles with the weight value, and price information.
Automatic gravimetric filling instrument	An automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk.
Discontinuous totaliser (totalising hopper weigher)	An automatic weighing instrument that determines the mass of a bulk product by dividing it into discrete loads. The mass of each discrete load is determined in sequence and summed. Each discrete load is then delivered to bulk.
Continuous totaliser	An automatic weighing instrument that continuously determines the mass of a bulk product on a conveyor belt, without systematic subdivision of the product and without interrupting the movement of the conveyor belt.
Rail-weighbridge	An automatic weighing instrument having a load receptor inclusive of rails for conveying railway vehicles.

SPECIFIC REQUIREMENTS

CHAPTER I

Requirements common to all types of automatic weighing instruments

1. **Rated Operating Conditions**

The manufacturer shall specify the rated operating conditions for the instrument as follows:

1.1. For the measurand:

The measuring range in terms of its maximum and minimum capacity.

1.2. For the electrical supply influence quantities:

In case of AC voltage supply	:	the nominal AC voltage supply, or the AC voltage limits.
In case of DC voltage supply	:	the nominal and minimum DC voltage supply, or the DC voltage limits.

1.3. For the mechanical and climatic influence quantities:

The minimum temperature range is 30 °C unless specified otherwise in the following chapters of this Annex.

The mechanical environment classes according to Annex I, point 1.3.2 are not applicable. For instruments which are used under special mechanical strain, e.g. instruments incorporated into vehicles, the manufacturer shall define the mechanical conditions of use.

1.4. For other influence quantities (if applicable):

The rate(s) of operation.

The characteristics of the product(s) to be weighed.

2. **Permissible effect of disturbances — Electromagnetic environment**

The required performance and the critical change value are given in the relevant Chapter of this Annex for each type of instrument.

3. **Suitability**

3.1. Means shall be provided to limit the effects of tilt, loading and rate of operation such that maximum permissible errors (MPEs) are not exceeded in normal operation.

3.2. Adequate material handling facilities shall be provided to enable the instrument to respect the MPEs during normal operation.

3.3. Any operator control interface shall be clear and effective.

3.4. The integrity of the display (where present) shall be verifiable by the operator.

3.5. Adequate zero setting capability shall be provided to enable the instrument to respect the MPEs during normal operation.

3.6. Any result outside the measurement range shall be identified as such, where a printout is possible.

4. **Conformity assessment**

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

For mechanical systems:

B + D or B + E or B + F or D1 or F1 or G or H1.

For electromechanical instruments:

B + D or B + E or B + F or G or H1.

For electronic systems or systems containing software:

B + D or B + F or G or H1.

CHAPTER II

Automatic Catchweighers

1. **Accuracy Classes**

1.1. Instruments are divided into primary categories designated by:

X or Y

as specified by the manufacturer.

1.2. These primary categories are further divided into four accuracy classes:

XI, XII, XIII & XIIII

and

Y(I), Y(II), Y(a) & Y(b)

which shall be specified by the manufacturer.

2. **Category X Instruments**

2.1. Category X applies to instruments used to check prepackages made up in accordance with the requirements of Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products [1] applicable to prepackages.

2.2. The accuracy classes are supplemented by a factor (x) that quantifies the maximum permissible standard deviation as specified in point 4.2.

The manufacturer shall specify the factor (x), where (x) shall be ≤ 2 and in the form 1×10^k, 2×10^k or 5×10^k, where k is a negative whole number or zero.

3. **Category Y Instruments**

Category Y applies to all other automatic catchweighers.

4. **MPE**

4.1. *Mean error Category X/MPE Category Y instruments*

Table 1

Net Load (m) in verification scale intervals (e)								Maximum permissible mean error	Maximum permissible error
XI	Y(I)	XII	Y(II)	XIII	Y(a)	XIIII	Y(b)	X	Y
0 < m ≤ 50 000		0 < m ≤ 5 000		0 < m ≤ 500		0 < m ≤ 50		± 0,5 e	± 1 e
50 000 < m ≤ 200 000		5 000 < m ≤ 20 000		500 < m ≤ 2 000		50 < m ≤ 200		± 1,0 e	± 1,5 e
200 000 < m		20 000 < m ≤ 100 000		2 000 < m ≤ 10 000		200 < m ≤ 1 000		± 1,5 e	± 2 e

4.2. *Standard deviation*

Maximum permissible value for the standard deviation of a class X (x) instrument is the result of the multiplication of the factor (x) by the value in Table 2 below.

Table 2

Net Load (m)	Maximum permissible standard deviation for class X(1)
m ≤ 50 g	0,48 %
50 g < m ≤ 100 g	0,24 g
100 g < m ≤ 200 g	0,24 %
200 g < m ≤ 300 g	0,48 g
300 g < m ≤ 500 g	0,16 %
500 g < m ≤ 1 000 g	0,8 g
1 000 g < m ≤ 10 000 g	0,08 %
10 000 g < m ≤ 15 000 g	8 g
15 000 g < m	0,053 %

For class XI and XII (x) shall be less than 1.

For class XIII (x) shall be not greater than 1.

[1] OJ L 46, 21.2.1976, p. 1.

For class XIIII (x) shall be greater than 1.

