

On the basis of article 14 paragraph 4 of the Law on Metrology ( "Official Gazette of Montenegro" no. 79/08) and article 6 of the Law on Technical Requirements for Products and Conformity Assessment ( „Official Gazette of Montenegro" no.53/11) Ministry of Economy has adopted

## **RULEBOOK ON METROLOGICAL REQUIREMENTS FOR NON-AUTOMATIC WEIGHING INSTRUMENTS**

*(The Rulebook has been published in the, "Official Gazette of Montenegro",  
No. 29/2013, dated 22 June 2013)*

### **Article 1**

This rulebook prescribes the requirements and the method of determining metrological requirements to be met by non-automatic weighing instruments, procedures of conformity assessment for non-automatic weighing instruments, as well as procedure for periodic and extra ordinary verification.

### **Article 2**

Terms used in this rulebook shall have the following meanings:

1. **Weighing instrument** is a measuring instrument serving to determine the mass of a body by using the action of gravity on that body and also may serve to determine other mass related magnitudes, quantities, parameters or characteristics;
2. **Non-automatic weighing instrument** (hereinafter referred to as "non-automatic weighing"): is a weighing instrument requiring the intervention of an operator during weighing.

### **Article 3**

This rulebook applies to non-automatic weighing instruments, used for determination of mass:

1. for commercial transactions;
2. for the calculation of a tolls, duties, taxes, tariff, tax, bonus, penalty, compensation for damages or similar type of payment;
3. for the application of laws, or for an expert opinion given in court proceedings;
4. in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
5. for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;

6. determination of price on the basis of mass for the purposes of direct sales to the public and the making-up of prepackaged products.

Provisions of Article 4 paragraph 1, Article 6 paragraph 1, and Article 9 paragraph 3 of this Rulebook apply also to non-automatic weighing instruments used for purposes other than those distinguished by the paragraph of this article.

#### **Article 4**

Non-automatic weighing instruments are putted on the market, if they meet the requirements of this Rulebook.

Non-automatic weighing instruments are putted in use, if they meet the requirements of this Rulebook and if they have the "CE" conformity mark (hereinafter referred to as CE mark) in accordance with Article 9 of this Rulebook.

#### **Article 5**

Non-automatic weighing instruments shall meet the requirements set out in Annex I, which is an integral part of this Rulebook.

If non-automatic weighing instruments contains or is associated with devices that are not used for determination of mass referred to in Article 3 paragraph 1 of this Rulebook, such devices are not subject to the requirements of this Rulebook.

#### **Article 6**

Non-automatic weighing instruments that meet the metrological requirements of this Rulebook can be putted on the market without additional tests and limits.

Non-automatic weighing instruments that meet the metrological requirements of this Rulebook can be putted in use without additional tests and limits.

#### **Article 7**

Non-automatic weighing are assumed to be in compliance with metrological requirements of Annex 1 of this Rulebook, if they are made/manufactured in accordance with Montenegrin standards transposing appropriate harmonized standards, and which of list of standards is published in the Official Gazette of Montenegro, in accordance with Article 7 paragraph 4 Law on technical requirements for products and conformity assessment.

List of standard referred to in paragraph 1 of this Article shall be published in the Official Gazette of Montenegro, adopted by the Ministry responsible for metrology.

### **Article 8**

Conformity assessment of non-automatic weighing instrument which comply metrology requirements of Annex I of this Rulebook, shall be conducted by the choice of the applicant, using one of the methods:

- (1) Measuring instrument type examination (EU-type examination) given in Annex II, item 1, which is an integral part of this Rulebook, which follows EU declaration of type conformity (manufacturer guarantee of production quality) referred to in Annex II, item 2, or by the EU verification as referred to in Annex II, item 3.
- (2) EU unit verification as referred to in Annex II, item 4.

EU-type examination is not required for non-automatic weighing that do not use electronic devices and measuring devices of which do not use a spring to balance the load;

Documents relating to the procedures referred to in paragraph 1 of this Article shall be kept in the Montenegrin language or in a language accepted by the body for conformity assessment.

If non-automatic weighing instruments must meet the requirements of other technical rulebooks, conformity mark implies that they meet the requirements of this rulebook and technical rulebooks.

### **Article 9**

Non-automatic weighing instruments that meet the metrological requirements of this Rulebook shall be affixed in the manner set out in Annex IV item 1, which is an integral part of this Rulebook, and with the CE mark, to be clear, visible, legible and indelible.

CE mark is affixed in compliance with the regulation that sets form, content and appearance of the conformity mark.

Inscriptions set out in Annex IV, item 2 of this Rulebook, shall be affixed in a clear, legible and indelible form to non-automatic weighing instruments from Article 3, paragraph 2 of this Rulebook.

