II

*(Preparatory Acts)*

# COMMISSION

## Proposal for a Directive of the European Parliament and of the Council on measuring instruments

(2001/C 62 E/01)

**(Text with EEA relevance)**

*COM(2000) 566 final — 2000/0233(COD)*

*(Submitted by the Commission on 15 September 2000)*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) A number of measuring instruments are covered by specific Directives, adopted on the basis of Directive 71/316/EEC on common provisions for both measuring instruments and methods of metrological control [1]. Specific directives that are technically outdated should be repealed and replaced by an independent directive, which is in the spirit of Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards [2]. Specific Directives that are not outdated should remain governed by Directive 71/316/EEC.

(2) Measuring instruments can be used for a variety of measurement tasks. Those responding to reasons of public interest, affecting the daily life of citizens in many ways directly and indirectly, require the use of legally controlled measuring instruments.

(3) Legal metrological control should not lead to barriers to the free movement of measuring instruments, the provision concerned should be the same in all Member States and proof of conformity accepted throughout the Community.

(4) 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 assessment of conformity should provide a high level of confidence.

(5) The performance of measuring instruments is particularly sensitive to the electromagnetic environment. Immunity of measuring instruments to electromagnetic interference forms an integral part of this Directive and the immunity requirements of Council Directive 89/336/EEC of 3 May 1989 on electromagnetic compatibility [3], as last amended by Directive 93/68/EEC [4], would therefore not apply.

(6) Community legislation should specify essential requirements that do not impede technical progress. The legal requirements should therefore preferably be performance requirements. Regulations to remove technical barriers to trade should follow the new approach provided for in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards.

(7) European technical standards should therefore be drawn up whose technical and performance specifications comply with the essential requirements laid down by this Directive. Conformity with the specifications of those standards would give rise to a presumption of conformity with the essential requirements laid down by this Directive. Standards harmonised at European level are drawn up by private bodies and must retain their non-mandatory status. For this purpose, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are recognised as being the bodies that are competent to adopt harmonised standards that follow the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984.

(8) The drawing up of harmonised standards by CEN and Cenelec is to be carried out at the request of the Commission pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services [5], as amended by Directive 98/48/EC [6]. In relation to standardisation, it is advisable for the Commission to be assisted by the Committee set up under Directive 98/34/EC. The Committee will, if necessary, consult technical experts.

(9) In certain specialised fields the technical and performance specifications of internationally agreed normative documents can also comply, in part or in full, with the product specifications laid down in legislation. In those cases the use of these internationally agreed normative documents can be an alternative to the use of European technical standards.

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[1] OJ L 202, 6.9.1971, p. 1.

[2] OJ C 136, 4.6.1985, p. 1.

[3] OJ L 139, 23.5.1989, p. 19.

[4] OJ L 220, 30.8.1993, p. 1.

[5] OJ L 204, 21.7.1998, p. 37.

[6] OJ L 217, 5.8.1998, p. 18.

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

(11) 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 measurement there must be an appropriate procedure or a choice between different procedures of equivalent stringency. The procedures adopted are as required by Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation Directives ([1]).

(12) In accordance with Article 2 of the Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([2]), measures necessary for the implementation of this Directive should be adopted by use of the advisory procedure provided for in Article 3 of that Decision.

(13) The Member States should actively survey their markets and take all appropriate measures to non-complying instruments from being placed on their markets or being used. Adequate cooperation among the market surveillance authorities of the Member States is therefore necessary to ensure a Community-wide effect of the market surveillance activities.

(14) Member States should take all appropriate measures to ensure that measuring instruments that carry the CE conformity marking and supplementary marking are correctly placed on the market. Manufacturers should be informed of the grounds on which negative decisions in respect of their products were taken, and the legal remedies available to them.

(15) This Directive should repeal the Community legislation in respect of the measuring instruments covered by the following Council Directives:

— 71/318/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to gas meters ([3]), as last amended by Commission Directive 82/623/EEC ([4]);

— 71/319/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to meters for liquids other than water ([5]);

— 71/348/EEC of 12 October 1971 on the approximation of the laws of the Member States relating to ancillary equipment for meters for liquids other than water ([6]), as last amended by the Act of Accession of Austria, Finland and Sweden;

— 73/362/EEC of 19 November 1973 on the approximation of the laws of the Member States relating to material measures of length ([7]), as last amended by Commission Directive 85/146/EEC ([8]);

— 75/33/EEC of 17 December 1974 on the approximation of the laws of the Member States relating to cold water meters ([9]);

— 75/410/EEC of 24 June 1975 on the approximation of the laws of the Member States relating to continuous totalising weighing machines ([10]);

— 76/891/EEC of 4 November 1976 on the approximation of the laws of the Member States relating to electrical energy meters ([11]);

— 77/95/EEC of 21 December 1976 on the approximation of the laws of the Member States relating to taximeters ([12]);

— 77/313/EEC of 5 April 1977 on the approximation of the laws of the Member States relating to measuring systems for liquids other than water ([13]) as amended by Commission Directive 82/625/EEC ([14]);

— 78/1031/EEC of 5 December 1978 on the approximation of the laws of the Member States relating to automatic checkweighing and weight grading machines ([15]);

— 79/830/EEC of 11 September 1979 on the approximation of the laws of the Member States relating to hot-water meters ([16]).

([1]) OJ L 220, 30.8.1993, p. 23.
([2]) OJ L 184, 17.7.1999, p. 23.
([3]) OJ L 202, 6.9.1971, p. 21.
([4]) OJ L 252, 27.8.1982, p. 5.
([5]) OJ L 202, 6.9.1971, p. 32.
([6]) OJ L 239, 25.10.1971, p. 9.
([7]) OJ L 335, 5.12.1973, p. 56.
([8]) OJ L 54, 23.2.1985, p. 29.
([9]) OJ L 14, 20.1.1975, p. 1.
([10]) OJ L 183, 14.7.1975, p. 25.
([11]) OJ L 336, 4.12.1976, p. 30.
([12]) OJ L 26, 31.1.1977, p. 59.
([13]) OJ L 105, 28.4.1977, p. 18.
([14]) OJ L 252, 27.8.1982, p. 10.
([15]) OJ L 364, 27.12.1978, p. 1.
([16]) OJ L 259, 15.10.1979, p. 1.

(16) Manufacturers should be offered the possibility to exercise the rights obtained before the entry into force of this Directive, during a reasonable period. Transitional arrangements are therefore necessary,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

**SCOPE AND OBJECT**

*Article 1*

**Scope**

This Directive applies to the devices and systems with a measuring function defined in the instrument specific annexes MI-001 to MI-011.

*Article 2*

**Object**

This Directive establishes the essential requirements that the devices and systems referred to in Article 1 have to satisfy if they are subject to legal metrological control in a Member State, and the conformity assessment that they have to undergo in those circumstances, with a view to their placing on the market and putting into use.

It is a specific Directive in respect of requirements for electromagnetic immunity in the sense of Article 2(2) of Directive 89/336/EEC.

CHAPTER II

**LEGAL METROLOGICAL CONTROL**

*Article 3*

**Definitions**

For the purposes of this Directive:

(a) 'measuring instrument' means any device or system with a measurement function that is covered by the scope and object of this Directive, as laid down in Articles 1 and 2;

(b) 'sub-assembly' means a hardware device that functions independently and together with other sub-assemblies with which it is compatible, makes up a measuring instrument;

(c) 'legal metrological control' means the control of the measurement tasks of a measuring instrument, prescribed by the Member States for reasons of public health, public safety, public order, protection of the environment, levying of taxes and duties, protection of the consumers and fair trading;

(d) 'manufacturer' means the physical or legal person who

— carries out the technical design of a measuring instrument, or has it carried out on his behalf, and

— manufactures the measuring instrument, or has it manufactured on his behalf, and

— places it lawfully on the market under his own name,

or,

the physical or legal person who

— takes responsibility for the conformity of the measuring instrument to the appropriate requirements of this Directive, and

— has taken all necessary measures to bear those responsibilities, and

— places the measuring instrument lawfully on the market under his own name;

(e) 'placing on the market' means the first passing of the product from the stage of manufacture to the stage of distribution and/or use on the Community market;

(f) 'putting into use' means the first use of a product for the purposes for which it was intended;

(g) 'authorised representative' means the physical or legal person who is authorised by a manufacturer, in writing, to act on his behalf for specified tasks. An authorised representative must be established within the Community if he is to act under this Directive;

(h) 'harmonised standard' means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (Cenelec) or jointly by both, at the request of the Commission pursuant to Directive 98/34/EC, and prepared in accordance with the General Guidelines agreed between the Commission and the European standards organisations;

(i) 'normative document' means a document containing normative elements drawn up by the Organisation Internationale de Métrologie Légale.

*Article 4*

**Essential requirements and assessment of conformity**

1. A measuring instrument shall meet the essential requirements laid down in Annex I and the relevant instrument specific Annex.

2. The conformity of a measuring instrument with the essential requirements shall be assessed in accordance with the provisions of Article 7.

3. Where a measuring instrument consists of a number of sub-assemblies and where specific annexes exist laying down the essential requirements for all of these sub-assemblies that together make up the measuring instrument, the provisions of this Directive shall apply *mutatis mutandis* to each of these sub-assemblies.

*Article 5*

**Conformity marking**

1. The conformity of a measuring instrument with all the obligations contained in this Directive shall be indicated by the presence on it of the CE conformity marking and the supplementary metrology marking as specified in Article 13.

2. The CE conformity marking and supplementary metrology marking shall be affixed by, or under the responsibility of the manufacturer.

3. The affixing of markings on a measuring instrument that are likely to deceive third parties as to the meaning and form of the CE marking or the supplementary metrology marking shall be prohibited. Any other marking may be affixed to a measuring instrument, provided that the visibility and legibility of the CE marking and the supplementary metrology marking is not thereby reduced.

*Article 6*

**Placing on the market and putting into use**

1. Without prejudice to the provisions of Articles 13 and 14, Member States shall not impede for reasons covered by this Directive the placing on the market and putting into use of any measuring instrument that carries the CE conformity marking and supplementary metrology marking in accordance with Article 5.

2. Member States shall ensure that the use of any measuring instrument that carries the CE conformity marking and supplementary metrology marking in accordance with Article 5 shall not be impeded by rules or conditions in respect of aspects covered by this Directive which are imposed by contracting entities in pursuit of the relevant activities, as referred to in Article 2 of Council Directive 93/38/EEC [1].

CHAPTER III

**ASSESSMENT OF CONFORMITY**

*Article 7*

**Assessment of conformity**

Assessment of conformity of a measuring instrument with its 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 specific annex concerning that instrument.

The conformity assessment modules making up the procedures are described in Annexes A to H1.

[1] OJ L 199, 9.8.1993, p. 84.

*Article 8*

**Notification**

1. Member States shall notify to the other Member States and the Commission the bodies which they have designated to carry out the tasks pertaining to the conformity assessment modules referred to in Article 7, together with the identification numbers given by the Commission according to paragraph 4, the kind(s) of measuring instrument for which each body has been designated and in addition, where relevant, the instrument classes, the measuring range, the measurement technology, and any other instrument characteristic limiting the scope of the notification.

2. Member States shall apply the criteria set out in Annex III for the designation of such bodies.

3. A Member State that has notified a body shall withdraw such notification if it finds that the body no longer meets the criteria referred to in paragraph 2. It shall forthwith inform the other Member States and the Commission of any such withdrawal of a notification.

4. Each of the bodies to be notified shall be given an identification number by the Commission. The Commission shall publish the list of bodies notified, together with the information in respect of the scope of the notification referred to in paragraph 1, in the C series of the *Official Journal of the European Communities* and shall ensure that the list is kept up to date.

CHAPTER IV

**PRESUMPTION OF CONFORMITY**

*Article 9*

**Harmonised standards and normative documents**

1. Member States shall presume conformity with the essential requirements referred to in Article 4 in respect of a measuring instrument that complies with the elements of the national standards implementing the European harmonised standard for that measuring instrument that correspond to those elements of this European harmonised standard whose references have been published in the C series of the *Official Journal of the European Communities*.

Where a measuring instrument complies only in part with the elements of the national standards referred to in the first subparagraph, Member States shall presume conformity with the essential requirements corresponding to the elements of the standards with which the instrument complies.

Member States shall publish the references of the national standards referred to in the first subparagraph.

2. Member States shall presume conformity with the essential requirements referred to in Article 4 in respect of a measuring instrument that complies with the normative document referred to in Article 11(2)(c), whose references have been published in the C series of the *Official Journal of the European Communities*.

Where a measuring instrument complies only in part with the normative document referred to in the first subparagraph, Member States shall presume conformity with the essential requirements corresponding to the normative elements with which the instrument complies.

Member States shall publish the references of the normative document referred to in the first subparagraph.

CHAPTER V

**COMMITTEES**

*Article 10*

**Committee on standards and technical regulations**

Where a Member State or the Commission considers that a European harmonised standard as referred to in Article 9(1) does not fully meet the essential requirements referred to in Article 4, the Member State or the Commission shall bring the matter before the Standing Committee set up under Directive 98/34/EC, giving its reasons for doing so. The Committee shall deliver an opinion without delay.

In the light of the Committee's opinion, the Commission shall inform the Member States whether or not it is necessary to withdraw the references of the national standards from the publication referred to in the third subparagraph of Article 9(1).

*Article 11*

**Measuring Instruments Committee**

1. The Commission shall be assisted by a Standing Committee, the Measuring Instruments Committee, composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

*Article 12*

**Functions of the Measuring Instruments Committee**

1. On request by a Member State or on its own initiative, the Commission, acting in accordance with the procedure referred to in Article 11(2), may take any appropriate measure to:

(a) amend instrument specific annexes in respect of:

— the maximum permissible errors and accuracy classes,

— the rated operating conditions,

— the critical change values,

— the list of conformity assessment procedures referred to in Article 7;

(b) amend the test programmes laid down in Annex II;

(c) request the Organisation Internationale de Métrologie Légale to draw up a normative document containing normative elements conformity with which provides presumption of conformity with the corresponding essential requirements of this Directive;

(d) publish the references of the normative document referred to in point (c) in the C series of the *Official Journal of the European Communities*.

2. Where a Member State or the Commission considers that a normative document whose references have been published in the C series of the *Official Journal of the European Communities* in accordance with paragraph 2(d), does not fully meet the essential requirements referred to in Article 4, that Member State or the Commission shall bring the matter before the Measuring Instruments Committee, giving its reasons for doing so.

