On the basis of article 14 paragraph 4 of the Law on Metrology (Official Gazette of Montenegro 79/08) and article 6 of the Law on Technical Requirements for Products and Conformity Assessment (Official Gazette of Montenegro 53/11), the Ministry of Economy has adopted

RULEBOOK
ON TECHNICAL AND METROLOGICAL REQUIREMENTS RELATING TO MEASURING INSTRUMENTS AND SYSTEMS WITH A MEASURING FUNCTION

(Official Gazette of Montenegro 041/17 of 28 June 2017)

PUBLISHER'S NOTE:

This regulation shall apply as of 1 January 2018.
The regulation that is currently in force can be accessed HERE.

I. Basic provisions

Subject

Article 1

This Rulebook prescribes the requirements for devices and systems with a measuring function (hereinafter referred to as: measuring instruments), that are placed on the market and/or use, conformity assessment procedure with prescribed requirements, requirements for bodies conducting conformity assessment and other issues of relevance for measuring instruments.

Measuring instrument

Article 2

Measuring instrument, within the meaning of this Rulebook, is a device or a system with a measuring function, intended to be used to make measurements, alone or in conjunction with supplementary device(s).

Application

Article 3

The provisions of this Rulebook shall apply to:

1) Water meters (MI-001),
2) Gas meters and volume conversion devices (MI-002);
3) Active electrical energy meters (MI-003);
4) Heat meters (MI-004);
5) Measuring systems for continuous and dynamic measurement of quantities of liquids other than water (MI-005);

6) Automatic weighing instruments (MI-006);
7) Taximeters (MI-007);
8) Material measures (MI-008);
9) Dimensional measuring instruments (MI-009) and
10) Exhaust gas analysers (MI-010).

Subassemblies

Article 4

Provisions of this Rulebook shall also apply to subassemblies, the essential requirements of which were defined in this Rulebook.

Definitions

Article 5

Terms used in this Rulebook shall have the following meaning:

1) ***subassembly*** shall mean a part of the computer (hardware), which operates independently and is an integral part of the measuring instrument together with other subassemblies with which it is compatible, or other measuring instrument with which it is compatible.
2) ***making available on the market*** shall mean any supply of a measuring instrument intended for distribution or use on the Montenegrin market in the framework of a commercial activity, either paid or free of charge.
3) ***placing on the market*** shall mean the first making available of a measuring instrument on the Montenegrin market;
4) ***putting into use means*** shall mean the first use of a measuring instrument intended for the end-user according to its purpose;
5) ***manufacturer*** shall mean a natural or legal person who manufactures a measuring instrument or represents himself as manufacturer by marketing that measuring instrument under his business name, title, trademark or any other recognizable mark;
6) ***authorised representative*** shall mean any natural or legal person established or residing in Montenegro who has received a written mandate from a manufacturer to act on his behalf in accordance with this Rulebook;
7) ***importer*** shall mean any natural or legal person established or residing in Montenegro, who imports a measuring instrument from a third country and places it on the Montenegrin market;
8) ***distributor*** shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a measuring instrument available on the market;
9) ***economic operators*** shall mean manufacturers, authorized representatives, importers and distributors;
10) ***technical specification*** shall mean a document that prescribes technical requirements to be met by a measuring instrument;

11) ***harmonized standard*** shall mean a European standard adopted based on the requirements laid down by the European Commission that have their reference published in the Official Journal of the European Union;
12) ***normative document*** shall mean a document containing technical specifications approved by the International Organization of Legal Metrology (Organisation Internationale Metrologie Legale);
13) ***conformity assessment*** shall mean the process demonstrating whether the requirements defined by this Rulebook relating to a measuring instrument have been fulfilled;
14) ***conformity assessment body*** shall mean a legal body performing conformity assessment activities including calibration, testing, certification and inspection (laboratories, certification bodies, control bodies, etc.);
15) ***notified body*** shall be a conformity assessment body which fulfils the requirements defined by a technical regulation and which was registered with the EU Commission by an EU Member State or a state which concludes with EU an Agreement of Conformity Assessment and Acceptance of Industrial Products.

Basic and specific requirements

Article 6

The basic provisions that the measuring instruments must fulfil are given in Annex 1 which forms an integral part of this Rulebook.

The specific requirements referred to in Article 3 of this Rulebook that need to be fulfilled relating to certain types of measuring instruments, shall be given in Annex 3 - 12 which form an integral part of this Rulebook.

In addition to the requirements referred to in this Article paragraphs 1 and 2, measuring instruments shall also fulfil the requirements with regard to radiation, as defined by the special regulation regulating electromagnetic compatibility.

Information contained in Annex 1 point 9 of this Rulebook and information given in Annex 3 – 12 of this Rulebook referring to the correct use of measuring instruments, shall be in Montenegrin.

Making available on the market and putting into use

Article 7

Measuring instruments fulfilling the requirements laid down by this Rulebook may be made available on the market and/or put into use.

When different accuracy classes are defined for a measuring instrument:

1) provisions of Annex 3 - 12 with regard to putting into use of measuring instruments, may indicate the accuracy classes (e) used for certain applications of a measuring instrument;

2) in other cases, accuracy classes to be used for specific applications may be determined, under the condition that they are within the defined accuracy classes as defined by this Rulebook.

In cases referred to in paragraph 2 of this Article, the owner of a measuring instrument may use measuring instruments of a better accuracy class.

Measuring instruments not in conformity with this Rulebook may be exhibited at trade fairs, exhibitions, public presentations or any other similar manifestations, provided that a visible sign clearly indicates their non-conformity to the requirements laid down by this Rulebook.

II. OBLIGATIONS OF ECONOMIC OPERATORS

Manufacturer

Article 8

Apart from the requirements prescribed by the Law, manufacturers shall ensure that the measuring instrument made available on the market and/or put into use has been designed and manufactured in accordance with the essential requirements set out in Annex I of this Rulebook and in the specific requirements referred to in Annexes 3 to 12 attached to this Rulebook with regard to specific types of measuring instruments.

Manufacturers shall carry out and ensure carrying out of the relevant conformity assessment procedures referred to in Article 14 of this Article and draw up the technical documentation referred to in Article 15 of this Rulebook.

Where conformity assessment procedure referred to in paragraph 2 of this Article demonstrates compliance of a measuring instrument with the requirements defined by this Rulebook, the manufacturer shall draw up a written EU declaration of conformity which is attached to Annex 13 and forms an integral part of this Rulebook (hereinafter referred to as "EU declaration of conformity") and shall affix the CE marking and the supplementary metrology marking to the measuring instrument.

Manufacturers shall keep the technical documentation and the EU declaration of conformity for at least 10 years from the date of placing the measuring instrument on the market.

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

Manufacturers shall ensure that measuring instruments which they have made available on the market are accompanied by an EU declaration of conformity, instructions and information in Montenegrin.

Manufacturers shall indicate their name, registered trade name or registered trade mark and a valid address as well as relevant contact details written in Montenegrin on the measuring instruments or, where that is not possible, on the packaging or in a document accompanying the measuring instrument.

Authorised representative

Article 9

Authorised representatives shall keep the EU declaration of conformity and the technical documentation with regard to the measuring instruments and make them available to the

competent authority in the period of 10 years from the date of placing the measuring instrument on the market and shall fulfil other obligations prescribed by the Law.

Importer

Article 10

Importers shall only place on the market measuring instruments compliant with the requirements prescribed in this Rulebook.

Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted, on the measuring instruments or, where that is not possible, on the packaging or in a document accompanying the measuring instrument. The contact details shall be in Montenegrin.

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

Importers shall keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the competent authority for 10 years from the date of placing the measuring instrument on the market, and shall fulfil other obligations as prescribed by the law.

Distributor

Article 11

In addition to the obligations laid down by the law, distributor shall verify that the measuring instrument, prior to its making available and/or placing on the market, bears the CE marking and the supplementary metrology marking, that it is accompanied by the EU declaration of conformity, by the required documents and by instructions and information in accordance with the requirements laid down in this Rulebook.

Identification of suppliers

Article 12

Suppliers shall, on request, submit to the competent authority information on each economic operator to whom they have supplied a measuring instrument.

Suppliers shall be able to present the information referred to in the first paragraph of this Article for 10 years from the date on which they have been supplied with the measuring instrument.

III. CONFORMITY OF MEASURING INSTRUMENTS

Presumption of conformity of measuring instruments

Article 13

Measuring instruments shall be presumed to be in conformity with the requirements laid down in this Rulebook, if they have been manufactured in accordance with Montenegrin standards or parts of Montenegrin standards, which have incorporated harmonized standards, the references of which have been published in the "Official Gazette of Montenegro".

A manufacturer may choose to use any conceptual design that complies with the essential requirements set out in Annex I and Annexes 3 to 12 of this Rulebook with regard to specific types of measuring instruments. In addition, the measuring instruments shall be considered complied with these requirements if the manufacturer has correctly applied the design set out in standards referred to in paragraph 1 of this Article.

Compliance with the appropriate tests mentioned in Article 15 paragraph 4 point 9 of this Rulebook shall be presumed, if the corresponding testing has been performed in accordance with the relevant standards and Annexes referred to in paragraphs 1 and 2 of this Article and if the test results ensure compliance with the essential requirements laid down in this Rulebook.

Conformity assessment procedures

Article 14

Conformity assessment of a measuring instrument with the requirements laid down in this Rulebook shall be carried out in accordance with the conformity assessment procedures given in Annex 2 which forms and integral part of this Rulebook, as well as in Annexes 3 to 12 which refer to the specific types of measuring instruments.

Records and correspondence relating to conformity assessment procedures shall be drawn up in Montenegrin or in the language accepted by the notified body carrying out the conformity assessment procedures.

Technical documentation
Article 15

Technical documentation on the measuring instrument shall include an intelligible description of the conceptual design and manufacturing drawings, manufacturing and operation of the measuring instrument.

Technical documentation referred to in paragraph 1 of this Article shall permit an assessment of conformity with the applicable requirements laid down in this Rulebook.

The technical documentation mentioned in paragraph 1 of this Article shall contain the relevant information to ensure:

1) the definition of the metrological characteristics;

2) the reproducibility of the metrological performances of produced measuring instruments when properly adjusted using appropriate means and

3) the integrity of the measuring instrument.

The technical documentation referred to in paragraph 1 of this Article shall insofar as relevant for assessment and identification of the type and/or the measuring instrument include the following information:

1) a general description of the measuring instrument;
2) conceptual design and technical drawings and plans of components, sub-assemblies, circuits, etc.;
3) manufacturing procedures to ensure consistent production;
4) if applicable, a description of the electronic devices with drawings, diagrams, flow diagrams of the logic and general software information explaining their characteristics and operation;
5) descriptions and explanations necessary for the understanding of the information referred to in points 2), 3) and 4) of this paragraph, including the operation of the measuring instrument;
6) a list of the Montenegrin standards and/or normative documents referred to in Article 13 of this Rulebook, applied in full or in part;
7) descriptions of the designs adopted to meet the essential requirements where Montenegrin standards referred to in Article 13 of this Rulebook and/or normative documents have not been applied, including a list of other relevant technical specifications applied;
8) results of design calculations, examinations, etc.;
9) the appropriate test results, where necessary, to demonstrate that the type and/or the measuring instruments comply with the following:
a) the requirements of this Rulebook under declared rated operating conditions and under specified environmental disturbances,
b) the durability specifications for gas-, water-, thermal energy-meters as well as for measuring systems for liquids other than water;
10) the EU-type examination certificates or EU design and technical drawing examination certificates in respect of measuring instruments containing parts identical to those in the created conceptual design.

The manufacturer shall specify where seals and markings are applied.
The manufacturer shall indicate the conditions for compatibility of measuring instruments with interfaces and sub-assemblies, where necessary.

EU declaration of conformity

Article 16

The EU declaration of conformity shall state the fulfilment of the essential requirements set out in Annex 1 of this Rulebook and the instrument-specific Annexes 3 to 12 of this Rulebook.

The EU declaration of conformity shall be drawn up using the form set out in Annex 13 of this Rulebook and contain the elements specified in the models of conformity assessment procedures referred to in Annex 2 of this Rulebook.

The EU declaration of conformity shall be done in Montenegrin and shall be continuously updated.

Where a measuring instrument is subject to more than one act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up, containing a list of the acts applied and reference numbers of the relevant Official Gazette.

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

Conformity marking

Article 17

Measuring instrument in conformity with the requirements specified in this Rulebook shall be indicated by the presence on it of the CE marking and supplementary metrology marking, in accordance with Article 18 and 19 of this Rulebook.

Unless otherwise defined, The CE marking shall be placed on measuring instruments in accordance with the act regulating the shape, content and design of the conformity marking of a product.

Supplementary metrology marking

Article 18

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

Unless otherwise defined, supplementary metrology marking shall be affixed in the same manner as the CE marking.

Special requirements for affixing the CE marking and the supplementary metrology marking

Article 19

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

Where a measuring instrument consists of a set of devices, other than sub-assemblies, operating together, the CE marking and the supplementary metrology marking shall be affixed on the instrument's main device.