4.3. *Verification scale interval — single interval instruments*

Table 3

Accuracy classes		Verification scale interval	Number of verification scale intervals n = Max/e	
			Minimum	Maximum
XI	Y(I)	0,001 g ≤ e	50 000	—
XII	Y(II)	0,001 g ≤ e ≤ 0,05 g	100	100 000
		0,1 g ≤ e	5 000	100 000
XIII	Y(a)	0,1 g ≤ e ≤ 2 g	100	10 000
		5 g ≤ e	500	10 000
XIIII	Y(b)	5 g ≤ e	100	1 000

4.4. *Verification scale interval — multi-interval instruments*

Table 4

Accuracy classes		Verification scale interval	Number of verification scale intervals n = Max/e	
			Minimum value [1] $n = Max_i/e_{(i+1)}$	Maximum value $n = Max_i/e_i$
XI	Y(I)	0,001 g ≤ e_i	50 000	—
XII	Y(II)	0,001 g ≤ e_i ≤ 0,05 g	5 000	100 000
		0,1 g ≤ e_i	5 000	100 000
XIII	Y(a)	0,1 g ≤ e_i	500	10 000
XIIII	Y(b)	5 g ≤ e_i	50	1 000

[1] For i = r the corresponding column of Table 3 applies with e replaced by e_r.

Where:

i = 1, 2, … r

i = partial weighing range

r = total number of partial ranges

5. **Measurement Range**

In specifying the measurement range for class Y instruments the manufacturer shall take account that the minimum capacity shall not be less than:

class Y(I)	:	100 e
class Y(II)	:	20 e for 0,001 g ≤ e ≤ 0,05 g, and 50 e for 0,1 g ≤ e
class Y(a)	:	20 e
class Y(b)	:	10 e
Scales used for grading, e.g. postal scales and garbage weighers	:	5 e

6. **Dynamic Setting**

6.1. The dynamic setting facility shall operate within a load range specified by the manufacturer.

6.2. When fitted, a dynamic setting facility that compensates for the dynamic effects of the load in motion shall be inhibited from operating outside the load range, and shall be capable of being secured.

7. **Performance Under Influence Factors And Electromagnetic Disturbances**

7.1. The MPEs due to influence factors are:

7.1.1. For category X instruments:

— For automatic operation; as specified in Tables 1 and 2,

— For static weighing in non-automatic operation; as specified in Table 1.

7.1.2. For category Y instruments

— For each load in automatic operation; as specified in Table 1,

— For static weighing in non-automatic operation; as specified for category X in Table 1.

7.2. The critical change value due to a disturbance is one verification scale interval.

7.3. Temperature range:

— For class XI and Y(I) the minimum range is 5 °C,

— For class XII and Y(II) the minimum range is 15 °C.

CHAPTER III

Automatic Gravimetric Filling Instruments

1. **Accuracy classes**

1.1. The manufacturer shall specify both the reference accuracy class Ref(x) and the operational accuracy class(es) X(x).

1.2. An instrument type is designated a reference accuracy class, Ref(x), corresponding to the best possible accuracy for instruments of the type. After installation, individual instruments are designated for one or more operational accuracy classes, X(x), having taken account of the specific products to be weighed. The class designation factor (x) shall be ≤ 2, and in the form 1×10^k, 2×10^k or 5×10^k where k is a negative whole number or zero.

1.3. The reference accuracy class, Ref(x) is applicable for static loads.

1.4. For the operational accuracy class X(x), X is a regime relating accuracy to load weight and (x) is a multiplier for the limits of error specified for class X(1) in point 2.2.

2. **MPE**

2.1. *Static weighing error*

2.1.1. For static loads under rated operating conditions, the MPE for reference accuracy class Ref(x), shall be 0,312 of the maximum permissible deviation of each fill from the average; as specified in Table 5; multiplied by the class designation factor (x).

2.1.2. For instruments where the fill may be made up from more than one load (e.g. cumulative or selective combination weighers) the MPE for static loads shall be the accuracy required for the fill as specified in point 2.2 (i.e. not the sum of the maximum permissible deviation for the individual loads).

2.2. *Deviation from average fill*

Table 5

Value of the mass, m (g), of the fills	Maximum permissible deviation of each fill from the average for class X(1)
m ≤ 50	7,2 %
50 < m ≤ 100	3,6 g
100 < m ≤ 200	3,6 %
200 < m ≤ 300	7,2 g
300 < m ≤ 500	2,4 %
500 < m ≤ 1 000	12 g
1 000 < m ≤ 10 000	1,2 %
10 000 < m ≤ 15 000	120 g
15 000 < m	0,8 %

Note:

The calculated deviation of each fill from the average may be adjusted to take account for the effect of material particle size.

2.3. *Error relative to pre-set value (setting error)*

For instruments where it is possible to pre-set a fill weight; the maximum difference between the pre-set value and the average mass of the fills shall not exceed 0,312 of the maximum permissible deviation of each fill from the average, as specified in Table 5.

3. **Performance Under Influence Factor And Electromagnetic Disturbance**

3.1. The MPE due to influence factors shall be as specified in point 2.1.

3.2. The critical change value due to a disturbance is a change of the static weight indication equal to the MPE as specified in point 2.1 calculated for the rated minimum fill, or a change that would give equivalent effect on the fill in the case of instruments where the fill consists of multiple loads. The calculated critical change value shall be rounded to the next higher scale interval (d).

3.3. The manufacturer shall specify the value of the rated minimum fill.

CHAPTER IV

Discontinuous Totalisers

1. **Accuracy Classes**

Instruments are divided into four accuracy classes as follows: 0,2; 0,5; 1; 2.