The Commission, acting in accordance with the procedure referred to in Article 11(2), shall inform the Member States whether or not it is necessary to withdraw the references of the normative document concerned from the publication referred to in the third subparagraph of Article 9(2).

CHAPTER VI

**MARKINGS**

*Article 13*

**Markings**

1. The CE conformity marking referred to in Article 5 consists of the letters CE according to the design laid down in paragraph I.B(d) of the Annex to Decision 93/465/EEC. The CE marking shall be at least 5 mm high.

2. The supplementary metrology marking referred to in Article 5 consists of the capital letter M and the year of its affixing, surrounded by a rectangle. The height of the rectangle shall be equal to the height of the CE conformity marking. The supplementary metrology marking shall immediately follow the CE conformity marking.

3. The identification number of the notified body concerned referred to in Article 8, if prescribed by the conformity assessment procedure, shall follow the CE conformity marking and supplementary metrology marking. The measuring instrument shall carry no identification number of a notified body where that is not prescribed by the conformity assessment procedure.

4. When a measuring instrument consists of a set of devices operating together, the markings shall be present on the instrument's main device.

When a measuring instrument is too small or too sensitive to carry the markings referred to in paragraph 1, the markings shall be carried by the packing in which the instrument is offered for sale or, if applicable, the container in which the instrument is supplied.

5. The CE conformity marking and supplementary metrology marking shall be indelible. The identification number of the notified body concerned shall be indelible or self destructive upon removal. All markings shall be clearly visible or easily accessible.

*Article 14*

**Market surveillance**

1. Member States shall take all appropriate measures to ensure that measuring instruments that carry the CE conformity marking and supplementary metrology marking according to Article 5 shall be placed on the market and put into use only if, when correctly installed and used in accordance with the manufacturer's instructions, they satisfy the essential requirements referred to in Article 4, and they have undergone conformity assessment in accordance with Article 7.

2. The competent authorities of the Member States shall assist each other in the fulfilment of their obligations to carry out market surveillance.

In particular, the competent authorities shall exchange information concerning the extent to which instruments they examine comply with the obligations of this Directive, and the results of such examinations.

Each Member State shall inform the other Member States and the Commission which competent authorities it has designated for such exchange of information.

Information exchanged shall be kept confidential.

3. If a Member State establishes that all or part of the measuring instruments of a particular model that bear the CE conformity marking and the supplementary metrology marking do not satisfy the conditions set out in paragraph 1, it shall take all appropriate measures to withdraw those instruments from the market, prohibit or restrict their further being placed on the market, or prohibit or restrict their further being used.

When deciding on the measures, the Member State shall take account of the systematic or incidental nature of the non-compliance. Where the Member State has established that the non-compliance is of a systematic nature, it shall immediately inform the Commission of the measures taken, indicating the reasons for its decision.

4. The Commission shall enter into consultation with the parties concerned as soon as possible.

Should the Commission find that the measures taken by the Member State concerned are justified, it shall immediately inform the Member State that took the action thereof, as well as the other Member States.

The competent Member State shall take appropriate action against whomsoever has affixed the markings and shall inform the Commission and the other Member States thereof.

Should the Commission find that the measures taken by the Member State concerned are not justified, it shall immediately inform the Member State that took the action thereof, as well as the manufacturer concerned or his authorised representative.

If the non-compliance is attributed to shortcomings in the standards, the Commission shall, after having consulted the parties concerned, bring the matter as soon as possible before the Committee referred to in Article 10.

The Commission shall ensure that the Member States are kept informed of the progress and outcome of the procedure.

CHAPTER VII

**GENERAL AND FINAL PROVISIONS**

*Article 15*

**Decisions entailing refusal or restriction**

Any decision taken by a Member State pursuant to this Directive which requires the withdrawal from the market of a measuring instrument, or prohibits or restricts the placing on the market or putting into use of an instrument, shall state the exact grounds on which it is based. Such a decision shall be notified forthwith to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

*Article 16*

**Repeals**

The following Directives are repealed as from (1 July 2002) without prejudice to Article 17:

— Directive 71/318/EEC;

— Directive 71/319/EEC;

— Directive 71/348/EEC;

— Directive 73/362/EEC;

— Directive 75/33/EEC;

— Directive 75/410/EEC;

— Directive 76/891/EEC;

— Directive 77/95/EEC;

— Directive 77/313/EEC;

— Directive 78/1031/EEC;

— Directive 79/830/EEC.

*Article 17*

**Transitional provisions**

By way of derogation from Article 18(2), Member States shall permit, for measurement tasks for which they have prescribed the use of a legally controlled measuring instrument, the placing on the market and putting into use of measuring instruments that satisfy the rules applicable before (1 July 2002) until the expiration of the validity of the type approval of those measuring instruments or, in case of a type approval of indefinite validity, for a period of ten years from (1 July 2002).

*Article 18*

**Transposition**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by (1 July 2002) at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

*Article 19*

**Entry into force**

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

*Article 20*

**Addressees**

This Directive is addressed to the Member States.

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*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 requirements that shall be met by measuring instruments to provide these objectives are set out below and are completed, where appropriate, by specific instrument requirements in Annexes MI-001 to MI-011 that provide more detail on certain aspects of the general requirements.

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

Instruments are deemed to satisfy the relevant aspects of requirements if manufacturers can demonstrate that the corresponding test programme(s) of Annex II has/have been performed and gave appropriate results.

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*

A disturbance is an influence quantity not normally making up the working conditions of the instrument for which values and performance requirements are prescribed.

*Critical change value*

The critical change value is the value at which the change in the measurement result is considered undesirable. The value is expressed in the unit of measurement in which the measurement result itself is expressed.

*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;

— the parties in the transaction must accept the measurement result on the spot and;

— the change of ownership and the payment take place on the spot, or their obligation is established on the spot, as a result of the acceptance by the parties of the measurement result.

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 value as laid down in the appropriate specific instrument requirements.

Unless stated otherwise, maximum permissible error 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 specific instrument requirements.

1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, taking account of the requirements for operating conditions laid down in the appropriate specific instrument requirements.

1.3.1. Climatic and mechanical environments are differentiated into classes A to I as described below.

C Climatic environments

*C1* This class applies to continuously temperature-controlled enclosed locations. Humidity is not controlled. Heating, cooling or humidification is used to maintain the required conditions, where necessary. Measuring instruments may be exposed to solar radiation, heat radiation, and to movements of ambient air due to drafts from the air-conditioning system or open windows; they are not subject to condensed water, precipitation, or ice formations.

The conditions of this class may be found in continuously manned offices, certain workshops, and other rooms for special applications.

*C2* This class applies to enclosed locations whose temperature and humidity are not controlled. Heating may be used to raise low temperatures, especially in case where there is a large difference between the conditions of this class and the open air conditions. Measuring instruments may be exposed to solar and heat radiation and drafts and may be subject to condensed water, water from sources other than rain and to ice formations.

The conditions of this class may be found in some entrances and staircases of buildings, in garages, cellars, certain workshops, factory buildings and industrial process plants, ordinary storage rooms for frost-resistant products, farm buildings, etc.

C3 This class applies to open locations with average climatic conditions, thus excluding polar and desert environments.

M Mechanical environments

M1 This class applies to 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 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 locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

*Table 1*

**Combined climatic and mechanical environments**

| Environments | C1 | C2 | C3 |
|---|---|---|---|
| M1 | A | B | C |
| M2 | D | E | F |
| M3 | G | H | I |

1.3.2. Electromagnetic environments are classified as E1 or E2;

E1 Residential, commercial and light industrial,

E2 Industrial

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.

3. **Repeatability**

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

3.2. For an instrument subject to significant random errors the difference between the mean values of subsequent series of results shall be small when compared with the maximum permissible error.

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 reasonable period of time 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 or can be easily and simply checked using devices apart from the instrument itself.

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 bearing in mind the intended user, shall not require unreasonable demands of the user in order to obtain a correct measurement result.

7.3. Where the measurand is the attribute of a product that is conditioned by the measuring instrument, the conditioning shall be carried out adequately, taking account of the maximum permissible error for the measurement.

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.

8. **Protection against corruption**

8.1. The metrological characteristics of a measuring instrument shall not be inadmissibly influenced 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. Its identification shall be easily available. Evidence of an intervention shall be available for a reasonable period of time.

8.4. Measurement data and metrologically important parameters stored or transmitted shall be adequately protected against accidental or intentional corruption.

8.5. The displays of utility measuring instruments 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:

— manufacturer's mark or name,

— information in respect of its accuracy,

plus, when applicable:

— pertinent data in respect of the conditions of use,

— identity marking,

— number of the type examination certificate.

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 accompanying container and/or associated documentation suitably marked.

9.3. A measuring instrument shall be accompanied by information on its operation. Information should include where relevant:

— rated operating conditions;

— climatic, mechanical and electromagnetic environment classes;

— instruction for installation, maintenance, repairs, permissible adjustments;

— instruction for correct operation and any special conditions of use.

9.4. Instruments used for utility measurements or groups of instruments do not necessarily require individual instruction manuals.

9.5. Unless specified otherwise in a specific instrument annex the scale interval for a measured value shall be in the form 1 × 10n, 2 × 10n, or 5 × 10n, 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.

9.7. The units of measurement used and their symbols shall be in accordance with the legal provisions at Community level on units of measurement and their symbols.

9.8. All marks and inscriptions required under any requirement shall be clear, indelible, 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.

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

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.

10.5. A measuring instrument intended for domestic utility measurement purposes from which the measurement data can be read either by a mobile data capture unit or remotely via a transmission link shall be fitted with a display accessible 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;

— the measuring instrument is for direct sales trading transactions and;

— the measurement is non-repeatable and;

— the measuring instrument is normally 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 requirements of this directive.

*ANNEX II*

**TEST PROGRAMMES**

INTRODUCTION

Appropriate results obtained having carried out the test programmes are deemed to satisfy the particular aspect of the product requirement under evaluation. In the case of a particular instrument, values attributed in the test programmes to severity levels or combinations of severity levels for the climatic and mechanical classes A-I may be changed by direct reference in the specific annex.

Test set-ups and test procedures shall be according to internationally agreed documents.

1. **TEST PROGRAMMES**

Test programmes are separated according to operating conditions as follows:

Programme 1: Electromagnetic environment

Programme 2: Climatic environment

Programme 3: Mechanical environment

Programme 4: Power supply

A further test programme, programme 5 concerns durability.

1.1. **Applicability of test programmes**

An instrument or sub-assembly is subjected to test according to its rated operating conditions which shall be in accordance with the requirements of the specific instrument annex.

1.2.1. *Climatic and mechanical classes*

The climatic and mechanical classes, A-I, are as outlined in Table 1 of Annex I.

The appropriate severity levels for testing are as set out below.

*Table 1*

**Severity levels**

| Description of test | Classes | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | A | B | C | D | E | F | G | H | I |
| Heat | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| Dry cold | 1 | 2 | 3 | 1 | 2 | 3 | 1 | 2 | 3 |
| Damp heat, steady state | — | 1 | 2 | — | 1 | 2 | — | 1 | 2 |
| Damp heat, cyclic | — | 1 | 2 | — | 1 | 2 | — | 1 | 2 |
| Vibration | — | — | — | 1 | 1 | 1 | 2 | 2 | 2 |
| Mechanical shock | — | — | — | 1 | 1 | 1 | 2 | 2 | 2 |

1.2.2. *Electromagnetic Environmental Classes*

Class E1— Residential, commercial and light industry environment

Class E2 — Industrial environment

1.3. **Basic rules concerning the determination of errors**

Errors shall be determined under normal test conditions. When the effect of one influence quantity is being evaluated, all other factors are to be kept relatively constant, at a value close to normal.

1.4. **Basic rules for testing**

Each influence quantity is applied and its effect evaluated separately. Metrological test 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.

2. **PROGRAMME 1: ELECTROMAGNETIC ENVIRONMENT**

The test programme as outlined in Tables 2, 3 and 4 apply to the instrument or sub-assembly according to the electromagnetic environment, E1 or E2, in which the instrument is intended to be used.

Where the instrument or sub-assembly is intended to be used in a permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field — amplitude modulated test shall be within maximum permissible error, in all other cases the critical change value and the permissible effect is that laid down in the specific instrument Annex.

*Table 2*

| Disturbance | Port | E1 | E2 |
|---|---|---|---|
| Voltage interruptions on AC supply | Input ports | > 95 % reduction over 5 000 ms | |
| Voltage dips on AC supply | Input ports | 30 % reduction over 10 ms<br>60 % reduction over 100 ms | |
| Electrostatic discharge | Enclosure port | 4 kV Contact<br>8 kV Air | |
| Fast transients ([1]) | — Ports for signal lines and data buses not involved in process control; | ± 500 V ([2]) | 1 000 V |
| | — Ports directly involved in process, and in process measurement, signalling and control; | ± 500 V ([2]) | ± 2 000 V |
| | — I/O DC power ports; | ± 500 V ([3]) | ± 2 000 V |
| | — I/O AC power ports; | ± 1 000 V | ± 2 000 V |
| | — Functional earth ports. | ± 500 V ([2]) | ± 1 000 V |
| Radio frequency electromagnetic field<br>Amplitude modulated | Enclosure port | 80-1 000 MHz<br>3 V/m<br>80 % MA<br>(1 kHz) | 80-1 000 MHz ([4])<br>10 V/m<br>80 % MA<br>(1 kHz) |
| Radio frequency electromagnetic field<br>Keyed carrier | Enclosure port | 900 ± 5 MHz<br>3 V/m<br>50 Duty cycle %<br>200 Rep. frequency Hz | 900 ± 5 MHz<br>10 V/m<br>50 Duty cycle %<br>200 Rep. frequency Hz |

([1]) 5 Tr/50 Th ns, 5 rep. Frequency kHz in all cases.

([2]) Applicable only to ports interfacing with cables whose total length according to the manufacturer's functional specification may exceed 3 m.

([3]) Not applicable to input ports intended for connection to a battery or a rechargeable battery which must be removed or disconnected from the apparatus for recharging. Apparatus with a DC power input port intended for use with an AC-DC power adapter shall be tested on the AC power input of the AC-DC power adapter specified by the manufacturer or where none is so specified using a typical AC-DC power adapter. The test is applicable to DC power input ports intended to be connected permanently to cables longer than 10 m.