The CE marking and the supplementary metrology marking shall be affixed before the measuring instrument is placed on the market. Where justified, they can be affixed on the measuring instrument during the production process.

The supplementary metrology marking shall immediately follow the CE marking.

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

The identification number of the notified body referred to in paragraph 5 of this Article shall be affixed by the conformity assessment body itself or, under its instructions, by the manufacturer or their authorised representative.

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

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

Requirements relating to notifying authorities

Article 20

Notifying authorities shall comply with the following requirements:

1) A notifying authority shall be established in Montenegro;

2) A notifying authority shall be independent from economic entities, natural and legal persons the measuring instrument of which it examines;

3) A competent person and persons responsible for carrying out conformity assessment shall not be designers, manufacturers, distributors, importers, installers, buyers, users or persons maintaining the measuring instrument which are being assessed, nor their authorised representative. This shall not exclude the use of a measuring instrument assessed for the purposes of performance of activities, i.e. for notifying authority's own needs.

4) A competent person and persons responsible for carrying out conformity assessment of measuring instruments shall not be directly involved in designing, manufacturing, construction, placing on the market, installation, use or maintenance of the measuring instruments and shall not represent the relevant parties included in these activities;

5) A notifying authority shall not participate in any activity which can compromise its independence and impartiality an shall not provide consulting services, except for exchange of technical data with the manufacturer aimed at conformity assessment of a measuring instrument;

6) Employees in the notified body shall carry out affairs relating to conformity assessment with the highest degree of professional ethical conduct and expertise in the field of metrology

and shall not be under pressure or influence of a person whose interest are the results of conformity assessment, which could affect the decision or results of the conformity assessment of a measuring instruments;

7) a notified body shall be able to correctly carry out conformity assessment procedures for which it was authorised in accordance with Annex 2 of this Rulebook, whether or not it these affairs are carried out by itself or a third party on its behalf and under its responsibility.

For each category of a measuring instrument for which it was appointed, the notified body shall have:

1) Personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks with regard to the measuring instruments;

2) Established descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures, as well as protocols and procedures in place that clearly distinguish between tasks it carries out as a notified body and other activities;

3) Established procedures for the performance of activities which take due account of the size of a legal person, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the size or serial nature of the production process.

4) Means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and the necessary equipment which is accessible.

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

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

2) Satisfactory knowledge of the requirements of conformity assessment in accordance with the provisions of this Rulebook and adequate authority to carry out these activities;

3) Appropriate knowledge and understanding of the essential requirements set out in Annex I of this Rulebook and in the applicable provisions of other regulations;

4) Ability and autonomy in drawing up certificates, records and reports on the activities that have been carried out with regard to conformity assessment in accordance with the provision of this Rulebook.

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

Conformity assessment bodies shall have a concluded liability insurance contract.

The personnel of a conformity assessment body shall preserve confidentiality of data and information with regard to conformity assessment of a measuring instrument in accordance with the Law.

Notified bodies shall participate in relevant activities with regard to standardization and the activities of the notified body coordination group of other notified bodies or they shall ensure that their personnel engaged in conformity assessment activities are informed on these activities in due time and that they observe the general instructions, decisions and documents drafted as a result of the work of the coordination group.

Presumption of conformity of notified bodies
Article 21

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the established Montenegrin standards referred to in Article 13 of this Rulebook, it shall be presumed to comply with the requirements set out in Article 20 of this Rulebook in so far as Montenegrin standards cover those requirements.

Conformity assessment activities that may be carried out by other legal persons

Article 22

A notified body may subcontract specific task connected with conformity assessment to another legal person which complies with the requirements referred to in Article 20 of this Rulebook and shall inform the notifying authority accordingly.

Notified bodies shall take full responsibility for the tasks performed by subcontractors in accordance with paragraph 1 of this Article.

Conformity assessment activities may be subcontracted by a legal person referred to in paragraph 1 of this Article only with the agreement of the client.

Notified bodies shall keep and make available to the competent authority the relevant documents concerning the conformity assessment procedure carried out by another legal person referred to in paragraph 1 of this Article.

Notified bodies that form part of a manufacturer
Article 23

A notified body that forms part of a manufacturer may be used to carry out conformity assessment activities set out in point 2 (Module A2) and point 5 (Module C2) of Annex II of this Rulebook.

A notified body that forms part of a manufacturer shall meet the following requirements:

1) it shall be accredited in accordance with the law that regulates the manner and procedure of accreditation;

2) it shall be a specific organizational unit within the manufacturer which it forms part of and it shall have the established reporting methods of the manufacturer in question;

3) the body and its personnel shall not be responsible for the design, production, supply, installation, operation or maintenance of the measuring instruments it assesses, nor shall they engage in any activity that might conflict with their independence of judgment or impartiality in relation to the conformity assessment procedure;

4) it shall carry out conformity assessment activities referred to in paragraph 1 of this Article, exclusively for the needs of the manufacturer the part of which it forms.

Notification procedure for notifying bodies
Article 24

Notification of notified bodies shall be carried out in accordance with the regulation regulating the manner of notification of conformity assessment bodies.

IV. TRANSITIONAL AND FINAL PROVISIONS

Measuring instruments in use

Article 25

Where measuring instruments are in use on the day of entry into force of this Rulebook, they can be submitted for initial and extraordinary verification, if compliant with the requirements laid down in regulations based on which they were put into use.

Delayed application

Article 26

Provisions of Article 8 paragraphs 2 to 6, Article 9, Article 10 paragraphs 2, 3 and 4, Articles 11, 12 and 14, Article 15 paragraph 4, point 10 and Articles 16 to 24 of this Rulebook shall be apply as of the day of Montenegro's accession to the European Union.

Provisions of Annex 2 and Annex 13 of this Rulebook, as well as the provisions of Annexes 3 to 12 which regulate conformity assessment procedures shall apply as of the day of Montenegro's accession to the European Union.

Up until Montenegro's accession to the European Union, assessment of conformity of a measuring instrument referred to in Article 3 of this Rulebook along with the requirements laid down in this Rulebook, shall be carried out in accordance with the regulation laying down the manner of assessing conformity to the metrological requirements with regard to measuring instruments.

Termination of validity

Article 28

As of the day of the beginning of application of this Rulebook, the Rulebook on requirements relating to devices and systems with a measuring function (Official Gazette of Montenegro 29/13) shall expire.

Entry into force

Article 29

This Rulebook shall enter into force on the eight day following that of its publication in the Official Gazette of Montenegro, and it shall apply as of 1 January 2018.

Number: 330-100/2017-3
Podgorica, 26 June 2017.
Minister
Dragica Sekulić, M.P.

**This Rulebook transposes the Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments as well as the Commission Delegated Directive (EU) 2015/13 of 31 October 2014 amending Annex III to Directive 2014/32/EU of the European Parliament and of the Council, as regards the flowrate range of water meters.*

PUBLISHER'S NOTE:

Annexes which form part of this regulation can be viewed here.

ANNEX 1

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 with regard to the measurement technology and security of the measurement data.

The designs adopted with the purpose of meeting essential requirements shall take into account the appropriate use of the measuring instrument and any foreseeable misuse thereof.

Expressions used in this Annex shall have the following meaning:

1) **Measurand** - the particular quantity subject to measurement;
2) **Influence quantity** - quantity that is not the measurand but that affects the result of measurement;
3) **Rated Operating Conditions** - the values for the measurand and influence quantities making up the standard working conditions of an instrument;
4) **Disturbance** - An influence quantity having a value within the limits specified in the appropriate requirement but outside the specified rated operating conditions of the measuring instrument. An influence quantity is a disturbance if for that influence quantity the rated operating conditions are not specified;
5) **Critical change value** - the value at which the change in the measurement result is considered undesirable;
6) **Material Measure** - a device intended to reproduce or supply in a permanent manner during its use one or more known values of a given quantity;
7) **A direct sale** is a trading transaction if:

– the measurement result serves as the basis for the price to pay;

- at least one of the parties involved in the transaction related to measurement is a consumer or any other party requiring a similar level of protection; and
- all the parties in the transaction accept the measurement result at that time and place.

8) **Climatic environments** - the conditions in which measuring instruments may be used. To cope with climatic differences between the Member States, a range of temperature limits has been defined.
9) **A supplier of energy/ energy products and water** is a a supplier of electricity, gas, thermal energy or water.

BASIC REQUIREMENTS RELATING TO MEASURING INSTRUMENTS

1. Allowable Errors

1.1. Under rated operating conditions and in the absence of a disturbance, the error of measurement shall not exceed the maximum permissible error (MPE) value as laid down in the appropriate instrument-specific requirements.
Unless stated otherwise in Annexes 3 – 12 of this Rulebook with regard to specific types of measuring instruments, MPE is expressed as a bilateral value of the deviation from the true measurement value.

1.2. Under rated operating conditions and in the presence of a disturbance, the performance requirement shall be as laid down in the appropriate instrument-specific requirements.
Where the instrument is intended to be used in a specified permanent continuous electromagnetic field the permitted performance during the radiated electromagnetic field-amplitude modulated test shall be within the limits of MPE.

1.3. The manufacturer shall specify the climatic, mechanical and electromagnetic environments in which the instrument is intended to be used, power supply and other influence quantities likely to affect its accuracy, taking account of the requirements laid down in Annexes 3 to 12 of this Rulebook with regard to specific types of measuring instruments.

1.3.1. Climatic environments

The manufacturer shall specify the upper temperature limit and the lower temperature limit from any of the values in Table 1 of this Annex, unless otherwise specified in the Annexes from 3 to 12 of this Rulebook, and indicate whether the instrument was designed for condensing or non-condensing humidity as well as the intended location for the instrument, i.e. open or closed.

Table 1: Temperature Limits

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

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

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

M3	This class applies to instruments used in locations where the level of vibration and shock is high and very high, e.g. for instruments mounted directly on machines, conveyor belts, etc.

(b) The following influence quantities shall be considered in relation with mechanical environments:
— Vibration;
— Mechanical shock.

1.3.3. (a) Electromagnetic environments are classified into classes E1, E2 or E3 as described below, unless otherwise laid down in the relevant instrument-specific Annexes from 3 to 12 of this Rulebook.

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

(b) The following influence quantities shall be considered in relation with electromagnetic environments:
— Voltage interruptions,
— Short voltage reductions,
— Voltage transients on supply lines and/or signal lines,
— Electrostatic discharges,
— Radio frequency electromagnetic fields,
— Conducted radio frequency electromagnetic fields on supply lines and/or signal lines,
— Surges on supply lines and/or signal lines.

1.3.4. In addition to influence quantities referred to in sub-point 1.3.3. of this Annex, where appropriate, other influence quantities are to be considered:
— Voltage variation,
— Mains frequency variation,
— Power frequency magnetic fields,
— Any other quantity likely to influence in a significant way the accuracy of the measuring instrument.

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

1.4.1. Basic rules for testing and the determination of errors

Essential requirements specified in 1.1 and 1.2 shall be verified for each relevant influence quantity. Unless otherwise specified in the relevant instrument-specific annex to this Rulebook, these essential requirements shall apply individually for each influence quantity when its effect is evaluated separately, whereby it is ensured that all other influence quantities are being kept relatively constant at their reference values.

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

1.4.2. Ambient humidity
— 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.

2. Reproducibility

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

3. Repeatability

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

4. Discrimination and Sensitivity

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

5. Durability

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

6. Reliability

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

7. Suitability

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

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

7.3. The errors of a utility measuring instrument or water at flows or currents outside the controlled range shall not contain an unacceptable systematic error.

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

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

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

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

8. Protection against non-authorised access

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

8.2. A hardware component that can have a negative impact on 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 can have a negative impact on metrological characteristics shall be identified as such and shall be secured. Software identification shall be easily provided by the measuring instrument.
Evidence of an intervention shall be available for a reasonable period of time.

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

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

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

9.1. A measuring instrument shall bear the following inscriptions:

a) manufacturer's name, registered trade name or registered trade mark, in accordance with this Rulebook;
b) information in respect of its accuracy,

and, when applicable:

c) information in respect of the conditions of use;
d) measuring capacity;
e) measuring range;
f) identity marking of the appointed body;
g) number of the EU-type examination certificates or the EU design examination certificates;
h) information whether or not additional devices providing metrological results comply with the defined requirements relating to the measuring instrument in question.

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

9.3. The instrument shall be accompanied by information on its operation, unless the simplicity of the measuring instrument makes this unnecessary. Information shall be easily understandable and shall include where relevant:
— rated operating conditions;
— mechanical and electromagnetic environment classes;
— the upper and lower temperature limit, whether condensation is possible or not, used in open or closed location;
— instructions for installation, maintenance, repairs, permissible adjustments;

— instructions for correct operation and any special conditions of use;
— conditions for compatibility with computer system units, sub-assemblies or measuring instruments.

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

9.5. Unless specified otherwise in an instrument-specific Annexes from 3 to 12 of this Rulebook, the scale interval for a measured value shall be in the form $1\times10n$, $2\times10n$, or $5\times10n$, where n is any integer or zero. The unit of measurement or its symbol shall be shown close to the numerical value.

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

9.7. The units of measurement used and their symbols shall be in accordance with the special provision regulating legal units of measurement.