2. **MPEs**

Table 6

Accuracy class	MPE of totalised load
0,2	± 0,10 %
0,5	± 0,25 %
1	± 0,50 %
2	± 1,00 %

3. **Totalisation scale interval**

The totalisation scale interval (d_t) shall be in the range:

0,01 % Max ≤ d_t ≤ 0,2 % Max

4. **Minimum Totalised Load (Σ_{min})**

The minimum totalised load (Σ_{min}) shall be not less than the load at which the MPE is equal to the totalisation scale interval (d_t) and not less than the minimum load as specified by the manufacturer.

5. **Zero Setting**

Instruments that do not tare weigh after each discharge shall have a zero setting device. Automatic operation shall be inhibited if zero indication varies by:

— 1 d_t on instruments with automatic zero setting device;

— 0,5 d_t on instruments with a semi-automatic, or non-automatic, zero setting device.

6. **Operator Interface**

Operator adjustments and reset function shall be inhibited during automatic operation.

7. **Printout**

On instruments equipped with a printing device, the reset of the total shall be inhibited until the total is printed. The printout of the total shall occur if automatic operation is interrupted.

8. **Performance under influence factors and electromagnetic disturbances**

8.1. The MPEs due to influence factors shall be as specified in Table 7.

Table 7

Load (m) in totalisation scale intervals (d_t)	MPE
0 < m ≤ 500	± 0,5 d_t
500 < m ≤ 2 000	± 1,0 d_t
2 000 < m ≤ 10 000	± 1,5 d_t

8.2. The critical change value due to a disturbance is one totalisation scale interval for any weight indication and any stored total.

CHAPTER V

Continuous Totalisers

1. **Accuracy classes**

Instruments are divided into three accuracy classes as follows: 0,5; 1; 2.

2. **Measurement Range**

2.1. The manufacturer shall specify the measurement range, the ratio between the minimum net load on the weighing unit and the maximum capacity, and the minimum totalised load.

2.2. The minimum totalised load Σ_{min} shall not be less than

800 d for class 0.5,

400 d for class 1,

200 d for class 2.

Where d is the totalisation scale interval of the general totalisation device.

3. **MPE**

Table 8

Accuracy class	MPE for totalised load
0,5	± 0,25 %
1	± 0,5 %
2	± 1,0 %

4. **Speed of the belt**

The speed of the belt shall be specified by the manufacturer. For single-speed beltweighers, and variable-speed beltweighers having a manual speed setting control, the speed shall not vary by more than 5 % of the nominal value. The product shall not have a different speed than the speed of the belt.

5. **General Totalisation Device**

It shall not be possible to reset the general totalisation device to zero.

6. **Performance under influence factors and electromagnetic disturbances**

6.1. The MPE due to influence factor, for a load not less than the Σ_{min}, shall be 0,7 times the appropriate value specified in Table 8, rounded to the nearest totalisation scale interval (d).

6.2. The critical change value due to a disturbance shall be 0,7 times the appropriate value specified in Table 8, for a load equal to Σ_{min}, for the designated class of the beltweigher; rounded up to the next higher totalisation scale interval (d).

CHAPTER VI

Automatic Rail Weighbridges

1. **Accuracy classes**

Instruments are divided into four accuracy classes as follows:

0,2; 0,5; 1; 2.

2. **MPE**

2.1. The MPEs for weighing-in-motion of a single wagon or a total train are shown in Table 9.

Table 9

Accuracy class	MPE
0,2	± 0,1 %
0,5	± 0,25 %
1	± 0,5 %
2	± 1,0 %

2.2. The MPEs for the weight of coupled or uncoupled wagons weighing-in-motion shall be one of the following values, whichever is the greatest:

— the value calculated according to Table 9, rounded to the nearest scale interval;

— the value calculated according to Table 9, rounded to the nearest scale interval for a weight equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings);

— one scale interval (d).

2.3. The MPEs for the weight of train weighing-in-motion shall be one of the following values, whichever is the greatest:

— the value calculated according to Table 9, rounded to the nearest scale interval;

— the value calculated according to Table 9, for the weight of a single wagon equal to 35 % of the maximum wagon weight (as inscribed on the descriptive markings) multiplied by the number of reference wagons (not exceeding 10) in the train, and rounded to the nearest scale interval;

— one scale interval (d) for each wagon in the train, but not exceeding 10 d.

2.4. When weighing coupled wagons; the errors of not more than 10 % of the weighing results taken from one or more passes of the train may exceed the appropriate MPE given in point 2.2, but shall not exceed twice the MPE.

3. **Scale interval (d)**

The relationship between the accuracy class and the scale interval shall be as specified in Table 10.

Table 10

Accuracy class	Scale interval (d)
0,2	d ≤ 50 kg
0,5	d ≤ 100 kg
1	d ≤ 200 kg
2	d ≤ 500 kg

4. **Measurement range**

4.1. The minimum capacity shall not be less than 1 t, and not greater than the value of the result of the minimum wagon weight divided by the number of partial weighings.

4.2. The minimum wagon weight shall not be less than 50 d.

5. **Performance under influence factor and electromagnetic disturbance**

5.1. The MPE due to an influence factor shall be as specified in Table 11.

Table 11

Load (m) in verification scale intervals (d)	MPE
0 < m ≤ 500	± 0,5 d
500 < m ≤ 2 000	± 1,0 d
2 000 < m ≤ 10 000	± 1,5 d

5.2. The critical change value due to a disturbance is one scale interval.

ANNEX IX

TAXIMETERS (MI-007)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex apply to taximeters.

DEFINITIONS

Taximeter

A device that works together with a signal generator [1] to make a measuring instrument.

This device measures duration, calculates distance on the basis of a signal delivered by the distance signal generator. Additionally, it calculates and displays the fare to be paid for a trip on the basis of the calculated distance and/or the measured duration of the trip.