([4]) Except for ITU broadcast frequency bands 87 MHz-108 MHz, 174 MHz-230 MHz, and 470 MHz-790 MHz where the level shall be 3 V.

*Table 3*

**Radio frequency — common code**

| Port | E1 | E2 |
|---|---|---|
| — Ports for signal lines and data buses not involved in process control,<br>— Ports directly involved in process, and in process measurement signalling and control | 0,15-80 Mhz (1)<br>3 V<br>80 % MA (1 kHz) | 0,15-80 MHz (1) (2)<br>10 V<br>80 % MA (1 kHz) |
| — I/O DC power ports | 0,15-80 MHz (1)<br>3 V<br>80 % MA (1 kHz) | 0,15-80 MHz (2)<br>10 V<br>80 % MA (1 kHz) |
| — I/O AC power ports,<br>— Functional earth ports | 0,15-80 MHz<br>3 V<br>80 % MA (1 kHz) | 0,15-80 MHz (2)<br>3 V<br>80 % MA (1 kHz) |

The test level can be defined as the equivalent current into a 150 ohm load.

(1) Applicable only to ports interfacing with cables whose total length according to the manufacturer's functional specification may exceed 3 m.

(2) Except for ITU broadcast frequency bands 47 MHz-68 MHz where the level shall be 3 V.

*Table 4*

**Surges**

| Port | E1 | E2 |
|---|---|---|
| Ports for signal lines and data buses not involved in process control | — | 1,2 Tr/50 Th ms (8/20) (2)<br>line to ground ± 2 kV<br>line to line ± 1 kV |
| Ports directly involved in process, and in process measurement, signalling and control | — | 1,2 Tr/50 Th ms (8/20)<br>line to ground ± 2 kV<br>line to line ± 1 kV |
| DC input ports | 1,2 Tr/50 Th µs (8/20) (1) (3)<br>line to ground ± 0,5 kV<br>line to line ± 0,5 kV | 1,2 Tr/50 Th ms (8/20)<br>line to ground ± 0,5 kV<br>line to line ± 0,5 kV |
| AC input ports | 1,2 Tr/50 Th µs (8/20)<br>line to ground ± 2 kV<br>line to line ± 1 kV | 1,2 Tr/50 Th ms (8/20)<br>line to ground ± 4 kV<br>line to line ± 2 kV |

(1) Apparatus with a DC power input port intended for use with an AC-DC power adapter shall be tested on the AC power input of the AC-DC power adapter specified by the manufacturer or where none is so specified using a typical AC-DC power adapter. The test is applicable to DC power input ports intended to be connected permanently to cables longer than 10 m.

(2) Applicable only to ports interfacing with cables whose total length according to the manufacturer's functional specification may exceed 10 m.

(3) Not applicable to input ports intended for connection to a battery or to a rechargeable battery which must be removed or disconnected from the apparatus for recharging.

3. **PROGRAMME 2: CLIMATIC ENVIRONMENT**

To verify operation within maximum permissible error under the relevant climatic environment conditions

3.1. **Static temperature**

Where practicable both dry heat and cold tests may be combined in a cycle.

3.1.1. *Dry heat*

To verify operation within maximum permissible error under conditions of high temperature.

| Severity level | 1 | 2 | 3 |
|---|---|---|---|
| Temperature (°C) | 30 | 40 | 55 |
| Duration (h) | 2 | 2 | 2 |

3.1.2. *Cold*

To verify performance within maximum permissible error under conditions of low temperature

| Severity level | 1 | 2 | 3 |
|---|---|---|---|
| Temperature (°C) | + 5 | – 10 | – 25 |
| Duration (h) | 2 | 2 | 2 |

3.2. **Ambient humidity**

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.

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.

3.2.1. *Damp heat, steady-state (non-condensing)*

To verify operation within maximum permissible error under conditions of high humidity and constant temperature.

| Severity level | 1 | 2 |
|---|---|---|
| Temperature (°C) | 30 | 40 |
| Relative humidity (%) | 85 | 93 |
| Duration (days) | 2 | 4 |

3.2.2. *Damp heat, cyclic (condensing)*

To verify operation within maximum permissible error under conditions of high humidity when combined with cyclic temperature changes.

| Severity level | 1 | 2 |
|---|---|---|
| Temperature range (°C) | 25-40 | 25-55 |
| Duration (cycles) | 2 | 2 |
| Relative humidity | 95 % at lower temperature phases and 93 % at upper temperature phases | 95 % at lower temperature phases and 93 % at upper temperature phases |

4. **PROGRAMME 3: MECHANICAL ENVIRONMENT**

To verify operation within maximum permissible error under the relevant mechanical environment conditions

4.1. **Vibration**

The random vibration test is appropriate for evaluation of conditions where the magnitude of the influence quantity is not stable. The test for sinusoidal vibration is appropraite for evaluation of conditions where the frequenc(y)(ies) and the level(s) of effective acceleration are known and stable, or when a relevant resonance frequency is known.

4.1.1. *Random vibration*

To verify operation within maximum permissible error under conditions of random vibration.

| Severity level | 1 | 2 |
|---|---|---|
| Total frequency range (Hz) | 10-15 | 10-150 |
| Total RMS level ($m.s^{-2}$) | 1,6 | 7 |
| ASD level 10-20 Hz ($m^2.s^{-3}$) | 0,048 | 1 |
| ASD level 20-150 Hz (dB/octave) | – 3 | – 3 |
| Number of axes | 3 | 3 |
| Duration per axis | Two minutes in each functional mode or a longer period if necessary for carrying out the measurement | |

4.1.2. *Sinsuidol vibration*

To verify operation within maximum permissible error under conditions of vibration of a consistent character.

| Severity level | 1 | 2 |
|---|---|---|
| Frequency range (Hz) | 10-150 | 10-150 |
| Max. acceleration level ($m.s^{-2}$) | 2 | 10 |
| Number of sweep cycles per axis | 20 | 20 |

4.2. **Mechanical shock**

To verify operation within maximum permissible error under conditions of mechanical shock

| Severity level | 1 | 2 |
|---|---|---|
| Height of fall (mm) | 25 | 50 |
| Number of falls (on each bottom edge) | 1 | 1 |

5. **PROGRAMME 4: POWER SUPPLY**

To verify operation within maximum permissible error under normal power supply conditions.

| Characteristic | Test specification |
|---|---|
| Mains voltage variation | 85-110 % nominal |
| DC voltage variation | to the limits as specified by the manufacturer |
| Mains frequency variation | 98-102 % nominal |

6. **PROGRAMME 5: DURABILITY**

To assess the possible occurrence of defects over the expected lifetime of the instrument or sub-assembly.

6.1. **Gas meters**

6.1.1. *Diaphragm meters*

6.1.1.1. Test specification: 5 000 hours at $Q_{max}$

6.1.1.2. Allowable errors

During and after test at flow rates of $Q_{min}$, 2 $Q_{min}$, 0,1 $Q_{max}$, 0,4 $Q_{max}$, 0,7 $Q_{max}$ and $Q_{max}$:

— the error of indication at each flow rate in the range $Q_t$ to $Q_{max}$ shall not differ from the corresponding initial value by more the 2 % for that flow rate,

— the error of indication shall be within twice the maximum permissible error.

6.1.2. *Rotary positive displacement and turbine meters*

6.1.2.1. Test specification: 1 000 hours, total duration shall not last more than two months.

6.1.2.2. Allowable errors

After test at flow rates of $Q_{min}$, 0,05 $Q_{max}$, 0,15 $Q_{max}$, 0,25 $Q_{max}$, 0,4 $Q_{max}$, 0,7 $Q_{max}$ and $Q_{max}$:

— the error of indication at each test flow rate shall not differ from the corresponding initial value by more than one third of the maximum permissible error for that flow rate,

— the error of indication shall be within the maximum permissible error.

6.2. **Water meters**

6.2.1. *Water meters shall be submitted to two consecutive series of tests*

— $Q_3$ less than or equal to 16 $m^3/h$

— First series (Cyclic test): 100 000 discontinuous cycles during which the flow-rate may vary between zero and $Q_3$. Each cycle shall include at least one period during which the flow-rate must be zero and at least one period during which the flow-rate must be $Q_3$.

— Second series (Continuous test): continuous flow at $Q_4$ during 100 hours.

— $Q_3$ greater than 16 $m^3/h$

— First series: Continuous flow at $Q_3$ during 750 hours

— Second series: Continuous flow at $Q_4$ during 200 hours.

6.2.2. *Allowable errors*

6.2.2.1. Variation on measurement error after each series of tests when compared to initial measurement error 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.

6.2.2.2. Measurement error on volume metered after each series of tests 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.

6.2.3. *Volume of water*

The volume of water passed through each tested meter and due to the two series of tests as defined in 2.1 must be at least:

$600 \times Q_3$ (in $m^3$) for $Q_3 < 16$ $m^3/h$

$1\,000 \times Q_3$ (in $m^3$) for $Q_3 > 16$ $m^3/h$.

6.2.4. *Tested flow rates*

Measurement errors on volume of water must be determined at reference conditions before and after each series of tests, for each tested meter and at least for the following flow rates:

$Q_1$ - $(Q_1 + Q_2)/2$ - $Q_2$ - $0{,}1Q_3$ - $0{,}3Q_3$ - $0{,}5Q_3$ - $Q_3$ - $Q_4$.

6.2.5. *Test conditions*

Tests shall be carried out with water of an appropriate temperature to test the meter for the temperature range for which it is intended. Water used in testing shall be clean water having no solid particles in suspension, a low agressivity and a low proportion of calcium carbonate.

*ANNEX III*

**CRITERIA TO BE SATISFIED BY BODIES DESIGNATED BY THE MEMBER STATES FOR THE CARRYING OUT OF TASKS PERTAINING TO THE CONFORMITY ASSESSMENT MODULES**

Set out below are the criteria that Member States shall apply for the designation of bodies according to Article 8, paragraph 1.

1. The body, its director and the staff involved in conformity assessment work shall not be the designer, manufacturer, supplier, installer or user of the measuring instruments that they inspect, nor the authorised representative of any of these persons. Also they may not be directly involved in the design, manufacture, marketing or maintenance of the instruments, nor represent the parties engaged in these activities. The preceding criteria do not, however, preclude in any way the possibility of exchanges of technical information for purposes of conformity assessment, between the manufacturer and the body.

2. The body and its staff involved in conformity assessment work shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment work, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment tasks shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology.

   Should the body subcontract specific tasks connected with the establishment or verification of product performance or specifications, it shall first ensure that the subcontractor meets the provisions of this Directive, and in particular of this Annex. The body shall keep the relevant documents assessing the subcontractor's qualifications and the work carried out by him under this Directive at the disposal of the national authorities.

4. The body shall be able to carry out all the tasks assigned to such bodies by the Annex for which it has been notified, whether these tasks are carried out by the body itself or on its behalf and under its responsibility. It shall dispose in particular of the necessary staff and possess the necessary facilities for carrying out the technical and administrative tasks entailed in assessment and verification in a proper manner. It shall also have access to the equipment necessary for the required verification.

5. The body shall have

   — sound vocational training, covering all assessment and verification operations for which the body was designated;

   — satisfactory knowledge of the rules in respect of the inspections which it carries out, and adequate experience of such inspections;

   — the ability required to draw up the certificates, records and reports to demonstrate that the inspections were carried out.

6. The impartiality of the body must be guaranteed. Its remuneration must not depend on the number of inspections carried out, nor on the results of the inspections.

7. The body must have taken out civil liability insurance, unless liability is assumed by the Member State under national legislation or the Member State carries out the inspections itself directly.

8. The body's staff are bound to observe professional secrecy with regard to all information obtained in the course of exercising their duties pursuant to this Directive or any provision of national law putting this Directive into effect, except vis-à-vis the competent administrative authorities of the Member State in which their activities are carried out.

*ANNEX IV*

**TECHNICAL DOCUMENTATION**

The technical documentation shall render the design, manufacture and operation of the measuring instrument intelligible and shall enable assessment of its conformity with the appropriate requirements of this Directive.

The documentation shall include in so far as relevant for assessment:

— a general description of the instrument;

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

— descriptions and explanations necessary for the understanding of the above, including the operation of the instrument;

— a list of the standards referred to in Article 9, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the standards referred to in Article 9 have not been applied;

— results of design calculations, examinations, etc.;

— test reports;

— the EC type examination certificates or EC design examination certificates in respect of instruments containing parts identical to those in the design.

*ANNEX A*

## DECLARATION OF CONFORMITY BASED ON INTERNAL PRODUCTION CONTROL

1. The declaration of conformity based on internal production control is the conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter, and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

**Technical documentation**

2. The manufacturer shall establish the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured.

**Manufacturing**

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

**Written declaration of conformity**

5.1. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking to each measuring instrument that satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument of that model has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall also be sent to one of the bodies notified for type examination according to Article 8 whose responsibility it shall be to periodically make the list of declarations of conformity received available to all Member States.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

**Authorised representative**

6. The manufacturer's obligations contained in paragraphs 3 and 5.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligations mentioned above shall be the responsibility of the importer or any other person who places the instrument on the Community market.

*ANNEX A1*

## DECLARATION OF CONFORMITY BASED ON INTERNAL PRODUCTION CONTROL PLUS PRODUCT TESTING BY A NOTIFIED BODY

1. The declaration of conformity based on internal production control plus product testing by a notified body is the conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter, and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

### Technical documentation

2. The manufacturer shall establish the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured.

### Manufacturing

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

### Product checks

5. A notified body chosen by the manufacturer shall carry out product checks at random intervals, or have them carried out. An adequate sample of the final products, taken by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant document(s) referred to in Article 9, or equivalent tests, shall be carried out to check the conformity of the instruments with the appropriate requirements of this Directive. In the absence of a relevant document, the 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 the notified body shall take appropriate measures.

### Written declaration of conformity

6.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 5, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

   A copy of the declaration shall also be sent to one of the bodies notified for type examination according to Article 8 whose responsibility it shall be to periodically make the list of declarations of conformity received available to all Member States.

   A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

### Authorised representative

7. The manufacturer's obligations contained in paragraphs 3 and 6.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

   Where neither the manufacturer nor his authorised representative is established within the Community, the obligations mentioned above shall be the responsibility of the importer or any other person who places the instrument on the Community market.