9.8. All marks and inscriptions, which, in accordance with this Rulebook, are placed on the measuring instrument, shall be clear, non-erasable, unambiguous and non-transferable.

10. Indication of result

10.1. Indication of the result shall be by means of a display device or in hard copy (paper or unalterable record in an electronic data storage device).

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

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

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

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

11. Further processing of data to conclude the trading transaction

11.1. A measuring instrument other than a utility measuring instrument shall record by a durable means the measurement result accompanied by information to identify the particular transaction, when:
— the measurement is non-repeatable and;
— the measuring instrument is normally intended for use in the absence of one of the trading parties.

11.2. In addition to the requirements referred to in sub-point 11.1 of this point, a durable proof of the measurement result and the information to identify the transaction shall be available at the time the measurement is concluded.

12. Conformity evaluation

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

ANNEX 2

CONFORMITY ASSESSMENT PROCEDURE

MODULE A: INTERNAL PRODUCTION CONTROL

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

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Rulebook. It shall, as far as relevant for such assessment, cover the conceptual design and manufacturing drawings, manufacturing and operation of the instrument, as well as the appropriate risk analysis and assessment.

3. Manufacturing

The manufacturer shall take all measures in the process of manufacturing and monitors the process of manufacturing necessary in order to ensure conformity of the manufactured instruments with the appropriate technical documentation referred to in point 2 of this Module, with essential requirements laid down in this Rulebook and special requirements defined in the instrument-specific Annexes 3 to 12 of this Rulebook.

4. Conformity marking and EU declaration of conformity

4.1. The manufacturer shall affix the 'CE' marking, and the supplementary metrology marking laid down in this Rulebook to each measuring instrument that meets the essential requirements of this Rulebook and special requirements referred to in instrument-specific Annexes from 3 to 12 of this Rulebook.

4.2. An EU declaration of conformity is drawn up for each instrument model of a measuring instrument and along with the accompanying technical documentation, shall be kept at the disposal of the public body responsible for at least ten years from the day of placing the instrument and/or making it available on the market. The EU declaration of conformity shall identify the measuring 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. However, only one copy of the EU declaration of conformity shall be required in those cases where a large number of instruments from the same batch is delivered to a single user.

5. Authorised representative

The manufacturer's obligations set out in point 4 of this Module may be fulfilled by his authorised representative, provided that they are specified in the manufacturer's mandate.

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

1. **Internal production control plus supervised instrument checks at random intervals** is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5 of this Module, and ensures and declares on his sole responsibility that the measuring instruments concerned meet the requirements of this Rulebook that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook, ensuring assessment of conformity of measuring instruments with the requirements laid down in this Rulebook. Technical documentation shall, as far as relevant for such assessment, cover the conceptual design and manufacturing drawings, manufacturing and operation of the instrument, as well as the appropriate risk analysis and assessment.

3. Manufacturing

The manufacturer shall take all measures necessary in the process of manufacturing and its monitoring, in order to ensure conformity of the manufactured instruments with the technical documentation referred to in point 2 of this Module and the essential requirements defined by this Rulebook and requirements set out in the instrument-specific Annexes from 3 to 12 of this Rulebook.

4. Product checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the instrument, taking into account, inter alia, the technological complexity of the instruments and the quantity of production. An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the Montenegrin standards referred to in Article 13 of this Rulebook, and/or normative document, and/or equivalent tests set out in other relevant technical specifications referred to in Article 15 of this Rulebook, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Rulebook. In the absence of a relevant Montenegrin standard or normative document, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.

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

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

5. Conformity marking and EU declaration of conformity

5.1 The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Rulebook to each individual instrument that meets the essential requirements of this Rulebook as well as special requirements referred to in instrument-specific Annexes from 3 to 12 of this Rulebook.

5.2. A declaration of conformity is drawn up for each instrument model of a measuring instrument and along with the accompanying technical documentation, it shall be kept at the disposal of the competent public body for ten years after the instrument has been placed and/or made available on the market. The EU declaration of conformity shall identify the model of the instrument for which it was drawn up.

A copy of the EU declaration on conformity shall be supplied with each measuring instrument that is placed on the market. However, in those cases where a large number of instruments from the same batch is delivered to a single user, the manufacturer may supply a copy of the EU declaration of conformity with a group of products or an individual delivery.

6. Authorised representative

The manufacturer's obligations set out in point 5 of this Module may be fulfilled by his authorised representative, provided that they are specified in the manufacturer's mandate.

MODULE B: EU- TYPE EXAMINATION

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

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

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

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

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

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

3. The manufacturer shall submit an application for EU-type examination to a sinlge notified body of his choice.

The requirement referred to in paragraph 1 of this point shall include in particular:

a) the name and address of the manufacturer and, if the application is submitted by the authorised representative, his name and address in addition;
b) a written declaration of the submitter that the same application has not been submitted to any other notified body;
c) the technical documentation as described in Article 15 of this Rulebook. The documentation shall enable assessment of the conformity of the instrument with the appropriate requirements of this Rulebook. It shall, as far as relevant for such assessment, cover the technical design, manufacture and operation of the instrument;
d) the specimens, representative of the production envisaged, as required by the notified body;
e) where necessary, the supporting evidence for the adequacy of the technical design, containing the appropriate documents that have been applied, and where the relevant Montenegrin standards referred to in Article 13 of this Rulebook and/or normative documents have not been applied in full, the application shall include the results of the examination carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility, by applying other appropriate technical specifications.

4. The notified body shall:

For the measuring instruments:

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

For the specimens:

4.2. carefully examine the technical documentation, verify if the type of a measuring instrument is manufactured in conformity with it and identify the elements which have been designed in accordance with the relevant ducuments referred to in Article 15 of this Rulebook, as well as the designs which have been designed in accordance with other appropriate technical specifications;

4.3. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the designs referred to in the relevant documents laid down in Article 15 of this Rulebook, these have been applied correctly;

4.4. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has applied the designs in the relevant documents referred to in Article 15 of this Rulebook and whether these have been applied correctly;

4.5. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has not applied the designs from documents referred to in Article 15 of this Rulebook, as well as whether the designs of the manufacturer comply with the essentail requirements laid down in this Rulebook.

4.6 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 and evidence to assess the adequacy of the technical design and other parts of measuring instruments.

5. **The notified body** shall draw up an evaluation report that records the activities as undertaken in accordance with paragraph 4 of this Module and their outcomes. The notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

6. Where the technical design meets the requirements of this Rulebook that apply to the measuring instrument in question, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer and, if appropriate, of his authorised representative, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the instrument. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information for conformity evaluation control of measuring instruments during their use. In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:
— the metrological characteristics of the type of instrument;
— measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);
— information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;
— if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;
— in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or measuring instruments.

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

Where the type of a measuring instrument does not satisfy the requirements of this Rulebook that apply to it, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

In the case referred to in paragraph 4 of this point, the notified body shall draw up a report and make it available to the competent body, in accordance with the law.

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

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

9. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn.

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

The notified body shall hold the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the certificate.

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

11. The authorized representative may submit the application referred to in point 3 and carry out the obligations mentioned in points 8 and 9 of this Module, provided that they are specified in the mandate.

MODULE C: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Declaration of conformity to type based on internal production control is part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4 of this Module and ensures and declares that the measuring instruments concerned are in conformity with the type as described in the EU-type examination certificate and meet the appropriate requirements of this Rulebook.

2. Manufacturing

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

3. Conformity marking and EU declaration of conformity

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

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

A copy of the EU declaration of conformity shall be supplied with each measuring instrument that is placed on the market. However, in those cases where a large number of instruments from the same batch is delivered to a single user, the manufacturer may supply only one copy of the EU declaration of conformity.

4. Authorised representative

The manufacturer's obligations set out in point 4 of this Module may be fulfilled by his authorised representative, provided that they are specified in the mandate.

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

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

2. Manufacturing

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

3. Instrument checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out instrument checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the instrument, taking into account, in particular, the technological complexity of the measuring instruments and the quantity of production.

An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the Montenegrin standards referred to in Article 13 of this Rulebook, and/or normative documents, and/or equivalent tests set out in other relevant technical specifications as provided in Article 15 of this Rulebook, shall be carried out to verify the conformity of the instrument with the relevant requirements of this Rulebook.

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

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the instrument performs within acceptable limits, with a view to ensuring conformity of the instrument to the requirements defined in this Rulebook. The manufacturer shall, with the assent and under the responsibility of the notified body carrying out the conformity assessment procedure, affix the notified body's identification number during the manufacturing process.

4. Conformity marking and EU declaration of conformity

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

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

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

5. Authorized representative

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

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

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

2. Manufacturing

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

3. Quality system

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

The application referred to in paragraph 1(3) shall include in particular:

a) the name and address of the manufacturer and, if the application is submited by the authorised representative, his name and address as well,
b) a written declaration that the same application has not been submited to any other notified body,
c) all relevant information for the instrument category envisaged;
d) the documentation concerning the quality system;
e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

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

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

The documentation shall, in particular, contain an adequate description of:

a) the quality objectives and the organisational structure, responsibilities and powers of the responsible persons of manufacturers with regard to product quality;

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

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

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

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

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

The quality system shall be considered to be in conformity with the requirements set out in point 3.2 of this Module, if it complies with the Montenegrin standards referred to in Article 13 of this Rulebook.

In addition to experience in quality management system audit and assessment, the notified body shall have at least one member with experience in the relevant field of metrology and instrument technology concerned, as well as knowledge of the applicable requirements of this Rulebook. The audit and assessment of the quality management system shall include a visit to the manufacturer's premises for the purposes of the assessment of the quality management system concerned.

The notified body shall review the technical documentation referred to in point 3.1. of this Module, to verify that the manufacturer has observed the requirements of this Rulebook and ensured compliance of the instrument with those requirements.

The notified body shall submit the decision on audit and assessment results to the manufacturer. The decision shall contain the conclusions of the audit and the reasoned assessment decision.

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

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

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

4. Surveillance under the responsibility of the notified body

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

4.2. During the quality system surveillance procedure, the manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, along with all necessary information, in particular:

(a) the quality system documentation;

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

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

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

5. Conformity marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Rulebook, and, with the consent and under the responsibility of the notified body referred to in this Rulebook, the notified body's identification number to each individual measuring instrument that is in conformity with the instrument model described in the EU declaration of conformity.

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

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

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

(a) the documentation referred to in point 3.1 of this Module,

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

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

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, without delay, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. Authorised representative

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

MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. **Quality assurance of the production process** is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole

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

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements laid down in this Rulebook. The technical documentation shall include, as far as relevant for the assessment, conceptual design and manufacturing drawings, manufacturing and operation of the instrument, as well as an adequate analysis and assessment of the risk(s).

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

4. Manufacturing

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

5. Quality system

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

The application shall include:

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

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

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

(d) the documentation concerning the quality system;

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

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

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

It shall, in particular, contain a description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the responsible persons with regard to the quality of a measuring instrument;

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

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

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

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

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

It shall presume conformity with requirements referred to in point 5.2 of this Module if it complies with Montenegrin standards referred to in Article 13 of this Rulebook.

The notified body shall have experience in quality management system audit and assessment and at least one member with relevant experience in the relevant metrology field and instrument technology concerned, and knowledge of the applicable requirements of this Rulebook. The audit shall include an assessment visit to the manufacturer's premises.

The notified body shall review the technical documentation referred to in point 2 of this Module in order to verify if the manufacturer has applied the relevant requirements of this Rulebook and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

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

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

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

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

6. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

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

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

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

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

7. Conformity marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Rulebook, and, with the consent and under the responsibility of the notified body referred to in this Rulebook, the notified body's identification number to each individual measuring instrument that is in conformity with the instrument model described in the EU-type examination certificate.

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

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

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

(a) the documentation referred to in point 5.1 of this Module;

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

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

9. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, without delay, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

10. Authorised representative

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

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

2. Manufacturing

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

3. Quality system

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

The requirement referred to in paragraph 1 of this sub-point shall include, in particular:

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

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

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

(d) the documentation concerning the quality system;

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

3.2. The quality system shall ensure compliance of the measuring instruments with the applicable requirements of this Rulebook.

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

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management

with regard to product quality;

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

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

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

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

The quality system shall presume conformity with the requirements referred to in point 3.2 of this Module, if it complies with the Montenegrin standard set out in Article 13 of this Rulebook.

The notified body shall have experience in quality management system audit and assessment and at least one member with relevant experience in the relevant metrology field and instrument technology concerned, and knowledge of the applicable requirements of this Rulebook. The audit shall include an assessment visit to the manufacturer's premises.

The notified body shall review the technical documentation referred to in point 3.1 of this Module, in order to verify the manufacturer's ability to apply the relevant requirements of this Rulebook and to carry out the necessary examinations with a view to ensuring compliance of the instrument with those requirements.

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

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

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

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

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

4. Surveillance under the responsibility of the notified body

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

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture,

inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

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

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

5. Conformity marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking, the supplementary metrology marking set out in this Rulebook, and, with the consent and under the responsibility of the notified body referred to in this Rulebook, the notified body's identification number to each individual measuring instrument that is in conformity with the instrument model described in the EU declaration of conformity.