Fare

The total amount of money due for a trip based on a fixed initial hire fee and/or the length and/or the duration of the trip. The fare does not include a supplement charged for extra services.

Cross-over speed

The speed value found by division of a time tariff value by a distance tariff value.

Normal calculation mode S (single application of tariff)

Fare calculation based on application of the time tariff below the cross-over speed and application of the distance tariff above the cross-over speed.

Normal calculation mode D (double application of tariff)

Fare calculation based on simultaneous application of time tariff and distance tariff over the whole trip.

Operating position

The different modes in which a taximeter fulfils the different parts of its functioning. The operating positions are distinguished by the following indications:

'For Hire'	:	The operating position in which the fare calculation is disabled
'Hired'	:	The operating position in which the fare calculation takes place on the basis of a possible initial charge and a tariff for distance travelled and/or time of the trip
'Stopped'	:	The operating position in which the fare due for the trip is indicated and at least the fare calculation based on time is disabled.

DESIGN REQUIREMENTS

1. The taximeter shall be designed to calculate the distance and to measure the duration of a trip.

2. The taximeter shall be designed to calculate and display the fare, incrementing in steps equal to the resolution fixed by the Member State in the operation position 'Hired'. The taximeter shall also be designed to display the final value for the trip in the operating position 'Stopped'.

3. A taximeter shall be able to apply the normal calculation modes S and D. It shall be possible to choose between these calculation modes by a secured setting.

4. A taximeter shall be able to supply the following data through an appropriate secured interface(s):

   — operation position: 'For Hire', 'Hired' or 'Stopped';

   — totaliser data according to point 15.1;

[1] The distance signal generator is outside the scope of this Directive.

— general information: constant of the distance signal generator, date of securing, taxi identifier, real time, identification of the tariff;

— fare information for a trip: total charged, fare, calculation of the fare, supplement charge, date, start time, finish time, distance travelled;

— tariff(s) information: parameters of tariff(s).

National legislation may require certain devices to be connected to the interface(s) of a taximeter. Where such a device is required; it shall be possible, by secured setting, to inhibit automatically the operation of the taximeter for reasons of the non-presence or improper functioning of the required device.

5. If relevant, it shall be possible to adjust a taximeter for the constant of the distance signal generator to which it is to be connected and to secure the adjustment.

RATED OPERATING CONDITIONS

6.1. The mechanical environment class that applies is M3.

6.2. The manufacturer shall specify the rated operating conditions for the instrument, in particular:

— a minimum temperature range of 80 °C for the climatic environment;

— the limits of the DC power supply for which the instrument has been designed.

MAXIMUM PERMISSIBLE ERRORS (MPEs)

7. The MPE, excluding any errors due to application of the taximeter in a taxi, are:

— For the time elapsed: ± 0,1 %

minimum value of mpe: 0,2 s;

— For the distance travelled: ± 0,2 %

minimum value of mpe: 4 m;

— For the calculation of the fare: ± 0,1 %

minimum, including rounding: corresponding to the least significant digit of the fare indication.

PERMISSIBLE EFFECT OF DISTURBANCES

8. **Electromagnetic immunity**

8.1. The electromagnetic class that applies is E3.

8.2. The MPE laid down in point 7 shall also be respected in the presence of an electromagnetic disturbance.

POWER SUPPLY FAILURE

9. In case of a reduction of the voltage supply to a value below the lower operating limit as specified by the manufacturer, the taximeter shall:

— continue to work correctly or resume its correct functioning without loss of data available before the voltage drop if the voltage drop is temporary, i.e. due to restarting the engine;

— abort an existing measurement and return to the position 'For Hire' if the voltage drop is for a longer period.

OTHER REQUIREMENTS

10. The conditions for the compatibility between the taximeter and the distance signal generator shall be specified by the manufacturer of the taximeter.

11. If there is a supplement charge for an extra service, entered by the driver on manual command, this shall be excluded from the fare displayed. However, in that case a taximeter may display temporarily the value of the fare including the supplementary charge.

12. If the fare is calculated according to calculation mode D a taximeter may have an additional display mode in which only the total distance and duration of the trip are displayed in real time.

13. All values displayed for the passenger shall be suitably identified. These values as well as their identification shall be clearly readable under daylight and night conditions.

14.1. If the fare to be paid or the measures to be taken against fraudulent use can be affected by the choice of functionality from a pre-programmed setting or by free data setting, it shall be possible to secure the instrument settings and data entered.

14.2. The securing possibilities available in a taximeter shall be such that separate securing of the settings is possible.

14.3. The provisions in point 8.3 of Annex I apply also to the tariffs.

15.1. A taximeter shall be fitted with non-resettable totalisers for all of the following values:

— The total distance travelled by the taxi;

— The total distance travelled when hired;

— The total number of hirings;

— The total amount of money charged as supplements;

— The total amount of money charged as fare.

The totalised values shall include the values saved according to point 9 under conditions of loss of power supply.

15.2. If disconnected from power, a taximeter shall allow the totalised values to be stored for one year for the purpose of reading out the values from the taximeter to another medium.

15.3. Adequate measures shall be taken to prevent the display of totalised values from being used to deceive passengers.

16. Automatic change of tariffs is allowed due to the:

— distance of the trip;

— duration of the trip;

— time of the day;

— date;

— day of the week.

17. If properties of the taxi are important for the correctness of the taximeter, the taximeter shall provide means to secure the connection of the taximeter to the taxi in which it is installed.