*ANNEX B*

**Type examination**

1. Type examination is the part of a conformity assessment procedure whereby a notified body examines the technical design of a measuring instrument and ascertains and attests that the technical design meets the provisions of this Directive that apply to the measuring instrument.

2. Type examination may be carried out in either of the following manners. The notified body decides on the appropriate manner and the specimens required.

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

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

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

3. The application for type examination shall be lodged by the manufacturer or his authorised representative established within the Community with a notified body of his choice.

   The application shall include:

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

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

   — the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument;

   — the specimens, representative of the production envisaged, as required by the notified body;

   — the supporting evidence for the adequacy of the technical design of those parts of the measuring instrument for which no specimens are required. This supporting evidence shall mention any relevant documents that have been applied, in particular where the relevant documents referred to in Article 9 have not been applied in full, and shall include, where necessary, the results of tests carried out 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 specimens:**

4.1. examine the technical documentation, verify that the specimens have been manufactured in conformity with it and identify the elements which have been designed in accordance with the relevant provisions of the relevant documents referred to in Article 9, as well as the elements which have been designed without applying the relevant provisions of those documents;

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

4.3. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen not to apply the solutions in the relevant documents, the solutions adopted by the manufacturer meet the corresponding essential requirements of this Directive;

4.4. agree with the applicant on the location where the examinations and tests shall be carried out.

**For the other parts of the measuring instrument:**

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

**For the manufacturing process:**

4.6. examine the technical documentation to assure that the manufacturer has adequate means to ensure consistent production.

5. Where the technical design meets the provisions of this Directive that apply to the measuring instrument, the notified body shall issue an EC type examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the instrument.

All relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

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

6. The applicant shall inform the notified body that holds the technical documentation concerning the EC type examination certificate of all modifications to the instrument that may affect the conformity of the instrument with the essential requirements or the conditions for validity of the certificate. Such modifications require additional approval in the form of an addition to the original EC type examination certificate.

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

— EC type examination certificates issued;

— EC type examination certificates refused;

— additions and amendments relating to certificates already issued.

Each notified body shall inform all Member States immediately of the withdrawal of an EC type examination certificate. Each Member State shall make this information available to the bodies that it has notified.

8. The other notified bodies may receive a copy of the EC type examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorised representative established within the Community shall keep a copy of the EC type examination certificate and its additions with the technical documentation for a period ending 10 years after the last measuring instrument has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the importer or any other person who places the measuring instrument on the Community market.

*ANNEX C*

## DECLARATION OF CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. The declaration of conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC type examination certificate and satisfy the appropriate requirements of this Directive.

**Manufacturing**

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the type as described in the EC type examination certificate and with the appropriate requirements of this Directive.

**Written declaration of conformity**

3.1. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking to each measuring instrument that is in conformity with the type as described in the EC type examination certificate and satisfies the appropriate requirements of this Directive.

3.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

**Authorised representative**

4. The manufacturer's obligations contained in paragraph 3.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligations mentioned above shall be the responsibility of the importer or any other person who places the instrument on the Community market.

*ANNEX C1*

## DECLARATION OF CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS PRODUCT TESTING BY A NOTIFIED BODY

1. The declaration of conformity to type based on internal production control plus product testing by a notified body is the part of a conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC type examination certificate and satisfy the appropriate requirements of this Directive.

### Manufacturing

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the type as described in the EC type examination certificate and with the appropriate requirements of this Directive.

### Product checks

3. A notified body chosen by the manufacturer shall carry out product checks at random intervals, or have them carried out. An adequate sample of the final products, taken by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant document(s) referred to in Article 9, or equivalent tests, shall be carried out to check the conformity of the product with the type as described in the EC type examination certificate and the appropriate requirements of the Directive. In the absence of a relevant document, the 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 the notified body shall take appropriate measures.

### Written declaration of conformity

4.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3 the latter's identification number, to each measuring instrument that is in conformity with the type as described in the EC type examination certificate and satisfies the appropriate requirements of this Directive.

4.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

   A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

### Authorised representative

5. The manufacturer's obligations contained in paragraph 4.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

   Where neither the manufacturer nor his authorised representative is established within the Community, the obligations mentioned above shall be the responsibility of the importer or any other person who places the instrument on the Community market.

*ANNEX D*

## DECLARATION OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. The declaration of conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfills the obligations laid down hereafter and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC type examination certificate and satisfy the appropriate requirements of this Directive.

**Manufacturing**

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

**Quality system**

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system;

— the technical documentation of the approved type and a copy of the EC type examination certificate.

3.2. The quality system shall ensure compliance of the instruments with the type as described in the EC type examination certificate and the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

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

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;

— the means to monitor 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 paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

**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 allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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 an audit report to the manufacturer.

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

**Written declaration of conformity**

5.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that is in conformity with the type as described in the EC type examination certificate and satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

6. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in paragraph 3.1, second indent;

— the updating referred to in paragraph 3.5, as approved;

— the decisions and reports from the notified body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX D1*

## DECLARATION OF CONFORMITY BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. The declaration of conformity based on quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfills the obligations laid down hereafter and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

### Technical documentation

2. The manufacturer shall establish the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured.

### Manufacturing

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

### Quality system

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system;

— the technical documentation referred to in paragraph 2.

5.2. The quality system shall ensure compliance of the instruments with the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

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

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;

— the means to monitor 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 paragraph 5.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 5.2 or whether a re-assessment is required.

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

**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 allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the technical documentation referred to in paragraph 2;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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 an audit report to the manufacturer.

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

**Written declaration of conformity**

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

7.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

8. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in paragraph 5.1, second indent;

— the updating referred to in paragraph 5.5, as approved;

— the decisions and reports from the notified body referred to in paragraphs 5.5, 6.3 and 6.4.

9. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

10. The manufacturer's obligations contained in paragraphs 5.1, 5.5, 7.2 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX E*

## DECLARATION OF CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF FINAL PRODUCT INSPECTION AND TESTING

1. The declaration of conformity to type based on quality assurance of final product inspection and testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EC type examination certificate and satisfy the appropriate requirements of this Directive.

**Manufacturing**

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

**Quality system**

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system;

— the technical documentation of the approved type and a copy of the EC type examination certificate.

3.2. The quality system shall ensure compliance of the instruments with the type as described in the EC type examination certificate and the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

— the examinations and tests that will be carried out after manufacture;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;

— the means to monitor 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 paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

**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 allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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 an audit report to the manufacturer.

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

**Written declaration of conformity**

5.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that is in conformity with the type as described in the EC type examination certificate and satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

6. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of paragraph 3.1;

— the updating referred to in the second paragraph of paragraph 3.5, as approved;

— the decisions and reports from the notified body which are referred to in the final paragraph of paragraph 3.5, paragraph 4.3 and paragraph 4.4.

7. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX E1*

## DECLARATION OF CONFORMITY BASED ON QUALITY ASSURANCE OF FINAL PRODUCT INSPECTION AND TESTING

1. The declaration of conformity based on quality assurance of final product inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned are in conformity with the appropriate requirements of this Directive.

### Technical documentation

2. The manufacturer shall establish the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured.

### Manufacturing

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

### Quality system

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system;

— the technical documentation referred to in paragraph 2.

5.2. The quality system shall ensure compliance of the instruments with the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

— the examinations and tests that will be carried out after manufacture;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc;

— the means to monitor 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 paragraph 5.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 5.2 or whether a re-assessment is required.

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

**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 allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the technical documentation referred to in paragraph 2;

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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 an audit report to the manufacturer.

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

**Written declaration of conformity**

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

7.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

8. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in paragraph 5.1, second indent;

— the updating referred to in paragraph 5.5, as approved;

— the decisions and reports from the notified body referred to in paragraphs 5.5, 6.3 and 6.4.

9. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

10. The manufacturer's obligations contained in paragraphs 5.1, 5.5, 7.2 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX F*

**DECLARATION OF CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION**

1. The declaration of conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments that have been subjected to the provisions of point 3 are in conformity with the type as described in the EC type examination certificate and satisfy the appropriate requirements of this Directive.

**Manufacturing**

2. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the approved type as described in the EC type examination certificate and the appropriate requirements of this Directive.

**Verification**

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

The examinations and tests to check the conformity with the metrological requirements will be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 4, or by examination and testing of the instruments on a statistical basis as specified in paragraph 5.

4. Verification of conformity with the metrological requirements by examination and testing of every instrument

4.1. All instruments shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 9, or equivalent tests, shall be carried out to verify their conformity with the metrological requirements that apply to them. In the absence of a relevant 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.

5. Statistical verification of conformity with the metrological requirements

5.1. The manufacturer shall have taken all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced, and shall present his instruments for verification in the form of homogeneous lots.

5.2. A random sample shall be drawn from each lot according to the requirements of paragraph 5.3. All instruments in the sample shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 9, or equivalent tests, to establish their conformity with the metrological requirements that apply to them shall be carried out to determine whether the lot is accepted or rejected. In the absence of a relevant 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 level of quality corresponding to a probability of acceptance of 95 %, with a non-conformity percentage of less than 1 %;

— a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of less than 7 %.

5.4. If a lot is accepted all instruments of the lot are approved, except for those instruments from the sample that were 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 available for inspection by the national authorities.

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.

**Written declaration of conformity**

6.1. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking to each measuring instrument that is in conformity with the approved type and satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

If agreed upon by the notified body referred to in paragraph 3, the manufacturer shall also affix the notified body's identification number to the measuring instruments under the notified body's responsibility.

7. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the measuring instruments during the manufacturing process.

**Authorised representative**

8. The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community, except for the obligations contained in paragraphs 2 and 5.1.

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*ANNEX F1*

**DECLARATION OF CONFORMITY BASED ON PRODUCT VERIFICATION**

1. The declaration of conformity based on product verification is the conformity assessment procedure whereby the manufacturer or his authorised representative fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments that have been subjected to the provisions of point 5 are in conformity with the appropriate requirements of this Directive.

**Technical documentation**

2. The manufacturer shall establish the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

3. The manufacturer shall keep the technical documentation at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured.

**Manufacturing**

4. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instruments with the appropriate requirements of this Directive.

**Verification**

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

The examinations and tests to check the conformity with the metrological requirements will be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in paragraph 6, or by examination and testing of the instruments on a statistical basis as specified in paragraph 7.

6. Verification of conformity with the metrological requirements by examination and testing of every instrument

6.1. All instruments shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 9, or equivalent tests, shall be carried out to verify their conformity with the metrological requirements that apply to them. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

6.2. 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.

7. Statistical verification of conformity with the metrological requirements

7.1. The manufacturer shall have taken all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced, and shall present his instruments for verification in the form of homogeneous lots.

7.2. A random sample shall be drawn from each lot according to the requirements of paragraph 7.3. All instruments in the sample shall be individually examined and appropriate tests as set out in the relevant documents referred to in Article 9, or equivalent tests, to establish their conformity with the metrological requirements that apply to them, shall be carried out to determine whether the lot is accepted or rejected. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

7.3. The statistical procedure shall meet the following requirements:

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

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

— a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of less than 7 %.

7.4. If a lot is accepted all instruments of the lot are approved, except for those instruments from the sample that were 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 available for inspection by the national authorities.

7.5. 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.

**Written declaration of conformity**

8.1. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking to each measuring instrument that satisfies the appropriate requirements of this Directive.

8.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

If agreed upon by the notified body referred to in paragraph 5, the manufacturer shall also affix the notified body's identification number to the measuring instruments under the notified body's responsibility.

9. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the measuring instruments during the manufacturing process.

**Authorised representative**

10. The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community, except for the obligations contained in paragraphs 4 and 7.1.

*ANNEX G*

## DECLARATION OF CONFORMITY BASED ON UNIT VERIFICATION

1. The declaration of conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that a measuring instrument that has been subjected to the provisions of paragraph 4, is in conformity with the appropriate requirements of this Directive.

### Technical documentation

2. The manufacturer shall establish the technical documentation as described in Annex IV and make it available to the notified body referred to in paragraph 4. The technical documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive and shall, as far as relevant for such assessment, cover the design, manufacture and operation of the instrument.

### Manufacturing

3. The manufacturer shall take all measures necessary to ensure conformity of the manufactured instrument with the appropriate requirements of this Directive.

### Verification

4. A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests as set out in the relevant documents referred to in Article 9, or equivalent tests, to check the conformity of the instrument with the appropriate requirements of this Directive, or have them carried out. In the absence of a relevant document, the notified body concerned shall decide on the appropriate tests to be carried out.

   The notified body shall affix its identification number to the approved instrument, or have it affixed under its responsibility.

### Written declaration of conformity

5.1. The manufacturer shall affix the CE conformity marking and the supplementary metrology marking to the measuring instrument that satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity shall be drawn up and kept at the disposal of the national authorities for a period ending ten years after the instrument has been manufactured. It shall identify the instrument for which it was drawn up.

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

### Authorised representative

6. The manufacturer's obligations contained in paragraph 5.2 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX H*

## DECLARATION OF CONFORMITY BASED ON FULL QUALITY ASSURANCE

1. The declaration of conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

**Manufacturing**

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

**Quality system**

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system.

3.2. The quality system shall ensure compliance of the instruments with the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall contain in particular an adequate description of:

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

— the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 9 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 instruments will be met;

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

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

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

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

— the means to monitor 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 paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

**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 allow the notified body entrance for inspection purposes to the locations of manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

— the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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 an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out under its responsibility, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**Written declaration of conformity**

5.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

5.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up.

A copy of the declaration shall also be sent to one of the bodies notified for type examination according to Article 8 whose responsibility it shall be to periodically make the list of declarations of conformity received available to all Member States.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

6. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation concerning the quality system referred to in paragraph 3.1, second indent;

— the updating referred to in paragraph 3.5, as approved;

— the decisions and reports from the notified body referred to in paragraphs 3.5, 4.3 and 4.4.

7. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

8. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 5.2 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX H1*

## DECLARATION OF CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. The declaration of conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down hereafter and ensures and declares that the measuring instruments concerned satisfy the appropriate requirements of this Directive.

### Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instrument concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 5. The adequacy of the technical design of the measuring instrument shall have been examined according to the provisions of paragraph 4.

### Quality system

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

The application shall include:

— all relevant information for the instrument category envisaged;

— the documentation concerning the quality system.