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

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

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

(a) the documentation referred to in point 3.1 point b) of this Module;

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

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

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, without delay, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. Authorised representative

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

MODULE E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING

1. Quality assurance of final instrument inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7 of this Annex, and ensures and declares on his sole responsibility that the measuring instruments concerned comply with the type described in the EU-type examination certificate and satisfy the requirements of this Rulebook that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook, ensuring assessment of conformity to the requirements laid down in this Rulebook. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, conceptual design and manufacturing drawings, manufacturing and operation of the instrument, as well as an adequate analysis and assessment of the risk(s).

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

4. Manufacturing

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

5. Quality system

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

The application referred to in paragraph 1 of this subpoint shall include, in particular:

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

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

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

(d) the documentation concerning the quality system;

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

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

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

The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

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

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

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

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

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

It shall presume conformity with the requirements referred to in point 5.2 of this Module, if it complies with the Montenegrin standards laid down in Article 13 of this Rulebook.

The notified body shall have experience in quality management system audit and assessment and at least one member with relevant experience in the relevant metrology field and instrument technology concerned, and knowledge of the applicable requirements of this Rulebook. During the audit and testing procedure, the notified body shall carry out an assessment of the technical documentation referred to in point 2 of this Module, in order to determine whether the manufacturer has applied the requirements laid down in this Rulebook and verify that the measuring instruments concerned are in conformity to these requirements.

The decision on audit and testing results shall be notified to the manufacturer. It shall contain the conclusions of the audit and the reasoned assessment decision.

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

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

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

It shall submit its decision and the reasoned justification to the manufacturer.

6. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

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

(c) the quality records, such as inspection reports and test data, calibration data, qualification reports on 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 the manufacturer with an audit report.

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

7. Conformity marking and EU declaration of conformity

7.1. The **manufacturer** shall affix the CE marking, the supplementary metrology marking set out in this Rulebook, and, with the consent and under the responsibility of the notified body referred to in this Rulebook, the notified body's identification number referred to in point 5.1 of this Module to each individual measuring instrument that is in conformity with the instrument model described in the EU-type examination certificate.

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

The manufacturer shall make available a copy of the EU declaration of conformity to the relevant authorities upon request.

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

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

(a) the documentation referred to in point 5.1 of this Module,

(b) the information relating to the change referred to in points 5.5 of this Module, as approved;

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

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

10. Authorised representative

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

MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

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

2. Manufacturing

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

3. Verification

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

The examinations and tests to verify the conformity with the appropriate requirements of the measuring instruments referred to in paragraph 1 of this point, shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 4, or by examination and testing of the measuring instruments on a statistical basis as specified in point 5 of this Module.

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

4.1. All measuring instruments shall be individually examined and appropriate tests set out in the Montenegrin standards as specified in Article 13 of this Rulebook and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable metrological requirements and with the approved type described in the EU-type examination certificate.

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

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

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

5. Statistical verification of conformity

5.1. The manufacturer shall present for verification the measuring instruments from the same production lot and shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced.

5.2. A random sample shall be taken from each lot according to the requirements of point 5.3 of this Module. All measuring instruments in a sample shall be individually examined and appropriate tests carried out in accordance with the Montenegrin standards referred to in Article 13 of this Rulebook and/or normative documents, or equivalent tests shall be carried out set out in other relevant technical specifications in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable metrological requirements of this Rulebook, and to determine whether the lot is accepted or rejected. In the absence of the Montenegrin standards and/or normative documents, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. The statistical procedure shall be carried out in the following manner:

The statistical control will be based on the properties of the measuring instruments concerned. The sampling system shall ensure:

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

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

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

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

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

5.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of

that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification.

6. Conformity marking and EU declaration of conformity

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

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

The manufacturer shall make available a copy of the EU declaration of conformity to the relevant authorities upon request.

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

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

8. Authorised representative

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

MODULE F1: CONFORMITY BASED ON PRODUCT VERIFICATION

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

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements as specified in this Rulebook, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, conceptual design and manufacturing drawings, manufacturing and operation of the instrument.

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

3. Manufacturing

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

4. Verification

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

The examinations and tests to verify the conformity with the requirements referred to in paragraph 1 of this sub-point shall be carried out, at the choice of the manufacturer, either by examination and testing of every instrument as specified in point 5, or by examination and testing of the measuring instruments on a statistical basis as specified in point 6 of this Module.

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

5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the Montenegrin standards referred to in Article 13 of this Rulebook and/or normative documents, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of Montenegrin standards, and/or normative documents, the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, or shall give consent to the manufacturer to affix the notified body's identification number to each approved instrument.

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

6. Statistical verification of conformity

6.1. The manufacturer shall present for verification the measuring instruments from the same production lot shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced.

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

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

appropriate tests to be carried out.

6.4. The statistical procedure shall be carried out in the following manner:

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

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

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

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

If a lot is expected, the notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall give consent to the manufacturer to affix its identification number to each approved instrument.

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

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

7. Conformity marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking and the supplementary metrology marking set out in this Rulebook, and under the responsibility of the notified body referred to in point 4 of this Module, the latter's identification number to each individual measuring instrument that is in conformity to the type described in the EU-type examination certificate and satisfies the applicable requirements of this Rulebook.

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

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

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

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

MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 6 and 7 of this Rulebook and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of point 4 of this Module, is in conformity with the requirements of this Rulebook that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in Article 15 of this Rulebook. This documentation shall make it possible to assess the instrument's conformity with the relevant requirements as specified in this Rulebook, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, conceptual design and manufacturing drawings, manufacturing and operation of the instrument.

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

3. Manufacturing

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

4. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the Montenegrin standards referred to in Article 13 of this Rulebook, and/or normative documents, or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Rulebook, or have them carried out. In the absence of the appropriate Montenegrin standard, or normative document, the notified body concerned shall decide on the appropriate tests to be carried out.

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

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

5. Conformity marking and EU declaration of conformity

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

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

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

6. Authorised representative

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

MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE

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

2. Manufacturing

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

3. Quality system

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

The application shall include:

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

(b) the technical documentation, as described in Article 15 of this Rulebook, for one model of each category of measuring instruments intended to be manufactured. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument,

(c) the documentation concerning the quality system, and

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

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

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

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

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

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

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

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

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

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

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

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

It shall be presumed that the quality system is in conformity with the requirements referred to in point 3.2 of this Module, if it complies with the Montenegrin standards of Article 13 of this Rulebook.

The notified body shall have experience in quality management systems audit and assessment and at least one member experienced as an assessor in the relevant metrology field and instrument technology concerned, as well as knowledge of the applicable requirements of this Rulebook. The audit shall include a visit to the manufacturer's premises aimed at the assessment of his quality system.

The notified body shall submit the decision on the audit and assessment results to the manufacturer. It shall contain the conclusions of the audit and the reasoned assessment decision.

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

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

The notified body shall evaluate any proposed changes and decide whether the modified quality system will

continue to satisfy the requirements referred to in point 3.2 of this Module or whether a re-assessment is necessary. It shall notify the manufacturer or its authorised representative of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

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

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

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

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

5. Conformity marking and EU declaration of conformity

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

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

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

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

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

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

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

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

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, without delay, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5.2 and 6 of this Module may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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

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

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the measuring instruments concerned as specified in point 5 of this Module. The adequacy of the technical design of the measuring instrument shall be subject to examination as specified in point 5 of this Module.

3. Quality system

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

The application referred to in paragraph 1 of this point shall include:

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

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

(c) the documentation concerning the quality system;

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

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

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

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

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

(b) the technical design specifications, including standards, that will be applied and, where the relevant Montenegrin standards and/or normative documents will not be applied in full, the means that will be used to ensure that the measuring instruments comply with the laid down in Annexes 3-12 of this Rulebook that apply to the specific instruments model;

(c) the design control and design verification techniques, processes and systematic actions that will be used;

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

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

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

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this Module. It shall be presumed that the quality system is in conformity with the requirements referred to in point 3.2 of this Module, if it complies with the Montenegrin standards referred to in Article 13 of this Rulebook.

The notified body shall have experience in quality management system audit and assessment and at least one member experienced as an assessor in the relevant metrology field and instrument technology concerned, as well as knowledge of the applicable requirements of this Rulebook. The audit shall include a visit to the manufacturer's premises aimed at the assessment of his quality system.

The notified body shall submit the decision on the audit and assessment results to the manufacturer. It shall contain the conclusions of the audit and the reasoned assessment decision.

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

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

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

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

3.6. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall without delay, inform the notifying authority on the suspension of the quality system.

4. Design examination

4.1. The manufacturer shall submit an application for examination of the design to the notified body referred to in point 3.1 of this Module.

4.2. The application referred to in point 4.1 of this Module shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the relevant requirements of this Rulebook.

The application referred to in paragraph 1 of this point shall include:

(a) the name and address of the manufacturer;

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

(c) the technical documentation as described in Article 15 of this Rulebook. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements of this Rulebook, and shall include an adequate analysis and assessment of the risk(s). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall specify any documents that have been used, in particular where the relevant Montenegrin standards and/or normative documents 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 referred to in point 4.2 of this Module, and where the design meets the provisions of this Rulebook that apply to the instrument it shall issue an EU design examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. All relevant parts of technical documentation shall be attached to the certificate, which may have one or more annexes.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured measuring instruments with the examined design to be evaluated and to allow for in-service control.

It shall allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

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

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

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

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

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

The notified body shall establish an evaluation report in this regard and keep it at the disposal of the relevant national authority. The notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

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

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

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

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

4.5. Each notified body shall periodically inform its notifying authority of the EU design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, without delay, make available to its notifying authority the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

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

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

5. Surveillance under the responsibility of the notified body

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

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

(a) the quality system documentation;

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

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

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

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

6. Conformity marking and EU declaration of conformity

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

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

The manufacturer shall supply a copy of the EU declaration of conformity with each measuring instrument that is placed on the market. However, where there is a delivery of a large number of instruments from the same batch to a single user, the manufacturer shall supply only one copy of the EU declaration of conformity.

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

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

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

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

8. Authorised representative

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

ANNEX III

WATER METERS (MI-001).

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

The terms used in this annex shall have the following meaning:

DEFINITIONS

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

SPECIFIC REQUIREMENTS

Rated Operating Conditions

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

1. The flowrate range of the water.

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

$$Q_3/Q_1 \geq 10$$

$$Q_2/Q_1 = 1{,}6$$

$$Q_4/Q_3 = 1{,}25$$

2. The temperature range of the water.

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

   0,1 °C to at least 30 °C, or

   30 °C to at least 90 °C.

   The meter may be designed to operate over both ranges.

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

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

Maximum Permissible Errors (Hereinafter referred to as "MPE")

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

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

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

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

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

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

Permissible Effect of Disturbances

7.1. Electromagnetic immunity

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

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

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

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

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

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

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

— the volume corresponding to half of the magnitude of the MPE, considering the measured volume;

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

7.2. ***Durability***

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

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

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

__ 1,5 % of the metered volume between Q_2 (included) and Q_4 (included).

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

__ ± 6 % of the metered volume between Q_1 (included) and Q_2 (excluded);

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

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

Suitability

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

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

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

Units of Measurement

9. Metered volume shall be displayed in cubic metres.

Putting into Use

10. The distributer or any other person legally designated for installing the meter shall ensure compliance with the requirements under points 1, 2 and 3 of this Annex, so that the meter is appropriate for the accurate measurement of consumption that is foreseen or foreseeable.

CONFORMITY ASSESSMENT

The conformity assessment procedures that the manufacturer can choose between are:

B + F or B + D or H1.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for water gauges in this Annex.
Examination procedures for periodic and extraordinary verification are equal to the examination procedure for conformity assessment by means of inspection and examination of the measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

It is considered that the existing values of Qmin, QT and Qmax flow (which are in accordance with the legislation which was previosuly in force indicated on the measuring instruments) equal to Q1, Q2 and Q4 flow values of this Annex.

Water meters for warm water may be exceptionally examined during the regular verification, if this is prescribed in the type approval of the measuring instrument

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for water meters from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR WATER METERS IN USE
MPE for water meters in use is twice the MPE for periodic verification.

ANNEX IV

GAS METERS AND VOLUME CONVERSION DEVICES (MI-002)

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

The terms used in this Annex shall have the following meaning:

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

PART I

SPECIFIC REQUIREMENTS FOR GAS METERS

1. Rated operating conditions

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

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

Class	Q_{max}/Q_{min}	Q_{max}/Q_t	Q_r/Q_{max}

1,5	≥ 150	≥ 10	1,2
1,0	≥ 20	≥ 5	1,2

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

1.3. ***The fuel/gas related conditions***

The gas meter shall be designed for the range of gases and pressure inlets at the place of supply. In particular the manufacturer shall indicate:

— the gas family or group;

— the maximum operating pressure.

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

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

2. Maximum permissible error (hereinafter referred to as the "MPE")

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

Table 1

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

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

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

3. Permissible effect of disturbances

3.1. ***Electromagnetic immunity***

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

— the change in the measurement result is no greater than the critical change value as defined in point 3.1.3 of this Annex, 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 as a valid measuring result, e.g. it cannot be interpreted, memorised or transmitted as a measuring result.