18. For the purpose of testing after installation, the taximeter shall be equipped with the possibility to test separately the accuracy of time and distance measurement and the accuracy of the calculation.

19. A taximeter and its installation instructions specified by the manufacturer shall be such that, if installed according to the manufacturer's instructions, fraudulent alterations of the measurement signal representing the distance travelled are sufficiently excluded.

20. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of the customer, the driver, the driver's employer and the fiscal authorities are protected.

21. A taximeter shall be designed so that it can respect the MPEs without adjustment during a period of one year of normal use.

22. The taximeter shall be equipped with a real-timeclock by means of which the time of the day and the date are kept, one or both can be used for automatic change of tariffs. The requirements for the real-time clock are:

— the timekeeping shall have an accuracy of 0,02 %;

— the correction possibility of the clock shall be not more than 2 minutes per week. Correction for summer and wintertime shall be performed automatically;

— correction, automatic or manually, during a trip shall be prevented.

23. The values of distance travelled and time elapsed, when displayed or printed in accordance with this Directive, shall use the following units:

Distance travelled:

— kilometres;

— miles, in those Member States to which Article (1)(b) of Directive 80/181/EEC applies.

Time elapsed:

— seconds, minutes or hours, as may be suitable; keeping in mind the necessary resolution and the need to prevent misunderstandings.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX X

MATERIAL MEASURES (MI-008)

CHAPTER I

Material measures of length

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this chapter, apply to material measures of length defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument.

DEFINITIONS

Material measure of length	An instrument comprising scale marks whose distances are given in legal units of length.

SPECIFIC REQUIREMENTS

Reference Conditions

1.1. For tapes of length equal to or greater than 5 metres, the maximum permissible errors (MPEs) are to be met when a tractive force of fifty newtons or other force values as specified by the manufacturer and marked on the tape accordingly, or in the case of rigid or semi-rigid measures no tractive force is needed, is applied.

1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked on the measure accordingly.

MPEs

2. The MPE, positive or negative in mm, between two non-consecutive scale marks is (a + bL), where:

— L is the value of the length rounded up to the next whole metre; and

— a and b are given in Table 1 below.

When a terminal interval is bounded by a surface, the MPE for any distance beginning at this point is increased by the value c given in Table 1.

Table 1

Accuracy Class	a (mm)	b	c (mm)
I	0,1	0,1	0,1
II	0,3	0,2	0,2
III	0,6	0,4	0,3
D — special class for dipping tapes [1] Up to and including 30 m [2]	1,5	zero	zero
S — special class for tank strapping tapes For each 30 m length when the tape is supported on a flat surface	1,5	zero	zero

[1] Applies to the tape/dip weight combinations.
[2] If the nominal tape length exceeds 30 m, an additional mpe of 0,75 mm shall be permitted for each 30 m of tape length.

Dip tapes may also be of Classes I or II in which case for any length between two scale marks, one of which is on the sinker and the other on the tape, the MPE is ± 0,6 mm when application of the formula gives a value of less than 0,6 mm.

The MPE for the length between consecutive scale marks, and the maximum permissible difference between two consecutive intervals, are given in Table 2 below.

Table 2

Length i of the interval	MPE or difference in millimetres according to accuracy class		
	I	II	III
i ≤ 1 mm	0,1	0,2	0,3
1 mm < i ≤ 1 cm	0,2	0,4	0,6

Where a rule is of the folding type, the jointing shall be such as not to cause any errors, supplementary to those above, exceeding: 0,3 mm for Class II, and 0,5 mm for Class III.

Materials

3.1. Materials used for material measures shall be such that length variations due to temperature excursions up to ± 8 °C about the reference temperature do not exceed the MPE. This does not apply to Class S and Class D measures where the manufacturer intends that thermal expansion corrections shall be applied to observed readings where necessary.

3.2. Measures made from material whose dimensions may alter materially when subjected to a wide range of relative humidity, may only be included in Classes II or III.

Markings

4. The nominal value shall be marked on the measure. Millimetre scales shall be numbered every centimetre and measures with a scale interval greater than 2 cm shall have all scale marks numbered.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

F 1 or D1 or B + D or H or G.

CHAPTER II

Capacity serving measures

The relevant essential requirements of Annex I, and the specific requirements and the conformity assessment procedures listed in this chapter, apply to capacity serving measures defined below. However, the requirement for the supply of a copy of declarations of conformity may be interpreted as applying to a batch or consignment rather than each individual instrument. Also, the requirement for the instrument to bear information in respect of its accuracy shall not apply.

DEFINITIONS

Capacity serving measure	A capacity measure (such as a drinking glass, jug or thimble measure) designed to determine a specified volume of a liquid (other than a pharmaceutical product) which is sold for immediate consumption.
Line measure	A capacity serving measure marked with a line to indicate nominal capacity.
Brim measure	A capacity serving measure for which the internal volume is equal to the nominal capacity.
Transfer measure	A capacity serving measure from which it is intended that the liquid is decanted prior to consumption.
Capacity	The capacity is the internal volume for brim measures or internal volume to a filling mark for line measures.

SPECIFIC REQUIREMENTS

1. **Reference Conditions**

1.1. Temperature: the reference temperature for measurement of capacity is 20 °C.

1.2. Position for correct indication: free standing on a level surface.

2. **MPEs**

Table 1

	Line	Brim
Transfer measures		
< 100 ml	± 2 ml	− 0 + 4 ml
≥ 100 ml	± 3 %	− 0 + 6 %
Serving measures		
< 200 ml	± 5 %	− 0 + 10 %
≥ 200 ml	± (5 ml + 2,5 %)	− 0 + 10 ml + 5 %

3. **Materials**

Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the MPE.