3.2. The quality system shall ensure compliance of the instruments with the appropriate 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 must permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall contain in particular an adequate description of:

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

— the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 9 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 instruments will be met;

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

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

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

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

— the means to monitor 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 paragraph 3.2. It shall presume conformity with these requirements in respect of a quality system that complies with the corresponding specifications of the national standard that implements the relevant harmonised standard.

The auditing team shall include persons with experience in the instrument technology concerned and experience as a legal metrology assessor. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination 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 updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

**Design examination**

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

4.2. The application shall enable understanding of the design, manufacture and operation of the instrument, and shall enable assessment of conformity with the appropriate requirements of this Directive. It shall include:

— the name and address of the manufacturer;

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

— the technical documentation as described in Annex IV. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Directive. It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any standards that have been applied, in particular where the standards referred to in Article 9 have not been applied in full, and shall include, where necessary, the results of tests carried out 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 provisions of the Directive that apply to the measuring instrument it shall issue an EC design examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the approved instrument.

All relevant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

The certificate shall have a validity period of ten years from the date of its issue,

If the manufacturer is denied a design examination certificate, the notified body shall provide detailed reasons for such a denial.

4.4. The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of this Directive, the conditions for validity of the certificate or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EC design examination certificate.

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

— EC design examination certificates issued;

— EC design examination certificates refused;

— additions and amendments relating to certificates already issued.

Each notified body shall inform all Member States immediately of the withdrawal of an EC design examination certificate.

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

4.6. The other notified bodies may receive a copy of the EC design examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

4.7. The manufacturer or his authorised representative established within the Community shall keep a copy of the EC design examination certificate and its additions with the technical documentation for a period ending 10 years after the last measuring instrument has been manufactured.

Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the importer or any other person who places the measuring instrument on the Community market.

**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 allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation;

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

— the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of 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 an audit report to the manufacturer.

5.4. Additionally, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out under its responsibility, to verify that the quality system is functioning correctly. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**Written declaration of conformity**

6.1. The manufacturer shall affix the CE conformity marking, the supplementary metrology marking and, under the responsibility of the notified body referred to in paragraph 3.1, the latter's identification number to each measuring instrument that satisfies the appropriate requirements of this Directive.

6.2. A declaration of conformity is drawn up for each instrument model and shall be kept at the disposal of the national authorities for a period ending ten years after the last instrument has been manufactured. It shall identify the model of the instrument for which it was drawn up and shall mention the number of the design examination certificate.

A copy of the declaration shall be supplied with each measuring instrument that is placed on the market.

7. The manufacturer shall, for a period ending ten years after the last instrument has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in 3.1, second indent;

— the updating referred to in paragraph 3.5, as approved;

— the decisions and reports from the notified body referred to in paragraphs 3.5, 5.3 and 5.4.

8. Each notified body shall periodically make available to all Member States the list of quality system approvals issued or refused, and shall immediately inform all Member States of the withdrawal of a quality system approval.

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

**Authorised representative**

9. The manufacturer's obligations contained in paragraphs 3.1, 3.5, 6.2 and 7 may be fulfilled, on his behalf and under his responsibility, by his authorised representative established within the Community.

*ANNEX MI-001*

**WATER METERS**

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 used in non-negotiated transactions.

DEFINITIONS

**Water meter**

An instrument intended 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.

**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 maximum permissible error.

**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:

   $Q_3/Q_1 \geq 10$

   $Q_2/Q_1 = 1,6$

   $Q_4/Q_3 = 1,25$

   For a period of 5 years from the adoption of this directive the ratio $Q_2/Q_1$ may be: 1,5, 2,5, 4, or 6,3.

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 a high temperature, that temperature being 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.

4. The climatic and mechanical environment class B, C, E or F in which the instrument is intended to be used in accordance with Table 1 of Annex I.

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

**Maximum permissible error**

6. The maximum permissible error, 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.

7. The maximum permissible error, 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.

**Permissible effect of disturbances**

8.1. Electromagnetic immunity

8.1.1. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

8.1.2. 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 8.1.4, 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.

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

   — recover to operate within maximum permissible error, and

   — have all measurement functions safeguarded, and

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

8.1.4. The critical change value is the value of the maximum permissible error applied to the quantity corresponding to one minute at flowrate $Q_3$.

**Suitability**

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

9.2. 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 maximum permissible error shall apply to both forward and reverse flow.

   Water meters not designed to measure reverse flow shall be capable of withstanding an accidental reverse flow without any deterioration or change in metrological properties, and at the same time record such a reversal.

**Units of measurement**

10. Metered volume shall be displayed in cubic metres, symbol $m^3$.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.

*ANNEX MI-002*

**GAS METERS**

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 defined below intended for use in non-negotiated transactions.

DEFINITIONS

**Gas meter**

An instrument intended to measure, memorise and display the quantity of gas passing through the measurement transducer.

**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.

**Maximum flowrate ($Q_{max}$)**

The highest flowrate at which the gas meter provides indications that satisfy the requirements regarding maximum permissible error.

**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 maximum permissible error.

**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.

SPECIFIC REQUIREMENTS

**Rated operating conditions**

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

1. The flowrate range of the gas.

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

   $Q_{max}/Q_{min} > 20$

   $Q_{max}/Q_t \geq 5$

   $Q_r/Q_{max} = 1,2$

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

3. The fuel gas related conditions.

The instrument 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.

4. The climatic and mechanical environment in which the instrument or its sub-assemblies are intended to be used in accordance with Table 1 of Annex I, with a minimum temperature range of 60 °C.

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

**Base conditions for converted values**

6. The manufacturer shall specify the base conditions for converted values.

**Maximum permissible error**

7.1. Gas meter

*Table 1*

| Accuracy class | 1,5 | 1 |
|---|---|---|
| $Q_{min} \leq Q < Q_t$ | 3 % | 2 % |
| $Q_t \leq Q \leq Q_{max}$ | 1,5 % | 1 % |

When the errors between $Q_t$ and $Q_{max}$ all have the same sign, they shall all not exceed 1 % for class 1,5 and 0,5 % for Class 1.

7.2. Change in maximum permissible error due to a conversion device.

7.2.1. For an integrated temperature conversion device that only converts volume as a function of the temperature and only indicates the converted volume, the maximum permissible error of the meter is increased by 0,5 % in a range of 10 °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.

7.2.2. For conversion devices other than those covered by 7.2.1 the maximum permissible error is increased by 1 %.

**Permissible effect of disturbances**

8.1. Electromagnetic immunity

8.1.1. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

8.1.2. The effect of an electromagnetic disturbance on a gas meter shall be such that:

(i) the change in measurement is no greater than the critical change value as defined in 4.1.4, or

(ii) 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.

8.1.3. After undergoing a disturbance the gas meter shall:

— recover to operate within maximum permissible error, and

— have all measurement functions safeguarded, and

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

8.1.4. The critical change value is the value of the maximum permissible error applied to the quantity corresponding to one minute at flowrate $Q_{max}$.

**Suitability**

9.1. An instrument powered from the mains (AC or DC) shall be provided with an emergency power supply device or other means to assure during a failure of the principal power source that all measuring functions are safeguarded.

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

9.3. An indicating device shall have a sufficient number of digits to ensure that the quantity passed during at least two years at normal operation does not return the digits to their initial values.

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

9.5. 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 outside the operating range(s).

**Units**

10. Metered volume shall be displayed in cubic metre, symbol $m^3$.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.

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*ANNEX MI-003*

**Active electrical energy meters and measurement transformers**

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 of accuracy classes 1 and 2, and to measurement transformers for use in combination with any such active electrical energy meter.

**DEFINITIONS**

An active electrical energy meter is a device which measures the active electrical energy consumed in a circuit since the moment at which the display indicated zero. It may be used in combination with a measurement transformer, depending upon the measurement technique applied.

A measurement transformer is a device for use in combination with an active electrical energy meter, which offers to the meter a reduced value of the voltage at which the electricity is being supplied to the circuit, and/or a reduced value of the current flowing in the circuit, the reduction factors being constant.

$I$ = the electrical current flowing through the meter;

$I_n$ = the nominal value of I for which the meter has been designed;

$I_{st}$ = the lowest value of I at which the meter measures active electrical energy;

$I_{min}$ = the value of I from which onwards the error is intended to lie within prescribed limits;

$I_{tr}$ = the value of I from which onwards the error is intended to lie within the error limits corresponding to the accuracy class declared for the meter;

$I_{max}$ = the maximum value of I for which the meter has been designed;

$U$ = the potential of the electricity supplied to the meter;

$U_n$ = the nominal value of U for which the meter has been designed;

$f$ = the frequency of the electrical current flowing through the meter;

$f_n$ = the nominal value of f for which the meter has been designed;

PF = power factor = $\cos\Phi$ = the phase difference between I and U;

T = ambient temperature.

**SPECIFIC REQUIREMENTS**

PART 1 — METERS

1. The manufacturer shall specify the values of $f_n$, $U_n$, $I_n$, $I_{min}$, $I_{tr}$ and $I_{max}$ that apply to the meter. The values chosen shall fulfil the following conditions:

   $I_{min}/I_{st} \geq 10$;

   $I_{tr}/I_{st} \geq 20$;

   $I_{max}/I_{st} \geq 200$.

**Design prescriptions**

2. In the case of electrical energy meters designed for use in combination with a measurement transformer, $I_{max}$ shall be equal to $1{,}2.I_n$.

**Quality of the electricity**

3. A meter shall satisfy the accuracy requirements laid down in this Annex in the case of electricity with a quality as specified hereafter.

No legal requirements in respect of metrological performance apply when the electricity has a quality, even momentarily, which is worse than the quality specified hereafter.

The voltage and frequency values lie within the following limits:

$0{,}9.U_n \leq U \leq 1{,}1.U_n$;

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

The power factor lies within the following limits:

From $\cos\Phi = 0{,}5$ inductive to $\cos\Phi = 0{,}8$ capacitive.

**Rated operating conditions**

4. The manufacturer shall specify the climatic and mechanical environment class B or class C for which the meter has been designed in accordance with Table 1 of Annex I.

**Accuracy classes**

5. The following accuracy classes are defined: Class 1, Class 2.

**Maximum permissible errors**

6. Table 1 shows the maximum errors, expressed in percent of the true value, that must be respected by the electrical energy meter under rated operating conditions for electricity with a quality within the limits specified in requirement 3 of this Annex.

*Table 1*

**Maximum permissible errors (percent of true value)**

| Electrical current flowing through the meter | PF | Accuracy class | |
|---|---|---|---|
| | | 1 | 2 |
| *Single phase meter; Polyphase meter, if operating with balanced loads* | | | |
| $I_{tr} \leq I \leq I_{max}$ | 1 | 1 + Δ | 2 + Δ |
| $2I_{tr} \leq I \leq I_{max}$ | ≠ 1 | 1 + Δ | 2 + Δ |
| $I_{min} \leq I < I_{tr}$ | 1 | 1,5 + Δ | 2,5 + Δ |
| $2I_{min} \leq I < 2I_{tr}$ | ≠ 1 | 1,5 + Δ | 2,5 + Δ |
| *Polyphase meter, if operating with single phase load* | | | |
| $I_{tr} \leq I \leq I_{max}$ | 1 | 2 + Δ | 3 + Δ |
| $2I_{tr} \leq I \leq I_{max}$ | ≠ 1 | 2 + Δ | 3 + Δ |

$\Delta = k_1 + k_2 + k_3(T\text{-}T_n)$, where the values of $k_1$, $k_2$ and $k_3$ are given in Table 2.

*Table 2*

**k values for use in Table 1**

| Condition | | PF | Accuracy class | |
|---|---|---|---|---|
| | | | 1 | 2 |
| $K_1$ | U within the quality limits, and $U \neq U_n$ | 1 | 0,7 | 1 |
| | Idem | $\neq 1$ | 1 | 1,5 |
| | $U = U_n$ | | 0 | 0 |
| $K_2$ | f within the quality limits, and $f \neq f_n$ | 1 | 0,5 | 0,8 |
| | Idem | $\neq 1$ | 0,7 | 1 |
| | $f = f_n$ | | 0 | 0 |
| $K_3$ | T within rated conditions | 1 | 0,05 | 0,1 |
| | Idem | $\neq 1$ | 0,07 | 0,15 |

**Permissible effect of disturbances**

7.1. Electromagnetic immunity

7.1.1. The manufacturer shall specify the electromagnetic environment E1 or E2 for which the electrical energy meter has been designed in accordance with requirement 1.3.2 of Annex I.

7.1.2. The change in accuracy of an electrical energy meter due to the presence of an electromagnetic disturbance shall be less than the critical value given in Table 3, or the indication of the measurement result shall be such that it cannot be interpreted as a valid measurement result, such as a momentary variation that cannot be interpreted, memorised or transmitted as a measuring result.

*Table 3*

**Critical values of the change in accuracy under disturbances (percentage values are percent of true value)**

| Disturbance | Accuracy class | |
|---|---|---|
| Electromagnetic disturbances | 1 | 2 |
| Electromagnetic field | 3 % | 4 % |
| Magnetic induction | 2 % | 3 % |
| Electrostatic discharge | $10^{-6} \cdot m \cdot U_n \cdot I_{max}$ kWh<br>where m = the no. of measuring elements | |

7.1.3. After having undergone an electromagnetic disturbance, the electrical energy meter shall

— recover to operate within maximum permissible error, and

— have all measurement functions safeguarded, and

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

**Other requirements**

8. A meter shall have a display, visible by the consumer when installed in the normal installation position as specified by the manufacturer.

9. The display shall have a sufficient number of digits to ensure that the indication doesn't return to its initial value when the active electrical energy consumed in the circuit corresponds to operation of the meter for 1 500 h at $I = I_{max}$, $U = U_n$ and PF = 1.

10. When the electrical energy measured is indicated in different displays corresponding to different tariffs, the meter shall indicate the active tariff.

11. During use, it shall be impossible to reset the indication of the quantity of electrical energy measured.

12. A meter with a prepayment device shall show the value of the credit remaining.

The error of the value of electrical energy consumed per unit decrease of the credit remaining shall be ≤ 1 scale interval.

13. 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.

**Units**

14. The electrical energy measured shall be displayed in kilowatt-hours, symbol kWh.

PART 2 — MEASUREMENT TRANSFORMERS

**Quality of the electricity**

15. A measurement transformer shall satisfy the accuracy requirements laid down in this Annex in the case of electricity with a quality as specified in requirement 3 of this Annex.