3.1.2. After undergoing an electromagnetic disturbance, the gas meter shall:

— recover to operate within MPE, and

— have all measurement functions safeguarded, and

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

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

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

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

3.2. ***Effect of upstream-downstream flow disturbances***

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

4. Durability

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

4.1. ***Class 1,5 gas meters***

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

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

4.2. ***Class 1,0 gas meters***

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

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

5. Suitability

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

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

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

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

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

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

6. Units

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

PART II

SPECIFIC REQUIREMENTS FOR VOLUME CONVERSION DEVICES

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

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

7. Base conditions for converted quantities

The manufacturer shall specify the base conditions for converted quantities.

8. MPE

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

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

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

Note:

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

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

9. Suitability

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

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

PART III

PUTTING INTO USE AND CONFORMITY ASSESSMENT

Putting into use

10. (a) Measurement of residential use shall be performed by means of a Class 1,5 gas meter, and by Class 1,0 gas meter which have a Q_{max}/Q_{min} ratio equal or greater than 150.

(b) Measurement of commercial and/or light industrial use shall be performed using a Class 1,5 gas meter.

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

CONFORMITY ASSESSMENT

In accordance with Annex 2 of this Rulebook, the manufacturer may choose between the following conformity modules for conformity assessment of gas meters and conversion devices: B + F or B + D or H1.

PART IV

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE for regular and extraordinary verification is equal to the MPE in conformity assessment procedures for gas meters and volume conversion devices, in accordance with this Annex.

The conformity assessment procedures for periodic and extraordinary verification of gas meters and gas volume conversion devices are equal to the examination procedure for conformity assessment by means of visual inspection and examination of the measuring instrument concerned, in accordance with the technical documentation from Article 15 of this Rulebook.

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE IN USE

MPE of gas meters in use

Class	$Qmin \leq Q < Qt$	$Qt \leq Q \leq Qmax$
1,5	6 %	3 %

1,0	2 %	1 %

MPE of volume conversion devices is 1 %.

ANNEX 5

ACTIVE ELECTRICAL ENERGY METERS (MI-003)

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

Note:

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

The terms used shall have the following meaning:

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

1) **Active electrical energy meter** is a device used for measuring the active electrical energy consumed in an electrical circuit.

2) **I** is the electrical current flowing through the meter;

3) **In** is the specified reference current for which the transformer operated meter has been designed;

4) **Ist** is the lowest declared value of I at which the meter registers active electrical energy at unity power factor (polyphase meters with balanced load);

5) **Imin** is the value of I above which the error lies within maximum permissible errors (MPEs) (polyphase meters with balanced load);

6) **Itr** is the value of I above which the error lies within the smallest MPE corresponding to the class index of the meter;

7) **Imax** is the maximum value of I for which the error lies within the MPEs;

8) **U** is the voltage of the electricity supplied to the meter;

9) **Un** is the specified reference voltage;

10) **F** is the frequency of the voltage supplied to the meter;

11) **fn** is the specified reference frequency;

12) **PF** is the power factor = cosφ = the cosine of the phase difference φ between I and U.

SPECIFIC REQUIREMENTS

1. Accuracy

The manufacturer shall specify the class index of the active electrical energy meter. The accuracy of the meter concerned is defined as: Class A, B and C.

2. Rated operating conditions

The manufacturer shall specify the rated operating conditions of the active electrical energy meter; in particular:
The values of f_n, U_n, I_n, I_{st}, I_{min}, I_{tr} and I_{max} that apply to the meter. For the current values specified, the meter shall satisfy the conditions given in Table 1.

Table 1

	Class A	Class B	Class C
For direct-connected meters			
I_{st}	$\leq 0{,}05 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$
I_{min}	$\leq 0{,}5 \cdot I_{tr}$	$\leq 0{,}5 \cdot I_{tr}$	$\leq 0{,}3 \cdot I_{tr}$
I_{max}	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$	$\geq 50 \cdot I_{tr}$
For transformer-operated meters			
I_{st}	$\leq 0{,}06 \cdot I_{tr}$	$\leq 0{,}04 \cdot I_{tr}$	$\leq 0{,}02 \cdot I_{tr}$
I_{min}	$\leq 0{,}4 \cdot I_{tr}$	$\leq 0{,}2 \cdot I_{tr}$ (1)	$\leq 0{,}2 \cdot I_{tr}$
I_n	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$	$= 20 \cdot I_{tr}$
I_{max}	$\geq 1{,}2 \cdot I_n$	$\geq 1{,}2 \cdot I_n$	$\geq 1{,}2 \cdot I_n$
(1) $I_{min} \leq 0{,}4\ I_{tr}$ shall be applied for class B electro-mechanical energy meters.			

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

The voltage and frequency ranges shall be at least:

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

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

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

3. MPEs

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

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

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

Table 2

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

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

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

4. Permissible effect of disturbances

4.1. ***General***

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

The active electrical energy meter shall comply with the electromagnetic environment E2 and the additional requirements referred to in points 4.2 and 4.3 of this Annex.

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

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

4.2. ***Effect of disturbances of long duration***

Table 3

CRITICAL CHANGE VALUES FOR DISTURBANCES OF LONG DURATION			
Disturbance	**Critical change values in percent for meters of class**		
	A	**B**	**C**
Reversed phase sequence	1,5	1,5	0,3
Voltage unbalance (only applicable to polyphase meters)	4	2	1
Harmonic contents in the current circuits ([1])	1	0,8	0,5
DC and harmonics in the current circuit ([1])	6	3	1,5
Fast transient bursts	6	4	2
Magnetic fields; HF (radiated RF) electromagnetic field; Conducted disturbances introduced by radio-frequency fields; and Oscillatory waves immunity	3	2	1
([1]) In the case of electro-mechanical electrical meters, the critical change values for the harmonic contents in the current circuits and for DC are not defined.			

4.3. ***Permissible effect of transient electromagnetic phenomena***

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

— any output intended for testing the accuracy of the meter does not produce pulses or signals

corresponding to an energy of more than the critical change value,

and in reasonable time after the disturbance the meter shall:

— recover to operate within the MPE limits, and

— have all measurement functions safeguarded, and

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

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

The critical change value in kWh is $m \cdot U_n \cdot I_{max} \cdot 10^{-6}$
(m being the number of measuring elements of the meter, U_n in Volts and I_{max} in Amps).

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

5. Suitability

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

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

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

5.4. ***Running with no load***

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

5.5. ***Starting***

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

6. Units

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

7. Putting into use

(a) Measurement of residential electrical energy consumption shall be performed by means of any Class A meter. For specified purposes, any Class B meter may be used for such measurement.

(b) Measurement of commercial and/or light industrial consumption of electrical energy, shall be performed by any Class B meter. For specified purposes, any Class C meter may be used for such measurement.

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

CONFORMITY ASSESSMENT

The conformity assessment procedures for the active electrical energy meters referred to in Annex 2 of this Rulebook that the manufacturer can choose between are:

B + F or B + D or H1.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for active electrical energy meters in this Annex.
Examination procedure for periodic and extraordinary verification of active electrical energy meters are equal to the examination procedure for conformity assessment by means of inspection and examination of the measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for active electrical energy meters from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR ACTIVE ELECTRICAL ENERGY METERS IN USE

MPE for active electrical energy meters in use is equal to the MPE for periodic verification.

ANNEX 6

THERMAL ENERGY METERS (MI-004)

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

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

A thermal energy meter is either a complete instrument or a combined instrument consisting of the sub-assemblies, flow sensor, temperature sensor pair, and calculator, or a combination thereof.

1) **θ** is the temperature of the thermal energy-conveying liquid;
2) **θin** is the value of θ at the inlet of the thermal energy exchange circuit;
3) **θout** is the value of θ at the outlet of the thermal energy exchange circuit;
4) **Δθ** is the temperature difference θin — θ out with $\Delta\theta \geq 0$;
5) **θmax** is the upper limit of θ for the thermal energy meter to function correctly within the MPEs;
6) **θmin** is the lower limit of θ for the thermal energy meter to function correctly within the MPEs;
7) **Δθmax** is the upper limit of Δθ for the thermal energy meter to function correctly within the MPEs;
8) **Δθmin** is the lower limit of Δθ for the thermal energy meter to function correctly within the MPEs;
9) **q** is the flow rate of the thermal energy conveying liquid;
10) **qs** is the highest value of q that is permitted for short periods of time for the thermal energy meter to function correctly;

11) **qp** is the highest value of q that is permitted permanently for the thermal energy meter to function correctly;
12) **qi** is the lowest value of q that is permitted for the thermal energy meter to function correctly;
13) **P** is the thermal power of the thermal energy exchange;
14) **Ps** is the upper limit of P that is permitted for the thermal energy meter to function correctly.

SPECIFIC REQUIREMENTS

1. Rated operating conditions

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

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

__ for the temperature differences: $\Delta\theta_{max}$, $\Delta\theta_{min}$,

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

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

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

1.4. For the thermal power: P_s.

2. Accuracy classes

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

3. MPEs applicable to complete thermal energy meters

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

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

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

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

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

4. Permissible influences of electromagnetic disturbances

4.1. The thermal energy meter shall not be influenced by static magnetic fields and by electromagnetic fields at electrical grid frequency.

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

4.3. The critical change value for a complete thermal energy meter is equal to the absolute value of the MPE

applicable to that thermal energy meter (see point 3).

5. Durability

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

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

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

6. Inscriptions on a thermal energy meter

— Accuracy class
— Limits of flow rate
— Limits of temperature
— Limits of temperature difference
— Place of the flow sensor installation: flow or return
— Indication of the direction of flow

7. Sub-assemblies

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

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

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

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

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

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

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

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

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

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

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

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

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

7.5. Inscriptions on the sub-assemblies

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

PUTTING INTO USE

(a) Measurement of residential consumption shall be performed by means of a Class 3 thermal energy meter.

(b) Measurement of commercial and/or light industrial consumption shall be performed using a Class 2 thermal energy meter.

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

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Annex 2 of this Rulebook that the manufacturer can choose between are:

B + F or B + D or H1.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for thermal energy meters in this Annex.

Examination procedures for periodic and extraordinary verification of thermal energy meters are equal to the examination procedure for conformity assessment by means of inspection and examination of the measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Expanded measurement uncertainty of the testing device shall not exceed 1/5 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for thermal energy meters from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE OF THERMAL ENERGY METERS IN USE

MPE of thermal energy meters in use is twice the MPE for periodic verification.

ANNEX 6

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

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

The terms used in this Annex shall have the following meaning:

1) **Meter** is an instrument designed to measure continuously, memorise and display the quantity at metering conditions of liquid flowing through the measurement transducer in a closed, fully charged conduit.
2) **Calculator** is part of a meter that receives the output signals from the measurement transducer(s) and possibly, from associated measuring instruments and displays the measurement results.
3) **Associated measuring instrument** is an instrument connected to the calculator for measuring certain quantities which are characteristic of the liquid, with a view to make a correction and/or conversion.
4) **Conversion Device** is a part of the calculator which by taking account of the characteristics of the liquid (temperature, density, etc.) measured using associated measuring instruments, or stored in a memory, automatically converts:
    a. the volume of the liquid measured at metering conditions into a volume at base conditions and/or into mass, or
    b. the mass of the liquid measured at metering conditions into a volume at metering conditions and/or into a volume at base conditions. Note: A conversion device includes the relevant associated measuring instruments.

5) **Base conditions** are the specified conditions to which the measured quantity of liquid at metering conditions is converted.
6) **Measuring System** is a system that comprises the meter itself and all devices required to ensure correct measurement or intended to facilitate the measuring operations.
7) **Fuel dispenser** is a measuring system intended for the refuelling of motor vehicles, small boats and small aircraft.
8) **Self-service arrangement** is an arrangement that allows the customer to use a measuring system for the purpose of obtaining liquid for his own use.
9) **Self-service device** is a specific device that is part of a self-service arrangement and which allows one of more measuring systems to perform in this self-service arrangement.
10) **Minimum measured quantity (MMQ)** is the smallest quantity of liquid for which the measurement is metrologically acceptable for the measuring system.
11) **Direct indication** is the indication, either volume or mass, corresponding to the measure and that the meter is physically capable of measuring. Note: The direct indication may be converted into another quantity using a conversion device.
12) **Interruptible/non-interruptible measuring system** is a measuring system which is considered as interruptible/non-interruptible when the liquid flow can/cannot be stopped easily and rapidly.
13) **Flowrate range** is the range between the minimum flowrate (Qmin) and maximum flowrate (Qmax).

SPECIFIC REQUIREMENTS

1. Rated operating conditions

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

1.1. The flowrate range is subject to the following conditions:

a) the flowrate range of a measuring system shall be within the flowrate range of each of its elements in the specified measuring instrument;

b) Measuring instrument and measuring system:

Table 1.

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

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

- Temperature range;
- Pressure range;
- Density range;
- Viscosity range.