4. **Shape**

4.1. Transfer measures shall be designed so that a change of contents equal to the MPE causes a change in level of at least 2 mm at the brim or filling mark.

4.2. Transfer measures shall be designed so that the complete discharge of the liquid being measured will not be impeded.

5. **Marking**

5.1. The nominal capacity declared shall be clearly and indelibly marked on the measure.

5.2. Capacity serving measures may also be marked with up to three clearly distinguishable capacities, none of which shall lead to confusion one to the other.

5.3. All filling marks shall be sufficiently clear and durable to ensure that MPEs are not exceeded in use.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

A2 or F1 or D1 or E1 or B + E or B + D or H.

ANNEX XI

DIMENSIONAL MEASURING INSTRUMENTS (MI-009)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to dimensional measuring instruments of the types defined below.

DEFINITIONS

Length measuring instrument	A length measuring instrument serves for the determination of the length of rope-type materials (e.g. textiles, bands, cables) during feed motion of the product to be measured.
Area Measuring Instruments	An area measuring instrument serves for the determination of the area of irregular shaped objects, e.g. for leather.
Multi-dimensional Measuring Instruments	A multi-dimensional measuring instrument serves for the determination of the edge length (length, height, width) of the smallest enclosing rectangular parallelepiped of a product.

CHAPTER I

Requirements common to all dimensional measuring instruments

Electromagnetic immunity

1. The effect of an electromagnetic disturbance on a dimensional measuring instrument shall be such that:

   — the change in measurement result is no greater than the critical change value as defined in point 2; or

   — it is impossible to perform any measurement; or

   — there are momentary variations in the measurement result that cannot be interpreted, memorised or transmitted as a measuring result; or

   — there are variations in the measurement result severe enough to be noticed by all those interested in the measurement result.

2. The critical change value is equal to one scale interval.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

For mechanical or electromechanical instruments:

F1 or E1 or D1 or B + F or B + E or B + D or H or H1 or G.

For electronic instruments or instruments containing software:

B + F or B + D or H1 or G.

CHAPTER II

Length measuring instruments

Characteristics of the product to be measured

1. Textiles are characterised by the characteristic factor K. This factor takes the stretchability and force per unit area of the product measured into account and is defined by the following formula:

K	=	$\varepsilon \cdot (G_A + 2{,}2\ N/m^2)$, where ε is the relative elongation of a cloth specimen 1 m wide at a tensile force of 10 N, G_A is the weight force per unit area of a cloth specimen in N/m^2.

Operating conditions

2.1. *Range*

Dimensions and K-factor, where applicable, within the range specified by the manufacturer for the instrument. The ranges of K-factor are given in Table 1:

Table 1

Group	Range of K	Product
I	$0 < K < 2 \times 10^{-2}$ N/m^2	low stretchability
II	2×10^{-2} N/m^2 < K < 8×10^{-2} N/m^2	medium stretchability
III	8×10^{-2} N/m^2 < K < 24×10^{-2} N/m^2	high stretchability
IV	24×10^{-2} N/m^2 < K	very high stretchability

2.2. Where the measured object is not transported by the measuring instrument, its speed must be within the range specified by the manufacturer for the instrument.

2.3. If the measurement result depends on the thickness, the surface condition and the kind of delivery (e.g. from a big roll or from a pile), corresponding limitations are specified by the manufacturer.

MPEs

3. *Instrument*

Table 2

Accuracy class	MPE
I	0,125 %, but not less than 0,005 L_m
II	0,25 %, but not less than 0,01 L_m
III	0,5 %, but not less than 0,02 L_m

Where L_m is the minimum measurable length, that is to say the smallest length specified by the manufacturer for which the instrument is intended to be used.

The true length value of the different types of materials shall be measured using suitable instruments (e.g. tapes of length). Thereby, the material which is going to be measured shall be laid out on a suitable underlay (e.g. a suitable table) straight and unstretched.

Other requirements

4. The instruments must ensure that the product is measured unstretched according to the intended stretchability for which the instrument is designed.

CHAPTER III

Area measuring instruments

Operating conditions

1.1. *Range*

Dimensions within the range specified by the manufacturer for the instrument.

1.2. *Condition of the product*

The manufacturer shall specify the limitations of the instruments due to the speed, and thickness of the surface conditions if relevant, of the product.

MPEs

2. *Instrument*

The MPE is 1,0 %, but not less than 1 dm^2.

Other requirements

3. *Presentation of the product*

In the case of pulling back or stopping the product, it shall not be possible to have an error of measurement or the display must be blanked.

4. *Scale interval*

The instruments must have a scale interval of 1,0 dm^2. In addition, it must be possible to have a scale interval of 0,1 dm^2 for testing purposes.

CHAPTER IV

Multidimensional measuring instruments

Operating conditions

1.1. *Range*

Dimensions within the range specified by the manufacturer for the instrument.

1.2. *Minimum dimension*

The lower limit of the minimum dimension for all values of the scale interval is given in Table 1.

Table 1

Scale interval (d)	Minimum dimension (min) (lower limit)
d ≤ 2 cm	10 d
2 cm < d ≤ 10 cm	20 d
10 cm < d	50 d

1.3. *Speed of the product*

The speed must be within the range specified by the manufacturer for the instrument.

MPE

2. *Instrument:*

The MPE is ± 1,0 d.

ANNEX XII

EXHAUST GAS ANALYSERS (MI-010)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to exhaust gas analysers defined below intended for inspection and professional maintenance of motor vehicles in use.