No legal requirements in respect of metrological performance apply when the electricity has a quality, even momentarily, which is worse than the quality specified in requirement 3 of this Annex.

**Rated operating conditions**

16. The manufacturer shall specify the climatic and mechanical environment class B or class C for which the measurement transformer has been designed in accordance with Table 1 of Annex I.

**Accuracy classes**

17. The following accuracy classes are defined for measurement transformers intended for use in combination with an active electrical energy meter 0,1 - 0,2 - 0,5.

**Maximum permissible errors**

18. Table 4 shows the maximum errors, expressed in percent of the true value of the active electrical energy measured, that must be respected by the measurement transformer under rated operating conditions for electricity with a quality as specified in requirement 3 of this Annex.

*Table 4*

**Maximum permissible errors (percent of true value)**

| | Accuracy class | | |
|---|---|---|---|
| | 0,1 | 0,2 | 0,5 |
| *Current transformers for use in combination with induction type meters* | | | |
| $I = 0.05\ I_n$ | 0,4 | 0,75 | 1,5 |
| $I = 0.20\ I_n$ | 0,2 | 0,35 | 0,75 |
| $I = I_n$ | 0,1 | 0,2 | 0,5 |
| $I = 1.2\ I_n$ | 0,1 | 0,2 | 0,5 |
| *Current transformers for use in combination with static meters* | | | |
| $I = 0.01\ I_n$ | | 0,75 | 1,5 |
| $I = 0.05\ I_n$ | | 0,35 | 0,75 |
| $I = 0.20\ I_n$ | | 0,2 | 0,5 |
| $I = I_n$ | | 0,2 | 0,5 |
| $I = 1.2\ I_n$ | | 0,2 | 0,5 |
| *Voltage transformer* | | | |
| I = any value | 0,1 | 0,2 | 0,5 |

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.

*ANNEX MI-004*

**HEAT METERS**

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex apply to heat meters defined below.

**DEFINITIONS**

A heat meter is an instrument intended for measuring the heat which, in a heat exchange circuit, is absorbed or given up by a liquid called the heat conveying liquid.

A heat meter is either a complete instrument or an instrument made up of the sub-assemblies flow sensor, temperature sensor pair, and calculator, as defined in Article 3.2, or a combination of these.

$\vartheta$ = the temperature of the heat conveying liquid;

$\vartheta_{in}$ = the value of $\vartheta$ at the inlet of the heat exchange circuit;

$\vartheta_{out}$ = the value of $\vartheta$ at the outlet of the heat exchange circuit;

$\Delta\vartheta$ = $\vartheta_{in} - \vartheta_{out}$;

$\vartheta_{max}$ = the upper limit of $\vartheta$ for the heat meter to function correctly;

$\vartheta_{min}$ = the lower limit of $\vartheta$ for the heat meter to function correctly;

$\Delta\vartheta_{max}$ = the upper limit of $\Delta\vartheta$ for the heat meter to function correctly;

$\Delta\vartheta_{min}$ = the lower limit of $\Delta\vartheta$ for the heat meter to function correctly;

$q$ = the flow rate of the heat conveying liquid;

$q_s$ = the highest value of q that is permitted for short periods of time for the heat meter to function correctly;

$q_p$ = the highest value of q that is permitted permanently for the heat meter to function correctly;

$q_i$ = the lowest value of q that is permitted for the heat meter to function correctly;

$P$ = the thermal power of the heat exchange;

$P_s$ = the upper limit of P that is permitted for the heat meter to function correctly.

**SPECIFIC REQUIREMENTS**

PART 1 — METERS

**Rated operating conditions**

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

1.1. For the temperature of the liquid:

$\vartheta_{max}$, $\vartheta_{min}$, $\Delta\vartheta_{max}$, $\Delta\vartheta_{min}$, subject to the following restrictions:

$\Delta\vartheta_{max}/\Delta\vartheta_{min} \geq 10$;

$\Delta\vartheta_{min} = 2K$.

1.2. For the pressure of the liquid:

The maximum positive internal pressure that the heat meter can withstand permanently at the upper limit of the temperature range.

1.3. For the flow rate 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:

$P_s$.

1.5. For the climatic and mechanical influence quantities:

The environment class B, C, E or F for which the meter has been designed, in accordance with Table 1 of Annex I.

**Accuracy classes**

2. The following accuracy classes are defined for heat meters: class 2, class 3.

**Maximum permissible errors**

3. The maximum permissible errors for the accuracy classes, expressed in percent of the true value, are:

For class 2: $mpe = (3 + 4.\Delta\vartheta_{min}/\Delta\vartheta + 0{,}02.q_p/q)$

For class 3: $mpe = (4 + 4.\Delta\vartheta_{min}/\Delta\vartheta + 0{,}05.q_p/q)$

**Permissible effect of disturbances**

4.1. Electromagnetic immunity

4.1.1. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

4.1.2. The effect of an electromagnetic disturbance shall be such that:

the change in the measurement result is no greater than the critical change value as laid down in requirement 4.1.3, or

the indication of the measurement result is such that it cannot be interpreted as a valid result.

4.1.3. The critical change value is 0,5 of the mpe.

PART 2 — SUB-ASSEMBLIES

5. Where a heat meter is made up of sub-assemblies according to Article 4.3, the essential requirements for the heat meter apply to the sub-assemblies as relevant. In addition, the following requirements apply:

5.1. For the flow sensor:

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 mass or volume.

5.2. For the temperature sensor pair:

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

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

5.3. For the calculator:

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

where the error $E_c$ relates the value of the heat indicated to the true value of the heat.

5.4. For the combination of partial errors:

When the errors of a heat meter are determined from errors of subassemblies, the error of the heat meter is the arithmetic sum of the errors of the subassemblies.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.

*ANNEX MI-005*

## MEASURING SYSTEMS FOR THE CONTINUOUS AND DYNAMIC MEASUREMENT OF QUANTITIES OF LIQUIDS OTHER THAN WATER

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 of liquids other than water.

### 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 surcharged conduit.

**Measuring system**

A system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.

**Minimum measured quantity**

The minimum measured quantity is the smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.

**Base conditions**

The specified conditions to which the measured quantity of liquid is converted.

**Transfer point**

A point at which the liquid is defined as being delivered or received.

### SPECIFIC REQUIREMENTS

1. FLOWRATE RANGE

The flowrate range is specified by the manufacturer subject to the following conditions;

(i) the flowrate range of a measuring system shall be within the flowrate range of each of its elements;

(ii) Meter

*Table 1*

| Characteristic of liquid | Minimum ratio of $Q_{max}$: $Q_{min}$ |
|---|---|
| Liquefied gases (incl. Cryogenics) or viscosity ≥ 20 mPa.s | 5:1 |
| All other liquids | 10:1 |

(iii) Measuring system

*Table 2*

| Specific measuring system | Characteristic of liquid | Minimum ratio of $Q_{max}$: $Q_{min}$ |
|---|---|---|
| Fuel system for motor vehicles | Not LPG | 10:1 |
| | LPG | 5:1 |
| Measuring system | Cryogenic liquids | 5:1 |
| Measuring systems on pipelines or for loading/unloading ships | — | Free choice |
| All other measuring systems | — | 2:1 |

2. PROPERTIES OF THE LIQUID

The manufacturer shall specify the properties of the liquid by specifying the name or type of liquid or its relevant characteristics as follows:

— Temperature range;

— Pressure range;

— Density range;

— Viscosity range.

3. RATED OPERATING CONDITIONS

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

(i) the climatic and mechanical environment class B, C or I in which the instrument is intended to be used in accordance with Table 1 of Annex I, and observing the following conditions for temperature range:

— minimum range of 50 °C for classes C and I

— minimum range of 30 °C for class B

(ii) power supply: nominal AC voltage supply and/or limits of DC supply.

(iii) the base conditions for converted values.

4. ACCURACY CLASSIFICATION AND MAXIMUM PERMISSIBLE ERRORS

4.1. For quantities equal to or greater than two litres or the mass equivalent, the maximum permissible errors on indications are:

*Table 3*

| | 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 % |

4.2. For quantities less than two litres or the mass equivalent, the maximum permissible errors on indications are:

*Table 4*

| Measured quantity - V | Maximum permissible error |
|---|---|
| V < 0,1 L | 4 × value in Table 3, applied to 0,1 L |
| 0,1 L ≤ V < 0,2 L | 4 × value in Table 3 |
| 0,2 L ≤ V < 0,4 L | 2 × value in Table 3, applied to 0,4 L |
| 0,4 L ≤ V < 1 L | 2 × value in Table 3 |
| 1 L ≤ V < 2 L | value in Table 3, applied to 2 L |

*Note:* values given in litres are converted to the mass equivalent value for mass measuring instruments

4.3. However, no matter what the measured quantity may be, the magnitude of the maximum permissible error is given by the greater of the following two values:

— the absolute value of the maximum permissible error given in Table 3 or Table 4.

— the absolute value of the maximum permissible error for the minimum measured quantity ($E_{min}$).

4.4.1. $V_{min} \geq 2$ litres or mass equivalent

For minimum measured quantities greater than or equal to two litres or the mass equivalent,

*Alternative 1*

$E_{min}$ shall fulfil the condition: $E_{min} > 2R$, where R is the resolution of the indicating device.

*Alternative 2*

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

— $V_{min}$ is the minimum measured quantity,

— A is the numerical value specified in line A of Table 3.

4.4.2. $V_{min} < 2$ litres or mass equivalent

For minimum measured quantities less than two litres or the mass equivalent, $E_{min}$ is twice the value specified in Table 4, and related to line A of Table 3.

4.5. Conversion to base conditions

In case of converted indication to volume at base conditions or to mass the maximum permissible errors are as in line A of Table 3.

4.6. Conversion devices

Maximum permissible errors on converted indications due to a conversion device are equal to ± (A - B), A and B being the values specified in Table 1. However the magnitude of the maximum permissible error shall not be less than the greater of the two following values:

— one-half scale interval of the indicating device for converted indications,

— half of the value corresponding to $E_{min}$.

Parts of conversion devices that can be tested separately.

(a) Calculator

Maximum permissible error on quantities of liquid indications applicable to calculation, positive or negative, are equal to one-tenth of the maximum permissible error defined in line A of Table 3. However the magnitude of the maximum permissible error shall not be less than one half scale interval of the measuring system in which the calculator is intended to be used.

(b) Sensors

Sensors shall have an accuracy at least as good as the values in Table 5:

*Table 5*

| 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 |
| Pressure | Less than 1 Mpa: ± 50 k Pa<br>From 1 to 4 Mpa: ± 5 %<br>Over 4 Mpa: ± 200 kPa | | | | |
| Density | ± 1 kg/m$^3$ | | ± 2 kg/m$^3$ | | ± 5 kg/m$^3$ |

(c) Accuracy for calculating function

The maximum permissible error for the calculation of each characteristic quantity of the liquid, positive or negative, is equal to two fifths of the value fixed in (b) above. However the magnitude of the maximum permissible error shall not be less than one-half scale interval of the indicating device for converted indications.

5. MAXIMUM PERMISSIBLE EFFECT OF DISTURBANCES

5.1. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3 2 of Annex I.

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

— the change in the measurement result is no greater than the critical change value as defined in 5.3, 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 in the case of an interruptible system.

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

6. DURABILITY

6.1. An instrument shall be designed so that it can respect twice the maximum permissible error without adjustment during a period of one year of normal service after its first putting into use.

7. SUITABILITY

7.1. 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 self-service systems the scale intervals of all devices indicating the result of measurement shall be the same and results shall not deviate one from another.

7.2. A measuring system shall normally incorporate only one transfer point. When more than one transfer point is present under no circumstances shall it be possible to divert measured liquid.

7.3. 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 $V_{min}$. This value applies in the case of air or gas pockets.

7.4. Instruments for direct sales

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

7.4.2. The display of volume at metering conditions shall be permanent.

7.5. Fuel dispensers for motor vehicles

7.5.1. Displays on fuel dispensers for motor vehicles shall not be capable of being reset to zero during a measurement.

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

7.5.3. 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.

8. POWER SUPPLY FAILURE

8.1. A non-interruptible measuring system shall be provided with an emergency power supply device that will safeguard all measuring functions during the failure of the main power supply device.

8.2. An interruptible measuring system shall either comply with the above requirement for non-interruptible systems 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.

The absolute value of the maximum permissible error for the indicated quantity is increased by 5 % of the minimum measured quantity.

9. ACCURACY CLASSES AND USES

| Minimum 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:<br>— fuel dispensers for motor vehicles (other than LPG),<br>— measuring systems on road tankers for liquids of low viscosity<br>— measuring systems for unloading ship's tanks and rail and road tankers<br>— measuring systems for milk<br>— measuring systems for loading ships<br>— measuring systems for refuelling aircraft |
| 1,0 | — Measuring systems (other than LPG dispensers) for liquefied gases under pressure measured at a temperature equal to or above - 10 °C<br>— LPG dispensers for motor vehicles<br>— Measuring systems normally in class 0,3 or 0,5 but used for liquids<br>— whose temperature is less than - 10 °C or greater than 50 °C<br>— whose dynamic viscosity is higher than 1 000 mPa.s<br>— whose maximum volumetric flowrate is not higher than 20 L/h |
| 1,5 | Measuring systems for liquefied carbon dioxide<br>Measuring systems (other than LPG dispensers) 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) |

10. UNITS OF MEASUREMENT

Metered quantity shall be displayed in millilitres (ml) or cubic centimetres ($cm^3$), litres (l or L), cubic metres ($m^3$), grams (g), kilograms (kg) or tonnes (t).

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical systems: B+F, B+E, B+D, H1, G.

For electronic systems or systems containing software: B+F, B+D, H1, G.

*ANNEX MI-006*

## AUTOMATIC WEIGHING INSTRUMENTS

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in the different chapters 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 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.

**Weightgrader**

An automatic catchweigher that subdivides articles of different mass into several subgroups each characterised by a given mass range.

**Weigh labeller/price labeller**

An automatic catchweigher that labels/prices and labels individual articles.

**Automatic gravimetric filling instrument**

An automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk and which comprises essentially an automatic feeding device or devices associated with one or more weighing units and the appropriate control and discharge devices.