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

1.4. The base conditions for converted values is 15 ºC..

2. Accuracy class and maximum permissible errors (MPEs)

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

Table 2

	Accuracy Class				
	0,3	0,5	1,0	1,5	2,5
Measuring system (A)	0,3 %	0,5 %	1,0 %	1,5 %	2,5 %
Measuring instrument (B)	0,2 %	0,3 %	0,6 %	1,0 %	1,5 %

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

Table 3

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

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

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

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

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

Condition 1

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

Condition 2

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

— MMQ is the minimum measured quantity,

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

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

2.5. ***Converted indication***

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

2.6. ***Conversion devices***

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

Parts of conversion devices that can be tested separately are:

(a) Calculator

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

(b) Associated measuring instruments

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

Table 4

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

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

(c) Accuracy for calculating function

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

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

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

3. Maximum permissible effect of disturbances

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

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

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

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

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

4. Durability

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

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

5. Suitability

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

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

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

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

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

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

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

5.4. ***Instruments for direct sales***

5.4.1. A measuring system for direct sales shall be provided with means for resetting the display to zero and it shall not be possible to divert the measured quantity.

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

5.4.3. Measuring systems for direct sales shall be interruptible.

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

5.5. ***Fuel Dispensers***

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

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

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

6. Power supply failure

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

7. Putting into use

Table 5

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

	(other than cryogenic liquids)
2,5	Measuring systems for cryogenic liquids (temperature below – 153 °C)
(1) Measuring systems of accuracy class 0,3 of 0,5 may be applied in Montenegro when used for the for the levying of duties on mineral oils when (un)loading ships and rail and road tankers. Note: The manufacturer may specify a better accuracy for a certain type of measuring system.	

8. Units of measurement

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

CONFORMITY ASSESSMENT

The conformity assessment procedures with regard to measuring instruments and systems referred to in Annex 2 of this Rulebook that the manufacturer can choose between are:

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

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for measuring instruments and measuring systems for the measurement of quantities of liquids other than water in this Annex.

Before periodic and extraordinary verification, measuring instruments and measuring systems for the continuous and dynamic measurement of quantities of liquids other than water shall be set to ensure the minimum deviation of indication from the nominal value. Where the owner of the measuring instrument, at its place of use, has a large number of flow meters or measuring systems for the continuous and dynamic measurement of quantities of liquids other than water, the average deviation from the indication of the nominal value shall not be negative. The examination of measuring instruments and measuring systems for the measurement of quantities of liquid fuels during the filling of motor vehicle tanks shall be performed at minimum, medium and maximum flow, which are at the user's disposal. For each flow, at least one measurement is carried out, whereas examination of other measuring instruments and measuring system is carried out for the working flow.

This examination shall be carried out at least in two measurements.
The duration of the examination for each flow shall be at least one minute.
Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for flow meters or measuring system for the continuous or dynamic measurement of quantities of liquids other than water from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR FLOW METERS AND MEASURING SYSTEMS IN USE

MPE for flow meters and measuring system in use is equal to the MPE specified in this Annex.

ANNEX 8

AUTOMATIC WEIGHING INSTRUMENTS (MI-006)

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

The terms used in this Annex shall have the following meaning:

1) **Automatic weighing instrument** is 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.
2) **Automatic catchweigher** is an automatic weighing instrument that determines the mass of pre-assembled discrete loads (for example prepackages) or single loads of loose material.
3) **Automatic checkweigher** is 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.
4) **Weight labeller (self-indicating weighing instrument)** is an automatic catchweigher that labels individual articles with the weight value.
5) **Weight/price labeller** is an automatic catchweigher that labels individual articles with the weight value, and price information.
6) **Automatic gravimetric filling instrument** is an automatic weighing instrument that fills containers with a predetermined and virtually constant mass of product from bulk.
7) **Discontinuous totaliser (totalising hopper weigher)** is 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.
8) **Continuous totaliser (beltweigher)** is 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.
9) **Rail-weighbridge** is an automatic weighing instrument having a load receptor inclusive of rails for conveying railway vehicles.

SPECIFIC REQUIREMENTS

CHAPTER I

Requirements common to all types of automatic weighing instruments

1. Rated Operating Conditions

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

1.1. For the measurand:

The measuring range for automatic weighing instrument in terms of its maximum and minimum capacity.

1.2. For the electrical supply influence quantities:

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

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

1.3. For the mechanical and climatic influence quantities:

The minimum temperature range is 30 °C unless specified otherwise in this Annex.

The mechanical environment classes according to Annex I, point 1.3.2 are not applicable.

For instruments which are used under special mechanical strain, e.g. instruments incorporated into vehicles, the manufacturer shall define the mechanical conditions of use.

1.4. For other influence quantities (if applicable):

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

2. Permissible effect of disturbances — Electromagnetic environment

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

3. Suitability

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

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

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

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

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

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

4. Conformity assessment

The conformity assessment procedures that the manufacturer can choose between are:

For mechanical systems:

B + D or B + E or B + F or D1 or F1 or G or H1 referred to in Annex 2 of this Rulebook.

For electromechanical instruments:

B + D or B + E or B + F or G or H1 referred to in Annex 2 of this Rulebook.

For electronic systems or systems containing software:

B + D or B + F or G or H1 referred to in Annex 2 of this Rulebook.

CHAPTER II

Automatic Catchweighers

1. Accuracy Classes

1.1. These weighing instruments are divided into primary categories designated by:

X or Y

as specified by the manufacturer.

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

XI, XII, XIII & XIIII

and

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

which shall be specified by the manufacturer.

2. Category X Instruments

2.1. Category X applies to instruments used to check prepackages made up in accordance with the requirements of a specific regulation applicable to prepackages.

2.2. The accuracy classes are supplemented by a factor (x) that quantifies the maximum permissible standard deviation as specified in point 4.2.
The manufacturer shall specify the factor (x), where (x) shall be $x \leq 2$ and in the form 1×10^k, 2×10^k or 5×10^k, where k is a negative whole number or zero.

3. Category Y Instruments

Category Y applies to all other automatic weighing instruments for individual weighing (catchweighers).

4. MPE

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

Table 1

Value of Net Load (m) in verification scale intervals (e)								**X**		**Y**	
								Maximum permissible mean error		**Maximum permissible error**	
XI	**Y(I)**	**XII**	**Y(II)**	**XIII**	**Y(a)**	**XIIII**	**Y(b)**	**Conf. Assess.**	**In use**	**Conf. Assess.**	**In use**

0 < m ≤ 50 000	0 < m ≤ 5 000	0 < m ≤ 500	0 < m ≤ 50	± 0,5 e	± 1 e	± 1 e	± 1,5 e
50 000 < m ≤ 200 000	5 000 < m ≤ 20 000	500 < m ≤ 2 000	50 < m ≤ 200	± 1,0 e	± 2 e	± 1,5 e	± 2,5 e
200 000 < m	20 000 < m ≤ 100 000	2 000 < m ≤ 10 000	200 < m≤ 1 000	± 1,5 e	± 3 e	± 2 e	± 3,5 e

4.2. ***Standard deviation***

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

Table 2

Net Load Value (m)	**Maximum permissible standard deviation for class X(1)**	
	Conformity Assessment	**In use**
m ≤ 50 g	0,48 %	0,6 %
50 g < m ≤ 100 g	0,24 g	0,3 g
100 g < m ≤ 200 g	0,24 %	0,3 %
200 g < m ≤ 300 g	0,48 g	0,6 g
300 g < m ≤ 500 g	0,16 %	0,2 %
500 g < m ≤ 1 000 g	0,8 g	1,0 g
1 000 g < m ≤ 10 000 g	0,08 %	0,1 %
10 000 g < m ≤ 15 000 g	8 g	10 g
15 000 g < m	0,053 %	0,067 %

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

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

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

4.3. ***Verification scale interval — single interval weighing instruments***

Table 3

Accuracy classes		**Verification scale interval**	Number of verification scale intervals $n = Max/e$	
			Minimum	**Maximum**

XI	Y(I)	0,001 g ≤ e	50 000	—
XII	Y(II)	0,001 g ≤ e ≤ 0,05 g	100	100 000
		0,1 g ≤ e	5 000	100 000
XIII	Y(a)	0,1 g ≤ e ≤ 2 g	100	10 000
		5 g ≤ e	500	10 000
XIIII	Y(b)	5 g ≤ e	100	1 000

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

Table 4

Accuracy classes		**Verification scale interval**	Number of verification scale intervals $n = Max/e$	
			Minimum value ([1]) $n = Max_i/e_{(i+1)}$	**Maximum value** $n = Max_i/e_i$
XI	Y(I)	0,001 g ≤ e_i	50 000	—
XII	Y(II)	0,001 g ≤ e_i≤ 0,05 g	5 000	100 000
		0,1 g ≤ e_i	5 000	100 000
XIII	Y(a)	0,1 g ≤ e_i	500	10 000
XIIII	Y(b)	5 g ≤ e_i	50	1 000
([1]) For i = r the corresponding column from Table 3 is applied, where e is replaced with e_i				

Where:

i = 1, 2, … r

i = partial weighing range

r = total number of partial ranges

5. Measurement Range

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

class Y(I)	:	100 e
class Y(II)	:	20 e for 0,001 g ≤ e ≤ 0,05 g, and 50 e for 0,1 g ≤

		e
class Y(a)	:	20 e
class Y(b)	:	10 e
Scales used for grading, e.g. postal scales and garbage weighers	:	5 e

6. Dynamic Setting

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

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

7. Performance under Influence Factors and Electromagnetic Disturbances

7.1. The MPEs due to influence factors are:

7.1.1. For category X instruments:

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

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

7.1.2. For category Y instruments

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

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

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

7.3. Temperature range:

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

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

CHAPTER III

Automatic Gravimetric Filling Instruments

1. Accuracy classes

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

1.2. Each instrument type is designated a reference accuracy class, Ref(x), corresponding to the best possible accuracy for instruments of the type. After installation, individual instruments are designated for one or more

operational accuracy classes, X(x), having taken account of the specific products to be weighed. The class designation factor (x) shall be ≤ 2, and in the form 1×10^k, 2×10^k or 5×10^k where k is a negative whole number or zero.

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

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

2. MPE

2.1. ***Maximum permissible error for static weighing***

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

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

2.2. ***Deviation from average fill***

Table 5

Value of the mass of the fills - m (g)	**Maximum permissible deviation of each fill from the average for class X(1)**	
	Conformity Assessment	**In use**
m ≤ 50	7,2 %	9 %
50 < m ≤ 100	3,6 g	4,5 g
100 < m ≤ 200	3,6 %	4,5 %
200 < m ≤ 300	7,2 g	9 g
300 < m ≤ 500	2,4 %	3 %
500 < m ≤ 1 000	12 g	15 g
1 000 < m ≤ 10 000	1,2 %	1,5 %
10 000 < m ≤ 15 000	120 g	150 g
15 000 < m	0,8 %	1 %

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

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

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

3. Performance under Influence Factor And Electromagnetic Disturbance

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

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

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

CHAPTER IV

Discontinuous Totalizing Automatic Weighing Instruments

1. Accuracy Classes

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

2. MPEs

Table 6

Accuracy class	**MPE of totalised load**	
	Conformity assessment	**In Use**
0,2	± 0,10 %	± 0,20 %
0,5	± 0,25 %	± 0,5 %
1	± 0,50 %	± 1,00 %
2	± 1,00 %	± 2,00 %

3. Totalisation scale interval

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

0,01 % Max $\leq d_t \leq$ 0,2 % Max

4. Minimum Totalised Load (Σ_{min})

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

5. Zero Setting

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

— 1 d_t on instruments with automatic zero setting device;

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

6. Operator Interface

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

7. Printout

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

8. Performance under influence factors and electromagnetic disturbances

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

Table 7

Load (m) in totalisation scale intervals (d_t)	**MPE**
$0 < m \leq 500$	$\pm 0,5\ d_t$
$500 < m \leq 2\ 000$	$\pm 1,0\ d_t$
$2\ 000 < m \leq 10\ 000$	$\pm 1,5\ d_t$

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

CHAPTER V

Continuous Totalising Weighing Instruments (beltweighers)

1. Accuracy classes

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

2. Measurement Range

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

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

800 d for class 0.5,

400 d for class 1,

200 d for class 2.

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

3. MPE

Table 8

Accuracy class	**MPE for totalised load**	
	Conformity assessment	**In Use**
0,5	± 0,25 %	± 0,5 %
1	± 0,5 %	± 1,0 %
2	± 1,0 %	± 2,0 %

4. Speed of the belt

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

5. General Totalisation Device

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

6. Performance under influence factors and electromagnetic disturbances

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

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

CHAPTER VI

Automatic Rail Weighbridges

1. Accuracy classes

Instruments are divided into four accuracy classes as follows:

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

2. MPE

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

Table 9

Accuracy class	**MPE**	
	Conformity assessment	**In use**
0,2	± 0,1 %	± 0,2 %
0,5	± 0,25 %	± 0,5 %
1	± 0,5 %	± 1,0 %
2	± 1,0 %	± 2,0 %

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

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

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

— one scale interval (d).