DEFINITIONS

Exhaust gas analyser	An exhaust gas analyser is a measuring instrument that serves to determine the volume fractions of specified components of the exhaust gas of a motor vehicle engine with spark ignition at the moisture level of the sample analysed. These gas components are carbon monoxide (CO), carbon dioxide (CO_2), oxygen (O_2) and hydrocarbons (HC). The content of hydrocarbons has to be expressed as concentration of n-hexane (C_6H_{14}), measured with near-infrared absorption techniques. The volume fractions of the gas components are expressed as a percentage (% vol) for CO, CO_2 and O_2 and in parts per million (ppm vol) for HC. Moreover, an exhaust gas analyser calculates the lambda value from the volume fractions of the components of the exhaust gas.
Lambda	Lambda is a dimensionless value representative of the burning efficiency of an engine in terms of air/fuel ratio in the exhaust gases. It is determined with a reference standardised formula.

SPECIFIC REQUIREMENTS

Instrument Classes

1. Two classes (0 and I) are being defined for exhaust gas analysers. The relevant minimum measuring ranges for these classes are shown in Table 1.

Table 1

Classes and measuring ranges	
Parameter	Classes 0 and I
CO fraction	from 0 to 5 % vol
CO_2 fraction	from 0 to 16 % vol
HC fraction	from 0 to 2 000 ppm vol
O_2 fraction	from 0 to 21 % vol
λ	from 0,8 to 1,2

Rated operating conditions

2. The values of the operating conditions shall be specified by the manufacturer as follows:

2.1. For the climatic and mechanical influence quantities:

— a minimum temperature range of 35 °C for the climatic environment;

— the mechanical environment class that applies is M1.

2.2. For the electrical power influence quantities:

— the voltage and frequency range for the AC voltage supply;

— the limits of the DC voltage supply.

2.3. For the ambient pressure:

— the minimum and the maximum values of the ambient pressure are for both classes: $p_{min} \leq 860$ hPa, $p_{max} \geq 1\,060$ hPa.

Maximum permissible errors (MPEs)

3. The MPEs are defined as follows:

3.1. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to point 1.1 of Annex I is the greater of the two values shown in Table 2. Absolute values are expressed in % vol or ppm vol, percentage values are percent of the true value.

Table 2

MPEs		
Parameter	Class 0	Class I
CO fraction	± 0,03 % vol ± 5 %	± 0,06 % vol ± 5 %
CO_2 fraction	± 0,5 % vol ±5 %	± 0,5 % vol ± 5 %
HC fraction	± 10 ppm vol ± 5 %	± 12 ppm vol ± 5 %
O_2 fraction	± 0,1 % vol ± 5 %	± 0,1 % vol ± 5 %

3.2. The MPE on lambda calculation is 0,3 %. The conventional true value is calculated according to the formula set out in point 5.3.7.3 of Regulation No 83 of the Economic Commission for Europe of the United Nations (UN/ECE) [1].

For this purpose, the values displayed by the instrument are used for calculation.

Permissible effect of disturbances

4. For each of the volume fractions measured by the instrument, the critical change value is equal to the MPE for the parameter concerned.

5. The effect of an electromagnetic disturbance shall be such that:

— either the change in the measurement result is not greater than the critical change value laid down in point 4;

— or the presentation of the measurement result is such that it cannot be taken for a valid result.

Other requirements

6. The resolution shall be equal to or of one order of magnitude higher than the values shown in Table 3.

Table 3

Resolution				
	CO	CO_2	O_2	HC
Class 0 and class I	0,01 % vol	0,1 % vol	[1]	1 ppm vol

[1] 0,01 % vol for measurand values below or equal to 4 % vol, otherwise 0,1 % vol.

The lambda value shall be displayed with a resolution of 0,001.

[1] OJ L 42, 15.2.2012, p. 1.

7. The standard deviation of 20 measurements shall not be greater than one third of the modulus of the MPE for each applicable gas volume fraction.

8. For measuring CO, CO_2 and HC, the instrument, including the specified gas handling system, must indicate 95 % of the final value as determined with calibration gases within 15 seconds after changing from a gas with zero content, e.g. fresh air. For measuring O_2, the instrument under similar conditions must indicate a value differing less than 0,1 % vol from zero within 60 seconds after changing from fresh air to an oxygen-free gas.

9. The components in the exhaust gas, other than the components whose values are subject to the measurement, shall not affect the measurement results by more than the half of the modulus of the MPEs when those components are present in the following maximum volume fractions:

   6 % vol CO,

   16 % vol CO_2,

   10 % vol O_2,

   5 % vol H_2,

   0,3 % vol NO,

   2 000 ppm vol HC (as n-hexane),

   water vapor up to saturation.

10. An exhaust gas analyser shall have an adjustment facility that provides operations for zero-setting, gas calibration and internal adjustment. The adjustment facility for zero-setting and internal adjustment shall be automatic.

11. For automatic or semi-automatic adjustment facilities, the instrument shall be unable to make a measurement as long as the adjustments have not been made.

12. An exhaust gas analyser shall detect hydrocarbon residues in the gas handling system. It shall not be possible to carry out a measurement if the hydrocarbon residues, present before any measurement, exceed 20 ppm vol.

13. An exhaust gas analyser shall have a device for automatically recognising any malfunctioning of the sensor of the oxygen channel due to wear or a break in the connecting line.

14. If the exhaust gas analyser is capable to operate with different fuels (e.g. petrol or liquefied gas), there shall be the possibility to select the suitable coefficients for the Lambda calculation without ambiguity concerning the appropriate formula.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 17 that the manufacturer can choose between are:

B + F or B + D or H1.