**Discontinuous totalizer (totalizing 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 totalizer**

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 ONE OR MORE AUTOMATIC WEIGHING INSTRUMENTS

1.1. **Rated operating conditions**

The manufacturer shall specify the rated operating conditions for the instrument, in particular, values shall be specified for the following operating conditions:

(i) measurement range of the instrument in terms of its maximum and minimum capacity,

(ii) power supply; nominal AC supply voltage and/or limits of DC supply,

(iii) the climatic and mechanical environment class B, C or I in which the instrument or its sub-assemblies are intended to be used in accordance with Table 1 of Annex I, and observing the following conditions for temperature range:

— minimum range of 50 °C for classes C and I

— minimum range of 30 °C for class B

1.2. **Manufacturer's specification**

The manufacturer shall also specify:

(i) rate of operation,

(ii) where appropriate for the intended use of the instrument, the characteristics of the product to be weighed, such as:

— temperature,

— particle size,

— bulk density,

— viscosity

— or any other defining characteristic.

2. **Electromagnetic environment**

In accordance with requirement 1.3.2 of Annex I the manufacturer shall specify in which electromagnetic environment Class E1 or Class E2 the instrument is intended to be used.

The permitted performance and the critical change value are given in the relevant Chapter 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 are not exceeded in normal operation.

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

3.3. If present, the operator control interface shall be clear and effective.

3.4. The integrity of the display shall be verifiable by the operator.

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

3.6. Printout

A processed printing of results outside the measurement range shall be identified as such.

CHAPTER II — AUTOMATIC CATCHWEIGHERS

1. **Accuracy classes**

Instruments are divided into accuracy classes designated by:

X(x) or Y(y)

1.1. Class X(x)

Class X(x) applies to instruments used to check prepackages made up in accordance with the requirements of directives 75/106/EEC and 76/211/EEC as amended.

X is a regime relating accuracy to load weight and the class designation factor (x) is a multiplier for the limits of error specified for class X(1).

The manufacturer shall specify the class designation factor (x). (x) shall be $1 \times 10^k$, $2 \times 10^k$ or $5 \times 10^k$, where k is an integer or zero.

1.2. Class Y(y)

Class Y(y) applies to all other automatic catchweighers. Class Y has two sub-classes Y(a) or Y(b).

2. **Maximum permissible error**

2.1. Class X(x) instruments

2.1.1. Mean error

| Load (m) in verification scale intervals (e)<br>(x) ≤ 1 (x) > 1 | | Maximum permissible mean error |
|---|---|---|
| 0 < m ≤ 500 | 0 < m ≤ 50 | ± 0,5 e |
| 500 < m ≤ 2 000 | 50 < m ≤ 200 | ± 1,0 e |
| 2 000 < m ≤ 10 000 | 200 < m ≤ 1 000 | ± 1,5 e |

2.1.2. Standard deviation

| Load (m) | Maximum permissible standard deviation for class X(1) |
|---|---|
| m ≤ 50 g | 0,48 % |
| 50 < m ≤ 100 | 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 % |

2.2. Class Y(y) instruments

| Net load (m) in verification scale intervals (e)<br>Class Y(a) Class Y(b) | | Maximum permissible error |
|---|---|---|
| 0 < m ≤ 500 | 0 < m ≤ 50 | ± 1,5 e |
| 500 < m ≤ 2 000 | 50 < m ≤ 200 | ± 2,0 e |
| 2 000 < m ≤ 10 00 | 200 < m ≤ 1 000 | ± 2,5 e |

3. **Measurement range**

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

— 20 e for class Y(a)

— 10 e for class Y(b)

— 5 e for postal scales of class Y(a) or Y(b)

4. **Dynamic setting**

When fitted, a dynamic setting facility that compensates for the dynamic effects of the load in motion:

— shall be inhibited to operate outside the specified load range, and

— shall be capable of being secured.

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

5. **Performance under electromagnetic disturbances**

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

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: F1, E1, D1, B+F, B+E, B+D, H, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, G.

CHAPTER III — AUTOMATIC GRAVIMETRIC FILLING INSTRUMENTS

1. **Accuracy classes**

1.1. 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 in the form $1 \times 10^k$, $2 \times 10^k$ or $5 \times 10^k$, the index k being any integer or zero.

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

1.2. Reference accuracy class

The reference accuracy class, Ref(x), is applicable for static weighing for which the maximum permissible error shall be as given in 2.2 multiplied by the class designation factor (x).

1.3. Operational accuracy class

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 2.2.

2. **Maximum permissible error**

2.1. Maximum permissible static weighing error

For static loads under rated operating conditions, the maximum permissible error for reference accuracy class Ref(x), shall be 0,36 of the maximum permissible deviation of each fill from the average as specified in 2.2.

2.2. Deviation from average fill

| Value of the mass of the fills — M(g) | Maximum permissible deviation of each fill from the average for class X(1) |
|---|---|
| $M \leq 50$ | 6,3 % |
| $50 < M \leq 100$ | 3,15 g |
| $100 < M \leq 200$ | 3,15 % |
| $200 < M \leq 300$ | 6,3 g |
| $300 < M \leq 500$ | 2,1 % |
| $500 < M \leq 1\,000$ | 10,5 g |
| $1\,000 < M \leq 10\,000$ | 1,05 % |
| $10\,000 < M \leq 15\,000$ | 105 g |
| $15\,000 < M$ | 0,7 % |

*Note:* Maximum deviation of each fill from the average may be adjusted in the case of a positive error to account for the effect of material particle size.

2.3. Maximum permissible 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 0,36 of the maximum permissible deviation of each fill from the average, as specified in 2.2.

3. **Performance under electromagnetic disturbance**

The critical change value is equal to a change of static weight indication equal to the maximum permissible error as specified in 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.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: B+F, B+E, B+D, H1, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, G.

CHAPTER IV — DISCONTINUOUS TOTALIZERS

1. **Maximum permissible error**

| Accuracy class | Maximum permissible error of totalized load |
|---|---|
| 0,2 | ± 0,10 % |
| 0,5 | ± 0,25 % |
| 1 | ± 0,50 % |
| 2 | ± 1,00 % |

2.1. Totalization scale interval ($d_t$) shall be in the range:

0,01 % max < $d_t$ < 0.2 % max.

2.2. Minimum totalized load ($\Sigma_{min}$) shall be greater than the load at which the maximum permissible error is equal to the totalization scale interval ($d_t$) and greater than the minimum load.

2.3. Zero setting

Instruments that do not tare weigh after each discharge shall have a zero setting device and automatic operation shall be inhibited if zero indication > 0,5 d.

2.4. Operator interface

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

2.5. Printout

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

3. **Performance under electromagnetic disturbances**

The critical change value due to a disturbance is:

(a) one scale interval of weight indication; or

(b) one totalization scale interval for any stored total.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: B+F, B+E, B+D, H1, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, G.

CHAPTER V — CONTINUOUS TOTALIZERS

1. **Measurement range**

In specifying the measurement range the manufacturer shall take account that:

(i) The minimum instantaneous net load on the weighing unit shall not be less than 20 % of the maximum capacity.

(ii) The minimum totalized load $\Sigma_{min}$ shall not be less than the largest of the following values:

— 2 % of the load totalized in one hour at maximum flowrate;

— the load obtained at maximum flowrate in one revolution of the belt;

— the load corresponding to the following appropriate number of totalization scale intervals,

800 e for class 0.5

400 e for class 1

200 e for class 2.

2. **Maximum permissible error**

| Accuracy class | Percentage of the mass of the totalized load |
|---|---|
| 0,5 | 0,25 |
| 1 | 0,5 |
| 2 | 1,0 |

3. **Speed of the belt**

The speed of the belt shall be specified by the manufacturer. 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.

4. **It shall not be possible for the general totalization device to be reset to zero.**

5. **Performance under electromagnetic disturbances**

The critical change value due to a disturbance is 0,7 mpe.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: B+F, B+E, B+D, H1, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, G.

CHAPTER VI — AUTOMATIC RAIL WEIGHBRIDGES

1. **Maximum permissible error**

| Accuracy class | Percentage of mass of single wagon or total train, as appropriate |
|---|---|
| 0,2 | 0,1 |
| 0,5 | 0,25 |
| 1 | 0,5 |
| 2 | 1,0 |

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 maximum permissible error given in the above Table but shall not exceed twice that value.

2. **The scale interval shall not be greater than one tenth of the initial MPE applied to the minimum capacity.**

3. **Performance under electromagnetic disturbance**

The critical change value is one verification scale interval.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: B+F, B+E, B+D, H1, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, G.

*ANNEX MI-007*

**TAXIMETERS**

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

DEFINITIONS

A taximeter is a measuring instrument designed for installation in a motor vehicle that calculates and displays the fare to be paid for a trip, based on the distance travelled and the duration of the trip.

**SPECIFIC REQUIREMENTS**

**Design requirements**

1. A taximeter shall be designed to measure the following parameters:

   (a) the distance travelled;

   (b) the duration;

   (c) the period of time during which the speed of the car was below a certain threshold value. This threshold value of the speed shall be adjustable and it shall be possible to secure the adjustment.

2. In addition to the devices necessary to carry out the measurements referred to in requirement 1, a taximeter shall comprise the following auxiliary devices:

   — a printer interface or built-in printer;

   — a real time clock;

   — a device for data exchange to a central device.

   It shall be possible to disable the functioning of any of these auxiliary devices and to secure the disablement.

3. A taximeter shall be able to calculate the fare in both of the following manners:

   1. on the basis of parameters (a) and (b) of requirement 1;

   2. on the basis of parameters (a) and (c) of requirement 1.

   It shall be possible to disable the functioning of any of these two modes of calculation and to secure the disablement.

4. It shall be possible to adjust a taximeter for the vehicle constant of the taxi in which it is to be installed and to secure the adjustment.

**Rated operating conditions**

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

   — the climatic and mechanical environment class D, E or F in which the instrument is intended to be used in accordance with Table 1 of Annex I;

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

**Maximum permissible errors**

6. The maximum permissible errors are:

   — For the time elapsed: ± 0,1 %;

   — For the distance travelled: ± 0,2 %;

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

**Permissible effect of disturbances**

7.1. Electromagnetic immunity.

7.1.1. The electromagnetic class that applies is E2 in accordance with point 1.3.2. of Annex I.

7.1.2. The maximum permissible errors laid down in requirement 6 shall also be respected in the presence of an electromagnetic disturbance.

**Power supply failure**

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

— save and display the value of the fare at the moment the power supply failure took place, and return to the position 'for hire', or

— preserve its measuring functions and continue to meet the maximum permissible errors until it saves and displays the value of the fare and returns to the position 'for hire'.

**Other requirements**

9.1. A taximeter shall permanently display the fare in real-time.

9.2. If the fare includes a fixed sum, this shall be excluded from the fare displayed. However, in that case a taximeter may display temporarily the value of the fare inclusive of the fixed sum.

10. If the fare is calculated according to method 1 of requirement 3, a taximeter may have an additional display mode in which only distance travelled and duration of the trip are displayed in real time.

11. All values displayed for the passenger shall be clearly readable under daylight and night conditions.

12. If the fare to be paid can be effected by the choice of functionality from a pre-programmed set or by free data setting, it shall be possible to secure the instrument settings and data entered.

13. A taximeter shall be fitted with totalizers for all of the following values:

— the values of the parameters listed in requirement 1;

— the values of the fare.

The totalized values shall include the values saved according to requirement 8 under conditions of loss of power supply.

If disconnected from power, a taximeter shall retain the totalized values during at least six months.

14. It shall be impossible to change the tariff, tariff structure or mode of calculation of the fare with the taximeter in operation, other than automatic changes by the meter itself on the basis of

— the parameters listed in requirement 1; or

— the time of the day and day of the week if the taximeter is fitted with a real time clock.

15. It shall be possible to secure the connection of the taximeter to the taxi in which it is installed.

16. It shall be possible to verify the compliance of a taximeter installed in a taxi with the requirements on maximum permissible error.

17. 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 impossible.

18. A taximeter shall be designed so that it can respect the maximum permissible errors without adjustment during a period of 1 year of normal use.

19. For the auxiliary devices listed in requirement 2 whose functioning has not been disabled and secured as part of the conformity assessment, the following additional requirements apply:

for the printer interface or built-in printer:

— the functioning of the taximeter shall be inhibited when no printer is connected or when printing is impossible for other reasons;

for the real time clock:

— the possibility to adjust the time of the day shall be limited to 2 minutes per week. Adjustment to summer and winter time shall be automatic;

for the data exchange device:

— transfer to a central system of data that are subject to legal control by this Directive shall only be possible if the taximeter protects the data against accidental or deliberate interference during the transfer;

— transfer from a central system of data that are subject to legal control by this Directive is subject to the following requirements:

— it shall be easily possible to check the correct reception of the data by the taximeter;

— the taximeter shall transmit evidence of correct data reception to the central system.

20. The values of distance travelled and time elapsed, when displayed or printed in accordance with this Directive, shall use the following units:

distance travelled:

— in the United Kingdom and Ireland: until the date which will be fixed by these Member States according to Article (1)(b) of Directive 80/181/EEC, as last amended by Directive 89/617/EEC: kilometres or miles;

— in all other Member States: kilometres.

Time elapsed:

minutes.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.

*ANNEX MI-008*

## MATERIAL MEASURES

CHAPTER I — MATERIAL MEASURES OF LENGTH

The relevant essential requirements of Annex I, the specific requirements of this chapter and the conformity assessment procedures listed in this chapter apply to material measure of length defined below.

### DEFINITIONS

#### Material measure of length

An instrument whose scale marks determine the length of a measured object by direct comparison.

### SPECIFIC REQUIREMENTS

#### Reference conditions

1.1. For tapes of length equal to or greater than five metres, the maximum permissible errors are to be respected with a tractive force of twenty Newtons, unless otherwise specified by the manufacturer and marked accordingly.

1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked accordingly.

#### Maximum permissible errors

2. The maximum permissible error, positive or negative, between two non-consecutive scale marks is $L = a + bL$, 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 maximum permissible error for any distance beginning at this point is increased by the value c given in Table 1 below.