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

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

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

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

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

3. Scale interval (d)

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

Table 10

Accuracy class	**Scale interval (d)**

0,2	d ≤ 50 kg
0,5	d ≤ 100 kg
1	d ≤ 200 kg
2	d ≤ 500 kg

4. Measurement range

4.1. The minimum capacity shall not be less than 1 t, nor greater than the value of the result of the minimum wagon weight divided by the number of partial weighings.

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

5. Performance under influence factor and electromagnetic disturbance

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

Table 11

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

5.2. The critical change value caused by a disturbance is one scale interval.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures for certain types of automatic weighing instruments laid down in this Annex.
Automatic weighing instruments class (X), which have already been provided with a type approval certificate and initial verification, shall be verified according to the same procedure and with the same MPE:

- if (x) ≤ 1, as weighing instruments class XIII (x) laid down in this Annex,
- if (x) > 1, as weighing instruments class XIIII (x) laid down in this Annex.

Automatic weighing instruments class Y(a) and Y(b), which have already been provided with a type approval certificate and initial verification, shall be verified according to the same procedure and with the same MPE as class Y(a) and Y(b) weighing instruments laid down in this Annex.

Automatic gravimetric filling instruments which have already been provided with a type approval certificate and intitial verification, shall be verified according to the same procedure and with the same MPE:

- class A, as class X (1) weighing instruments laid down in this Annex,
- class B, as class X (2) weighing instruments laid down in this Annex.

Discontinuous totalizing automatic weighing instruments which have already been provided with a type approval of a measuring instrument and first verification, shall be verified:

- class III/D, according to the same procedure and with the same MPE as class 0,5 weighing instruments laid down in this Annex;
- class III/C, according to the same procedure and with half the value of the MPE as class 0,5 weighing instruments laid down in this Annex;

Continuous totalising weighing instruments (beltweighers), which have already been provided with a type approval of a measuring instrument and first verification, shall be verified according to the same procedure and within the limits of the same MPE:

- class 1, as class 1 weighing instruments laid down in this Rulebook;
- class 2, as class 2 weighing instruments laid down in this Rulebook;

Automatic rail weighbridges which have already been provided with a type approval of a measuring instrument and first verification, shall be verified according to the same procedure and within the limits of the same MPE as class 0,5 weighing instruments laid down in this Annex.

Weighing instruments used in the construction industry for the preparation of construction materials, shall be verified according to the same procedure and with the same MPE:

- class III/1 and III/2 as class III non-automatic weighing instruments;
- class IIII/2 and IIII/3 as class IIII non-automatic weighing instruments.

The expanded measurement uncertainty of the testing system shall not exceed 1/3 of the value of MPE for the specified load.

MPE OF AUTOMATIC WEGHING INSTRUMENTS IN USE

MPE of automatic weighing instruments in use for certain types of automatic weighing instruments is equal to the MPE in this Annex.

ANNEX 9

TAXIMETERS (MI-007)

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

Taximeter is a device that works together with a signal generator to make a measuring instrument. Provisions of this Rulebook shall not be applicable for signal generators.

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

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

Cross-over speed is the speed value found by division of a time tariff value by a distance tariff value.

Normal calculation mode S (single application of tariff) is a fare calculation based on application of the time tariff below the cross-over speed and application of the distance tariff above the cross-over speed.

Normal calculation mode D (double application of tariff) is a fare calculation based on simultaneous application of time tariff and distance tariff over the whole trip.

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

‘For	:	The operating position in which the fare calculation is disabled

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

DESIGN REQUIREMENTS

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

2. The taximeter shall be designed to calculate and display the fare, incrementing in steps in the operation position ‘Hired’. The taximeter shall also be designed to display the final value for the trip in the operating position ‘Stopped’.

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

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

   — operation position: ‘For Hire’, ‘Hired’ or ‘Stopped’;

   — totaliser data according to point 15.1;

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

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

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

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

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

RATED OPERATING CONDITIONS

6.1. The mechanical environment class that applies is M3.

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

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

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

MAXIMUM PERMISSIBLE ERRORS (MPEs)

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

— For the time elapsed: ± 0,1 %

minimum value of MPE: 0,2 s;

— For the distance travelled: ± 0,2 %

minimum value of MPE: 4 m;

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

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

PERMISSIBLE EFFECT OF DISTURBANCES

8. Electromagnetic immunity

8.1. The electromagnetic class that applies is E3.

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

POWER SUPPLY FAILURE

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

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

— abort existing measurements and return to the position ‘For Hire’ if the voltage drop is for a longer period.

OTHER REQUIREMENTS

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

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

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

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

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

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

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

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

— The total distance travelled by the taxi;

— The total distance travelled when hired;

— The total number of hirings;

— The total amount of money charged as supplements;

— The total amount of money charged as fare.

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

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

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

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

–– distance of the trip;

— duration of the trip;

— time of the day;

— date;

— day of the week.

17. If properties of the taxi are important for the correctness of the taximeter, the taximeter shall provide means to

secure the connection of the taximeter to the taxi in which it is installed.

18. For the purpose of testing after installation, the taximeter shall be equipped with the possibility to test separately the accuracy of time and distance measurement and the accuracy of the calculation.

19. A taximeter and its installation instructions specified by the manufacturer shall be such that, if installed according to the manufacturer's instructions, alterations of the measurement signal representing the distance travelled are sufficiently excluded.

20. The general essential requirement dealing with fraudulent use shall be fulfilled in such a way that the interests of the customer, the driver, the driver's employer and the fiscal authorities are protected.

21. A taximeter shall be designed so that it can respect the MPEs without adjustment during a period of one year of normal use.

22. The taximeter shall be equipped with a real-timeclock by means of which the time of the day and the date are kept, one or both can be used for automatic change of tariffs. The requirements for the real-time clock are:

    — the timekeeping shall have an accuracy of 0,02 %;

    — the correction possibility of the clock shall be not more than 2 minutes per week.

    — Correction for summer and wintertime shall be performed automatically;

    — correction, automatic or manually, during a trip shall be prevented.

23. The values of distance travelled and time elapsed, when displayed or printed in accordance with this Rulebook, shall use the following units:

Distance travelled:

— kilometres

Time elapsed:

— seconds, minutes or hours, as may be suitable; keeping in mind the necessary resolution and the need to prevent misunderstandings.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Annex 2 of this Rulebook that the manufacturer can choose between are:

B + F or B + D or H1.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for taximeters in this Annex.

Examination procedures for periodic and extraordinary verification are equal to the examination procedure for conformity assessment by means of inspection and examination of each measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for taximeters from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR ACTIVE TAXIMETERS IN USE

MPE for built-in taximeters amounts to:

- elapsed time: ± 1 %
- distance travelled: ± 2 %.

ANNEX 10

MATERIAL MEASURES (MI-008)

CHAPTER I

Material measures of length

The relevant essential requirements of Annex I of this Rulebook, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to material measures of length.

Material measures of length are instruments comprising scale marks whose distances are given in legal units of length.

SPECIFIC REQUIREMENTS

1. Reference Conditions

1.1. For tapes of length equal to or greater than 5 metres, the maximum permissible errors (MPEs) are to be met when a tractive force of fifty newtons or other force values as specified by the manufacturer and marked on the tape accordingly, or in the case of rigid or semi-rigid measures no tractive force is needed, is applied.

1.2. The reference temperature is 20 °C unless otherwise specified by the manufacturer and marked on the measure accordingly.

MPEs

2. The MPE, positive or negative in mm, between two non-consecutive scale marks is (a + bL), where:

— L is the value of the length rounded up to the next whole metre; and

— a and b are given in Table 1 below.

When a terminal interval is bounded by a surface, the MPE for any distance beginning at this point is increased

by the value c given in Table 1.

Table 1

Accuracy Class	a (mm)	b	c (mm)
I	0,1	0,1	0,1
II	0,3	0,2	0,2
III	0,6	0,4	0,3
D — special class for dipping tapes ([1]) Up to and including 30 m ([2])	1,5	zero	zero
S— special class for tank strapping tapes For each 30 m length when the tape is supported on a flat surface	1,5	zero	zero
([1]) It is applied on the combination of measuring tapes and a dip weight. ([2]) If the standard tape length exceeds 30 m, maximum permissible error of 0,75 mm shall be allowed for each 30 m of the tape's length.			

Dip tapes may also be of Classes I or II in which case for any length between two scale marks, one of which is on the sinker and the other on the tape, the MPE is ± 0,6 mm when application of the formula gives a value of less than 0,6 mm.

The MPE for the length between consecutive scale marks, and the maximum permissible difference between two consecutive intervals, are given in Table 2 below.

Table 2

Length i of the interval	**MPE or difference in millimetres according to accuracy class**		
	I	**II**	**III**
i ≤ 1 mm	0,1	0,2	0,3
1 mm < i ≤ 1 cm	0,2	0,4	0,6

Where a rule is of the folding type, the jointing shall be such as not to cause any errors, supplementary to those above, exceeding: 0,3 mm for Class II, and 0,5 mm for Class III.

Materials

3.1. Materials used for material measures of length shall be such that length variations due to temperature excursions up to ± 8 °C about the reference temperature do not exceed the MPE. This does not apply to Class S and Class D measures where the manufacturer intends that thermal expansion corrections shall be applied to observed readings where necessary.

3.2. Measures made from material whose dimensions may alter materially when subjected to a wide range of relative humidity, may only be included in Classes II or III.

Markings

4. The nominal value shall be marked on the measure. Millimetre scales shall be numbered on every centimetre and measures with a scale interval greater than 2 cm shall have all scale marks numbered.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Annex 2 of this Rulebook that the manufacturer can choose between are: F 1 or D1 or B + D or H or G.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification is equal to the MPE in conformity assessment procedures, which are set for material measures of length in this Annex.

Examination procedures for periodic and extraordinary verification are equal to the examination procedure for conformity assessment by means of inspection and examination of the measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for material measures from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR MATERIAL MEASURES OF LENGTH IN USE

MPE for material measures of length in use is equal to the MPE laid down in this Annex.

CHAPTER II

Capacity serving measures

The relevant essential requirements of Annex I of this Rulebook, and the specific requirements and the conformity assessment procedures listed in this Annex, apply to capacity serving measures defined below. The requirement for the instrument to bear information in respect of its accuracy shall not apply to capacity serving measures.

The terms used in this chapter shall have the following meaning:

1) **Capacity serving measure** is a capacity measure (such as a drinking glass, jug or similar) designed to determine a specified volume of a liquid (other than a pharmaceutical product) which is sold for immediate consumption.
2) **Line measure** is a capacity serving measure marked with a line to indicate nominal capacity.
3) **Brim measure** is a capacity serving measure for which the internal volume is equal to the nominal capacity.
4) **Transfer measure** is a capacity serving measure from which it is intended that the liquid is decanted prior to consumption.
5) **Capacity** is the internal volume for brim measures or internal volume to a filling mark for line measures.

SPECIFIC REQUIREMENTS

1. Reference Conditions

1.1. Temperature: the reference temperature for measurement of capacity is 20 °C.

1.2. Position for correct indication: free standing on a horizontal surface.

2. MPEs

Table 1

	Line	**Brim**
Transfer measures		
< 100 ml	± 2 ml	– 0 + 4 ml
≥ 100 ml	± 3 %	– 0 + 6 %
Serving measures		
< 200 ml	± 5 %	– 0 + 10 %
≥ 200 ml	± 5 ml + 2,5 %	– 0 + 10 ml + 5 %

3. Materials

Capacity serving measures shall be made of material which is sufficiently rigid and dimensionally stable to maintain capacity within the MPE.

4. Shape

4.1. Transfer measures shall be designed so that a change of contents equal to the MPE causes a change in level of at least 2 mm at the brim or filling mark.

4.2. Transfer measures shall be designed so that the complete discharge of the liquid being measured will not be impeded.

5. Marking

5.1. The nominal capacity declared shall be clearly and indelibly marked on the measure.

5.2. Capacity serving measures may also be marked with up to three clearly distinguishable capacities, none of which shall lead to confusion one to the other.

5.3. All filling marks shall be sufficiently clear and durable to ensure that MPEs are not exceeded in use.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Annex 2 of this Rulebook that the manufacturer can choose between are: A1 or F1 or D1 or E1 or B + E or B + D or H.

MPE FOR CAPACITY SERVING MEASURES IN USE

MPE for capacity serving measures in use is equal to the MPE laid down in this Rulebook.

ANNEX 11

DIMENSIONAL MEASURING INSTRUMENTS (MI-009)

The relevant essential requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to dimensional measuring instruments of the types defined below.

The terms used in this Annex shall have the following meaning:

1) Length measuring instrument is a measuring instrument that serves for the determination of the length of rope-type materials (e.g. textiles, bands, cables) during feed motion of the product to be measured.
2) Area measuring instrument is a measuring instrument that serves for the determination of the area of irregular shaped objects, e.g. for leather.
3) Multi-dimensional measuring instrument is a measuring instrument that serves for the determination of the edge length (length, height, width) of the smallest enclosing rectangular parallelepiped of a product.

CHAPTER I

Requirements common to all dimensional measuring instruments

Electromagnetic immunity

1. The effect of an electromagnetic disturbance on a dimensional measuring instrument shall be such that:

— the change in measurement result is no greater than the critical change value as defined in point 2.3; 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. The critical change value is equal to one scale interval.