ANNEX XIII

EU DECLARATION OF CONFORMITY (No XXXX) [1]

1. Instrument model/Instrument (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards or normative documents used or references to the other technical specifications in relation to which conformity is declared:

7. Where applicable, the notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

[1] It is optional for the manufacturer to assign a number to the declaration of conformity.

ANNEX XIV

PART A

Repealed Directive with list of the successive amendments thereto

(referred to in Article 52)

Directive 2004/22/EC of the European Parliament and of the Council (OJ L 135, 30.4.2004, p. 1).	
Council Directive 2006/96/EC (OJ L 363, 20.12.2006, p. 81).	Only point B.3 of the Annex
Regulation (EC) No 1137/2008 of the European Parliament and of the Council (OJ L 311, 21.11.2008, p. 1).	Only point 3.8 of the Annex
Commission Directive 2009/137/EC (OJ L 294, 11.11.2009, p. 7).	
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Only point (g) of Article 26(1)

PART B

Time-limits for transposition into national law and dates of application

(referred to in Article 52)

Directive	Time limit for transposition	Date of application
2004/22/EC	30 April 2006	30 October 2006
2006/96/EC		
2009/137/EC	1 December 2010	1 June 2011

ANNEX XV

CORRELATION TABLE

Directive 2004/22/EC	This Directive
Article 1	Article 2(1)
Article 2	Article 3
Article 3, first paragraph	Article 1
Article 3, second paragraph	Article 2(2)
Article 4	Article 4(1) to (4), (6) to (9)
—	Article 4(5) and (10) to (22)
Article 5	Article 5
Article 6(1)	Article 6
Article 6(2)	—
Articles 7(1)	Article 20
Article 7(2)	Article 22(4)
Article 7(3)	—
Article 7(4)	—
Article 8	Article 7
—	Article 8
—	Article 9
—	Article 10
—	Article 11
—	Article 12
—	Article 13
Article 9	Article 17
Article 10	Article 18
Article 11(1)	—
Article 11(2), first subparagraph	—
Article 11(2), second subparagraph	Article 23(2)
Article 12	—
Article 13(1)	—
Article 13(2)	—
—	Article 14(1)
—	Article 14(2)
Article 13(3)	Article 14(3)
Article 13(4)	Article 14(4)
Article 14	—
Article 15(1)	Article 46(1)
Article 15(2)	Article 46(3)

Directive 2004/22/EC	This Directive
Article 15(3)	—
Article 15(4)	—
Article 15(5)	—
Article 16(1)	Article 15
Article 16(2)	Article 47
Article 16(3)	Article 16
Article 16(4)	—
Article 17(1)	—
Article 17(2)	Article 21(2)
Article 17(3)	—
Article 17(4), first subparagraph	Article 22(2)
Article 17(4), second subparagraph	—
Article 17(5)	—
Article 18	—
—	Article 19
—	Article 21(1)
—	Article 22(1)
—	Article 22(3)
—	Article 22(5), second subparagraph
—	Article 22(5), third subparagraph
—	Article 22(6)
—	Article 23
—	Article 24
—	Article 25
—	Article 26
—	Article 27
—	Article 28
—	Article 29
—	Article 31
—	Article 32
—	Article 33
—	Article 34
—	Article 35
—	Article 36
—	Article 37
—	Article 38
—	Article 39
—	Article 40

Directive 2004/22/EC	This Directive
Article 19(1)	—
Article 19(2)(a), first subparagraph	—
Article 19(2)(a), second subparagraph	—
Article 19(2)(a), third subparagraph	Article 43(4)
Article 19(2)(b)	—
Article 20	—
Article 21	—
Article 22	—
Article 23	—
—	Article 41
—	Article 42
—	Article 43(1)
—	Article 43(2)
—	Article 43(3)
—	Article 44
—	Article 45
—	Article 48
—	Article 49
—	Article 50
Article 24	—
—	Article 51
Article 25	—
—	Article 52
Article 26	Article 53, first paragraph
—	Article 53, second paragraph
Article 27	Article 54
Annex I	Annex I
Annex A	Annex II, point 1
Annex A1	Annex II, point 2
Annex B	Annex II, point 3
Annex C	Annex II, point 4
Annex C1	Annex II, point 5
Annex D	Annex II, point 6
Annex D1	Annex II, point 7
Annex E	Annex II, point 8
Annex E1	Annex II, point 9
Annex F	Annex II, point 10
Annex F1	Annex II, point 11

Directive 2004/22/EC	This Directive
Annex G	Annex II, point 12
Annex H	Annex II, point 13
Annex H1	Annex II, point 14
Annex MI-001	Annex III
Annex MI-002	Annex IV
Annex MI-003	Annex V
Annex MI-004	Annex VI
Annex MI-005	Annex VII
Annex MI-006	Annex VIII
Annex MI-007	Annex IX
Annex MI-008	Annex X
Annex MI-009	Annex XI
Annex MI-010	Annex XII
—	Annex XIV
—	Annex XV

STATEMENT OF THE EUROPEAN PARLIAMENT

The European Parliament considers that only when and in so far as implementing acts in the sense of Regulation (EU) No 182/2011 are discussed in meetings of committees, can the latter be considered as 'comitology committees' within the meaning of Annex I to the Framework Agreement on the relations between the European Parliament and the European Commission. Meetings of committees thus fall within the scope of point 15 of the Framework Agreement when and insofar as other issues are discussed.