*Table 1*

| Accuracy class | a (mm) | b | c (mm) |
|---|---|---|---|
| I | 0,1 | $1,10^{-4}$ | 0,1 |
| II | 0,3 | $2,10^{-4}$ | 0,2 |
| III | 0,6 | $4,10^{-4}$ | 0,4 |

The maximum permissible error for the length of two 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 | Maximum permissible error or difference in millimetres according to accuracy class | | |
|---|---|---|---|
| | I | II | III |
| $i \leq 1$ mm | 0,1 | 0,2 | 0,3 |
| 1 mm $< i \leq 1$ cm | 0,2 | 0,4 | 0,6 |
| 1 cm $< i \leq 1$ dm | 0,3 | 0,5 | 0,9 |

**Materials**

3.1. Materials used for material measures of length shall have such a temperature stability that the maximum permissible error can be respected in a range of ± 8 K.

3.2. The materials used for material measures of length shall have such humidity stability that the maximum permissible error can be respected up to 85 % relative humidity.

**Markings**

4. The scale marks shall bear the value of length.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: A1, F1, E1, D1, B+E, B+D, H, G.

CHAPTER II - CAPACITY SERVING MEASURES

The relevant essential requirements of Annex I, the specific requirements of this chapter and the conformity assessment procedures listed in this chapter apply to capacity serving measures defined below.

**DEFINITIONS**

**Capacity serving measure**

A capacity measure intended to determine a specified volume of a liquid which is sold for immediate consumption.

**Line measure**

A capacity serving measure having a mark 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**

**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. Maximum permissible errors

*Table 1*

| | |
|---|---|
| Transfer measures | ± 3 % |
| Line measures < 200 ml | ± 5 % |
| Line measures ≥ 200 ml | ± 3 % |
| Brim measures < 200 ml | 0 to 10 % |
| Brim measures ≥ 200 ml | 0 to 6 % |

**Materials**

3. Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the maximum permissible error.

**Shape**

4.1. Transfer measures shall be designed so that a change of contents equal to the maximum permissible error causes a change in level of 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.

**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. A further half-capacity filling mark associated with one of the marked capacities is allowed provided it does not cause confusion.

5.3. All filling marks shall be sufficiently clear and durable to ensure that maximum permissible errors are not exceeded in use.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: A1, F1, E1, D1, B+E, B+D, H.

*ANNEX MI-009*

## DIMENSIONAL MEASURING INSTRUMENTS

The applicable 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.

### DEFINITIONS

#### Length measuring instrument

A length measuring instrument serves for the automatic determination of the length of materials in the form of bands and cables during feed motion of the product to be measured.

#### Area measuring instruments

An area measuring instrument serves for the automatic determination of the area of irregular shaped objects, e.g. for leather.

#### Multi-dimensional measuring instruments

A multi-dimensional measuring instrument serves for the automatic determination of the edge length (length, hight, width) of the smallest enclosing rectangular parallelepiped of a product.

### CHAPTER I — REQUIREMENTS COMMON TO ALL DIMENSIONAL MEASURING INSTRUMENTS

#### Mechanical and climatic environment

1. The manufacturer shall specify in which climatic and mechanical environment class the instrument is intended to be used in accordance with Table 1 of Annex I.

#### Electromagnetic immunity

2.1. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

2.2. 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 2.3; 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.

2.3. The critical change value is equal to one scale interval.

#### Durability

3. An instrument must be designed so that it can respect twice the maximum permissible error without adjustment, during a period of one year in normal use.

### CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Article 7 are:

For mechanical or electromechanical instruments: F1, E1, D1, B+E, B+D, H, G.

For electronic instruments or instruments containing software: B+F, B+D, H1, 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:

$K = \varepsilon(G_A + 2.2\ N/m^2)$, where

$\varepsilon$ 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 as given in Table 1:

*Table 1*

| Group | Range of K | Product |
|---|---|---|
| I | $0 < K < 2{,}10^{-2}\ N/m^2$ | 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.

**Maximum permissible errors**

3.1. Instrument

*Table 2*

| Accuracy class | Maximum permissible error |
|---|---|
| I | 0,125 % |
| II | 0,25 % |
| III | 0,5 % |

However, the maximum permissible absolute error cannot be less than the values given below:

Class I: 0,005 Lm

Class II: 0,01 Lm

Class III: 0,02 Lm

Where Lm 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.

**Other requirements**

4.1. 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.

**Maximum permissible errors**

2.1. Instrument

The initial 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 should 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. The range shall be one of the following:

— 0,5 cm to 5,0 cm;

— 1,0 cm to 80 cm;

— 5 cm to 2 m;

— 50 cm to 20 m.

1.2. Speed of the product

The speed must be within the range specified by the manufacturer for the instrument.

**Maximum permissible error**

2.1. Instrument:

*Table 1*

| Range | Maximum permissible error |
|---|---|
| 0,5 cm-5,0 cm | 0,1 cm |
| 1,0 cm-80 cm | 0,2 cm |
| 5 cm-200 cm | 1,0 cm |
| 50 cm-2 000 cm | 10 cm |

*ANNEX MI-010*

## EVIDENTIAL BREATH ANALYSERS

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex apply to evidential breath analysers defined below.

DEFINITIONS

An evidential breath analyser is a measuring instrument that serves to determine the concentration of ethanol in exhaled alveolar air and that is intended for use for evidential purposes.

### SPECIFIC REQUIREMENTS

#### Rated operating conditions

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

1.1. For the measurand:

— The measuring range, subject to the following constraint:

— The measuring range shall extend from 0 mg/l to at least 1,5 mg/l.

1.2. For the condition of the exhaled air:

— Volume range: 1.5-4.5 l;

— Duration of exhalation: 5-15 s.

1.3. For the climatic and mechanical influence quantities:

— For a non-portable instrument, the environment class that applies is class E;

— For a portable instrument, the environment class that applies is class I.

1.4. For the electrical supply influence quantities:

— In case of AC voltage supply: The voltage range, subject to the following constraints:

— The minimum value of the voltage range shall be ≤ nominal value − 8 %;

— The maximum value of the voltage range shall be ≥ nominal value + 24 %.

— In case of DC voltage supply:

— The limits of the DC voltage supply.

1.5. For the ambient pressure:

— The minimum and maximum values of the ambient pressure, subject to the following restrictions:

— Min ≤ 800 hPa

— Max ≥ 1 040 hPa

#### Maximum permissible error

2. The maximum error values permitted under rated operating conditions according to requirement 3.1 of Annex I are as shown in Table 1. Percentage values are percent of the true value.

*Table 1*

| True value (mg/l) | Maximum permitted error |
|---|---|
| < 0,4 | 0,02 mg/l |
| ≥ 0,4<br>≤ 2 | ± 5 % |
| > 2 | ± 20 % |

3. The verification scale interval = 0,001 mg/l.

**PERMISSIBLE EFFECT OF DISTURBANCES**

**Electromagnetic immunity**

4. The manufacturer shall specify the electromagnetic environment E1 or E2 in which the measuring instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

5. The effect of an electromagnetic disturbance shall be such that:

   (a) the change in measurement result is no greater than the maximum permissible error of the measurement result, or

   (b) the measurement result presented cannot be interpreted as a valid result in that:

   — the carrying out of any measurement is impossible, or

   — there are momentary variations in the measurement result that cannot be interpreted, memorised or transmitted as a measurement result, or

   — there are variations in the measurement result severe enough to be noticed by all those interested in the measurement result.

**Durability**

6. An evidential breath analyser shall be designed so that it can respect 1.6 times the maximum permissible error without adjustment during a period of 2 years after its first putting into use.

**Other requirements**

7. An evidential breath analyser shall indicate the measurement result in mg/l.

8. For any concentration up to 0,4 mg/l, the standard deviation of the results of 10 measurements shall be less than 0,007 mg/l.

   For any concentration equal to or greater than 0,4 mg/l and less than or equal to 2 mg/l, the standard deviation of the results of 10 measurements shall be less than 1,75 %.

   For any concentration greater than 2 mg/l, the standard deviation of the results of 10 measurements shall be less than 6 %.

9. An evidential breath analyser shall only carry out a measurement if the sample taken is recognised as being representative of the alveolar air. It shall in particular inhibit a measurement if the exhalation was discontinuous, or if the exhaled air contained breath from the upper respiratory tracts.

10. Before each measurement operation, the evidential breath analyser shall verify automatically that it is capable of carrying out a correct measurement, and shall in particular carry out an automatic adjustment. In case this automatic verification shows that not all conditions for correct operation are fulfilled, any measurement shall be automatically inhibited.

11. It shall be possible for the user to pre-set a numerical value in the evidential breath analyser. After each measurement with a result greater than this pre-set value, the analyser shall automatically, and before presenting the measurement result, repeat the verification referred to in requirement 10. In case this second verification shows that not all conditions for correct operation are fulfilled, no measurement result shall be presented.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: B+F, H1, G.

*ANNEX MI-011*

## EXHAUST GAS ANALYSERS

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

An exhaust gas analyser is a measuring instrument that serves to determine all of the volume fractions of the following components of the exhaust gas of a motor vehicle engine with spark ignition: carbon monoxide, carbon dioxide, hydrocarbons and oxygen.

An exhaust gas analyser may determine in addition the value of the parameter λ.

### SPECIFIC REQUIREMENTS

#### Instrument classes

1. Two instrument classes I and II are being defined for exhaust gas analysers, the measurement ranges for these classes being as shown in Table 1.

*Table 1*

**Classes and measurement ranges**

| Parameter | Class I | | Class II | |
|---|---|---|---|---|
| | Min | Max | Min | Max |
| CO fraction ($\%^{v}/_{v}$) | 0 | ≥ 5<br>< 7 | 0 | ≥ 7 |
| $CO_2$ fraction ($\%^{v}/_{v}$) | 0 | ≥ 16 | 0 | ≥ 16 |
| Hydrocarbon fraction ($\%^{v}/_{v}$) | 0 | ≥ 0,2 | 0 | ≥ 0,2 |
| $O_2$ fraction ($\%^{v}/_{v}$) | 0 | ≥ 21 | 0 | ≥ 21 |
| λ | ≤ 0,8 | ≥ 1,2 | ≤ 0,8 | ≥ 1,2 |

#### Rated operating conditions

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

2.1. For the climatic and mechanical influence quantities:

— The environment class that applies is class B, in accordance with Table 1 of Annex I.

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 maximum values of the ambient pressure, subject to the following restrictions:

| | $p_{min}$ | $p_{max}$ |
|---|---|---|
| Class I | 860 hPa | 1 060 hPa |
| Class II | 800 hPa | 1 040 hPa |

2.4. For the concentration of residue hydrocarbon present before a measurement:

The maximum value of the concentration, subject to the following constraint: For a class I instrument, this value shall be no greater than 20 ppm $^{v}/_{v}$.

**Maximum permissible errors**

3. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to requirement 1.1 of Annex I is the smaller of the two values shown in Table 2. Absolute values are expressed in $\%^{v}/_{v}$ or ppm $^{v}/_{v}$, percentage values are percent of the true value.

*Table 2*

**Maximum permissible errors**

| Parameter | Class I | Class II |
|---|---|---|
| CO fraction | ± 0,06 $\%^{v}/_{v}$<br>± 5 % | ± 0,2 $\%^{v}/_{v}$<br>± 10 % |
| $CO_2$ fraction | ± 0,5 $\%^{v}/_{v}$<br>± 5 % | ± 1 $\%^{v}/_{v}$<br>± 10 % |
| Hydrocarbon fraction | ± 12 ppm $^{v}/_{v}$<br>± 5 % | ± 30 ppm $^{v}/_{v}$<br>± 10 % |
| $O_2$ fraction | ± 0,1 $\%^{v}/_{v}$<br>± 5 % | ± 0,2 $\%^{v}/_{v}$<br>± 10 % |
| Λ | ± 0,3 % | ± 0,3 % |

**Permissible effect of disturbances**

4. Electromagnetic immunity

The manufacturer shall specify the electromagnetic environment E1 or E2 in which the instrument is intended to be used in accordance with requirement 1.3.2 of Annex I.

The effect of an electromagnetic disturbance shall be such that:

— either the change in the measurement result is no greater than the critical change value laid down in point 4.1.3,

— or the presentation of the measurement result is such that it cannot be taken for a valid result.

For each of the volume fractions measured by the instrument, the critical change value is equal to the maximum permissible error for the parameter concerned.

**Other requirements**

5. The maximum permitted scale intervals for each of the two instrument classes are as shown in Table 3:

*Table 3*

**Maximum permitted scale intervals**

| Parameter | Class I | Class II |
|---|---|---|
| CO fraction | 0,01 $\%^{v}/_{v}$ | 0,05 $\%^{v}/_{v}$ |
| $CO_2$ fraction | 0,1 $\%^{v}/_{v}$ | 0,1 $\%^{v}/_{v}$ |
| Hydrocarbon fraction | 1 ppm $^{v}/_{v}$ | 5 ppm $^{v}/_{v}$ |
| $O_2$ fraction | 0,02 $\%^{v}/_{v}$ if $O_2 \leq 4$ $\%^{v}/_{v}$<br>0,10 $\%^{v}/_{v}$ if $O_2 > 4$ $\%^{v}/_{v}$ | 0,1 $\%^{v}/_{v}$ |
| λ | 0,01 | 0,01 |

6. The standard deviation of 20 measurements shall not exceed mpe/3.

7. The indications of the measurement results shall have reached 95 % of the final values in no more than 15 s.

8. The components in the exhaust gas other than the component whose value is subject to measurement shall not affect the measurement result by more than 0.5 mpe, when those components are present in the following volume fractions:

   $CO \leq 6\ \%^{v}/_{v}$

   $CO_2 \leq 16\ \%^{v}/_{v}$

   $O_2 \leq 10\ \%^{v}/_{v}$

   $H_2 \leq 5\ \%^{v}/_{v}$

   $NO \leq 0{,}3\ \%^{v}/_{v}$

   $HC \leq 2\ 000\ \text{ppm}\ ^{v}/_{v}$

   Water vapour: any value.

9. An exhaust gas analyser that is equipped with an automatic or semi-automatic adjustment facility shall be unable to make a measurement as long as the adjustments have not been made.

10. An exhaust gas analyser with a hydrocarbon channel shall detect hydrocarbon residues in the gas handling system. It shall be impossible to carry out a measurement if the concentration of the residue hydrocarbon present before a measurement exceeds the rated value as specified by the manufacturer according to requirement 2.6 of this Annex.

**CONFORMITY ASSESSMENT**

The conformity assessment procedures referred to in Article 7 are: B+F, B+D, H1.