CONFORMITY ASSESSMENT

The conformity assessment procedures from this Chapter that the manufacturer can choose between are:

- For mechanical or electromechanical instruments, modules F1 or E1 or D1 or B + F or B + E or B + D or H or H1 or G referred to in conformity assessment procedures from Annex 2 of this Rulebook.

- For electronic instruments or instruments containing software, modules B + F or B + D or H1 or G modules referred to in conformity assessment procedures from Annex 2 of this Rulebook.

CHAPTER II

Length measuring instruments

Characteristics of the product to be measured

1. Textiles are characterised by the characteristic factor K. This factor takes the stretchability and force per unit area of the product measured into account and is defined by the following formula:

K	=	$\varepsilon \cdot (G_A + 2{,}2\,N/m^2)$, where: ε is the relative elongation of a cloth specimen 1 m wide at a tensile force of 10 N, G_A is the weight force per unit area of a cloth specimen in N/m^2.

Operating conditions

2.1. ***Range***

Dimensions and K-factor, where applicable, within the range specified by the manufacturer for the instrument in question. The ranges of K-factor are given in Table 1 below.

Table 1

Group	Range of K	Product
I	$0 < K < 2 \times 10^{-2}$ N/m^2	low stretchability
II	2×10^{-2} N/m^2 < K < 8×10^{-2} N/m^2	medium stretchability

III	8×10^{-2} N/m^2 < K < 24×10^{-2} N/m^2	high stretchability
IV	24×10^{-2} N/m^2 < K	very high stretchability

2.2. Where the measured object is not transported by the measuring instrument, its speed must be within the range specified by the manufacturer for the instrument.

2.3. If the measurement result depends on the thickness, the surface condition and the kind of delivery (e.g. from a big roll or from a pile), corresponding limitations are specified by the manufacturer.

MPEs

3. ***Measuring instrument of length***

Table 2

Accuracy class	MPE
I	0,125 %, but not less than 0,005 L_m
II	0,25 %, but not less than 0,01 L_m
III	0,5 %, but not less than 0,02 L_m

Where L_m is the minimum measurable length, that is to say the smallest length specified by the manufacturer for which the instrument is intended to be used.

The true length value of the different types of materials shall be measured using suitable instruments (e.g. tapes of length). Thereby, the material which is going to be measured shall be laid out on a suitable underlay (e.g. a suitable table) straight and unstretched.

Other requirements

4. The instruments must ensure that the product is measured unstretched according to the intended stretchability for which the instrument is designed.

CHAPTER III

Area measuring instruments

Operating conditions

1.1. ***Range***

Dimensions within the range specified by the manufacturer for the instrument.

1.2. ***Condition of the product***

The manufacturer shall specify the limitations of the instruments due to the speed, and thickness of the surface conditions if relevant, of the product.

MPEs

2. ***Area measuring instrument***

The MPE is 1,0 %, but not less than 1 dm^2.

Other requirements

Presentation of the product

3. In the case of pulling back or stopping the product, it shall not be possible to have an error of measurement or the display must be blanked.

Scale interval

4. The instruments must have a scale interval of 1,0 dm^2. In addition, it must be possible to have a scale interval of 0,1 dm^2 for testing purposes.

CHAPTER IV

Multidimensional measuring instruments

Operating conditions

1.1. Range

Dimensions must be within the range specified by the manufacturer for the instrument.

1.2. Minimum dimension

The lower limit of the minimum dimension for all values of the scale interval is given in Table 1.

Table 1

Scale interval (d)	Minimum dimension (min) (lower limit)
$d \leq 2$ cm	10 d
2 cm < $d \leq 10$ cm	20 d
10 cm < d	50 d

1.3. Speed of the product

The speed must be within the range specified by the manufacturer for the instrument.

MPE

2. ***Instrument:***

The MPE is ± 1,0 d.

PERIODIC AND EXTRAORDINARY VERIFICATION

MPE (maximum permissible error) for the periodic and extraordinary verification of dimensional measuring instruments is equal to the MPE in conformity assessment procedures, which are set for these intruments in this Annex.

Examination procedures for periodic and extraordinary verification are equal to the examination procedure for conformity assessment by means of inspection and examination of the measuring instrument concerned, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Length measuring instruments (instruments for measuring the length of a wire or cable) which have already been provided with a type approval certificate and intitial verification, shall be verified according to the procedure and with the same MPEs for accuracy classes III, in accordance with this Annex.

Expanded measurement uncertainty of the testing device shall not exceed 1/3 of MPE for measuring instruments referred to in this Annex. This condition shall be presumed to be fulfilled, if the requirements with regard to the testing devices for dimensional measuring instruments from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR DIMENSIONAL MEASURING INSTRUMENTS IN USE
MPE for dimensional measuring instruments in use is equal to the MPE laid down in this Annex.

ANNEX 12

EXHAUST GAS ANALYSERS (MI-010)

The relevant requirements of Annex I, the specific requirements of this Annex and the conformity assessment procedures listed in this Annex, apply to exhaust gas analysers defined below intended for inspection and professional maintenance of motor vehicles in use.

Exhaust gas analyser is a measuring instrument that serves to determine the volume fractions of specified components of the exhaust gas of a motor vehicle engine with spark ignition at the moisture level of the sample analysed. These gas components are carbon monoxide (CO), carbon dioxide (CO2), oxygen (O2) and hydrocarbons (HC).

The content of hydrocarbons has to be expressed as concentration of n-hexane (C6H14), measured with near-infrared absorption techniques.

The volume fractions of the gas components are expressed as a percentage (% vol) for CO, CO2 and O2 and in parts per million (ppm vol) for HC.

Moreover, an exhaust gas analyser calculates the lambda value from the volume fractions of the components of the exhaust gas.

Lambda is a dimensionless value representative of the burning efficiency of an engine in terms of air/fuel ratio in the exhaust gases. It is determined with a reference standardised formula.

SPECIFIC REQUIREMENTS

Instrument Classes

1. Two classes (0 and I) are being defined for exhaust gas analysers. The relevant minimum measuring ranges for these classes are shown in Table 1.

   Table 1

Classes and measuring ranges	
Parameter	Classes 0 and I
CO fraction	from 0 to 5 % vol
CO_2 fraction	from 0 to 16 % vol
HC fraction	from 0 to 2 000 ppm vol
O_2 fraction	from 0 to 21 % vol
λ	from 0,8 to 1,2

Rated operating conditions

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

   2.1. For the climatic and mechanical influence quantities:

   — a minimum temperature range of 35 °C for the climatic environment;

   — the mechanical environment class that applies is M1.

   2.2. For the electrical power influence quantities:

   — the voltage and frequency range for the AC voltage supply;

   — the limits of the DC voltage supply.

   2.3. For the ambient pressure:

   — the minimum and the maximum values of the ambient pressure are for both classes: $p_{min} \leq 860$ hPa, $p_{max} \geq 1\,060$ hPa.

Maximum permissible errors (MPEs)

3. The MPEs are defined as follows:

3.1. For each of the fractions measured, the maximum error value permitted under rated operating conditions according to point 1.1 of Annex I of this Rulebook is the greater of the two values shown in Table 2. Absolute values are expressed in % vol or ppm vol, percentage values are percent of the true value.

Table 2

Parameter	**Class 0**	**Class I**
CO fraction	± 0,03 % vol ± 5 %	± 0,06 % vol ± 5 %
CO_2 fraction	± 0,5 % vol ±5 %	± 0,5 % vol ± 5 %
HC fraction	± 10 ppm vol ± 5 %	± 12 ppm vol ± 5 %
O_2 fraction	± 0,1 % vol ± 5 %	± 0,1 % vol ± 5 %

3.2. The MPE on lambda calculation is 0,3 %. The conventional true value is calculated in the following manner: 0,01% vol for measurands less than or equal to 4%, otherwise 0,1 % vol.

For this purpose, the values displayed by the instrument are used for calculation.

Permissible effect of disturbances

4. For each of the volume fractions measured by the instrument, the critical change value is equal to the MPE for the parameter concerned.

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

— either the change in the measurement result is not greater than the critical change value laid down in point 4;

— or the presentation of the measurement result is such that it cannot be taken for a valid result.

Other requirements

6. The resolution shall be equal to or of one order of magnitude higher than the values shown in Table 3.

Table 3

Resolution				
	CO	CO_2	O_2	HC

Class 0 and class I	0,01 % vol	0,1 % vol	([1])	1 ppm vol
([1]) 0,01% vol for measurands less than 4% or equal to 4 % vol, otherwise 0,1% vol.				

The lambda value shall be displayed with a resolution of 0,001.

7. The standard deviation of 20 measurements shall not be greater than one third of the modulus of the MPE for each applicable gas volume fraction.

8. For measuring CO, CO_2 and HC, the instrument, including the specified gas handling system, must indicate 95 % of the final value as determined with calibration gases within 15 seconds after changing from a gas with zero content, e.g. fresh air.

   For measuring O_2, the instrument under similar conditions must indicate a value differing less than 0,1 % vol from zero within 60 seconds after changing from fresh air to an oxygen-free gas.

9. The components in the exhaust gas, other than the components whose values are subject to the measurement, shall not affect the measurement results by more than the half of the modulus of the MPEs when those components are present in the following maximum volume fractions:

   6 % vol CO,

   16 % vol CO2,

   10 % vol O2,

   5 % vol H2,

   0,3 % vol NO,

   2 000 ppm vol HC (as n-hexane),

   water vapour up to saturation.

10. An exhaust gas analyser shall have an adjustment facility that provides operations for zero-setting, gas calibration and internal adjustment. The adjustment facility for zero-setting and internal adjustment shall be automatic.

11. For automatic or semi-automatic adjustment facilities, the instrument shall be unable to make a measurement as long as the adjustments have not been made.

12. An exhaust gas analyser shall detect hydrocarbon residues in the gas handling system. It shall not be possible to carry out a measurement if the hydrocarbon residues, present before any measurement, exceed 20 ppm vol.

13. An exhaust gas analyser shall have a device for automatically recognising any malfunctioning of the sensor of the oxygen channel due to wear or a break in the connecting line.

14. If the exhaust gas analyser is capable to operate with different fuels (e.g. petrol or liquefied gas), there shall be

the possibility to select the suitable coefficients for the Lambda calculation without ambiguity concerning the appropriate formula.

CONFORMITY ASSESSMENT

The conformity assessment procedures referred to in Annex 2 of this Rulebook that the manufacturer can choose between are: B + F or B + D or H1.

PERIODIC AND EXTRAORDINARY VERIFICATION

Examination of exhaust gas analysers for periodic and extraordinary verification shall be conducted at the place of use of these instruments.

Examination procedures for periodic and extraordinary verification are equal to the examination procedure for conformity assessment by means of inspection and examination of each measuring instrument, in accordance with the technical documentation referred to in Article 15 of this Rulebook.

Certified reference materials shall be used for periodic and extraordinary verification of exhaust gas analysers.

Reference gas mixture shall contain at least 3 parts. These parts shall be within the capacity shares as follows:

CO: 0,5 % vol to 5 % vol

CO2: 4 % vol to 16 % vol

HC: 100 ppm vol to 2.000 ppm vol.

For oxygen (O_2) measurement, reading of the 20,9% volume share is tested by merging the intake of an exhaust gas analyser to the surrounding air.

The testing is performed for ambient pressure from 860 hPa to 1060hPa.

It is necessary to document the values of the volume share for each part of the testing gas, their measured value and maximum permissible error.

Warm-up period

The warm-up period for class I and 0 analysers must not be longer than 30 minutes. During the warming-up, class I and 0 analysers must not display the measured values of the volume gas share. After the warming-up, an exhaust gas analyser must comply with the metrological requirements set out in this Annex.

Propane/hexane factor

The proportion of hydrocarbons must be expressed as ppm vol. n-hexane (C_6H_{14}). The exhaust gas analyser is tested by means of propane (C_3H_8), and each measuring instrument must clearly indicate the propane hexane factor (PEF) at all times.

Exceptionally, it is permissible to show the types of conversion factors that satisfy the appropriate concentrations. The manufacturer must specify the PEF factor with at least three decimals to each analyser.

The value of the PEF factor is usually from 0.490 to 0.540.

If a gas-sensitive element is replaced or repaired, a new PEF factor must be indicated on the analyser.

The expanded measurement uncertainty of the testing device shall not exceed 1/2 of MPE for the measuring instruments in this Annex.

This condition shall be deemed fulfilled when the requirements for devices for examining material measures from the technical documentation referred to in Article 15 of this Rulebook are met.

MPE FOR EXHAUST GAS ANALYSERS IN USE

MPE for exhaust gas analysers in use is equal to the MPE laid down in this Annex.

ANNEX 13

EU DECLARATION OF CONFORMITY (No XXX)

1. Instrument model/Instrument (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of instrument allowing traceability; it may, where necessary for the identification of the instrument, include an image):

5. The object of the declaration described above is in conformity with the relevant European Union harmonisation legislation:

6. References to the relevant Montenegrin standards or normative documents used or references to the other technical specifications in relation to which conformity is declared:

7. Where applicable, the notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, position) (signature):