### **Article 10**

Where an non-automatic weighing instrument which is used within the meaning of Article 8, includes or is connected to devices that have not been subject to conformity assessment as referred to in Article 8 of this Rulebook, each of those devices shall bear

the symbol restricting its use, and the symbol shall be affixed to the devices in a clearly visible and indelible form.

Form and the dimensions of the symbol are set out in the Annex IV, item 3, of this Rulebook.

### **Article 11**

Upon the periodic and extra ordinary verification of non-automatic weighing instruments, compliance with metrological requirements for weighing instruments shall be determined in accordance with Montenegrin standard MEST EN 45501, Montenegrin standards transposing appropriate harmonized standards.

Maximum permissible errors in the periodic and extra ordinary verifications are defined in Annex IV, item 4.1 of this Rulebook.

Expanded measurement uncertainty of control weights, which are used for testing non-automatic weighing instruments may not exceed 1/3 of the largest error of weighing instruments for a given load.

### **Article 12**

Every importer or an exporter who puts non-automatic weighing instruments for the first time on the market or has a non-automatic weighing instrument prepared to put in the first use, shall inform Bureau of Metrology.

1. Announcements from the preceding item of this Article shall contain the following information:
  - name/term, and address of the importer/user of non-automatic weighing instrument;
  - type, purpose and place of use of non-automatic weighing instrument;
  - name of the manufacturer of non-automatic weighing instrument and its parts;
  - type-approval number or information about the documents referred to in Article 8 of this Rulebook which follow non-automatic weighing instrument;
  - date of purchase and start of using non-automatic weighing instrument.

### **Article 13**

The provisions of Article 4, 6, 8, 9, and Article 10 of this Rulebook, Annex II, Annex III, paragraph 1 and subparagraph 1., 2 seventh subparagraph and Annex IV, sub-paragraph 3 paragraph 3 of this Rulebook will come into force on the day of the accession of Montenegro to the European Union.

### **Article 14**

On the effective date of this Rulebook shall expire Metrological guidelines of the non-automatic mass-weighing instrument maximum measurements, accuracy class (I) (II) (III) and (III) ("SFRY Official Journal", No. 4/87).

### **Article 15**

These Rulebooks shall enter into force on the eighth day of its publication in the Official Gazette of Montenegro.

Directive 2009/23/EC of the European Parliament and of the Council of 23 April 2009 on non-automatic weighing instruments has been transposed to this Rulebook.

No: 0904-890/4  
Podgorica, 14 June 2013.

Minister,  
Dr Vladimir Kavaric, s.r.

*\* In these Rulebooks is transposed the Directive of the non-automatic weighing instrument of the European Parliament and of the Council 2009/23/EC of 23 April 2009.*

## **ANNEX I**

### **REQUIREMENTS OF NON-AUTOMATIC WEIGHING INSTRUMENTS**

#### **General Requirements**

Where an instrument includes, or is connected to, more than one indicating or printing device used for the applications listed in point (a) of Article 1(2), those devices which repeat the results of the weighing operation and which cannot influence the correct functioning of the instrument shall not be subject to the essential requirements if the weighing results are printed or recorded correctly and indelibly by a part of the instrument which meets the essential requirements and the results are accessible to both parties concerned by the measurement. However, in the case of instruments used for direct sales to the public, display and printing devices for the vendor and the customer must fulfill the essential requirements.

### **METROLOGICAL REQUIREMENTS**

The terminology used is that of the International Organization of Legal Metrology (OIML).

Metrological requirements to be met by non-automatic weighing instruments are:

1. Units of mass

It is permitted the use of the following units:

- SI units: kilogram, microgram, milligram, gram, tone,
- other non-SI unit: metric carat, if weighing precious stones.

2. Accuracy classes

2.1. The following accuracy classes have been defined:

- I special
- II high
- III medium
- IV ordinary

Characteristics of some classes in terms of the value of the test spacing (e) and the number of verification scale interval (n) are given in Table 1.

Table 1: Accuracy class

Accuracy class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale interval $n = \text{Max} / e$	
		Minimum value	Minimum value	Maximum value
I	$0,001 \text{ g} \leq e$	100e	50 000	-
II	$0,001 \text{ g} \leq e \leq 0,05 \text{ g}$	20e	100	100 000
	$0,1 \text{ g} \leq e$	50e	5 000	100 000
III	$0,1 \text{ g} \leq e \leq 2 \text{ g}$	20e	100	10 000
	$5 \text{ g} \leq e$	20e	500	10 000

III	$5 \text{ g} \leq e$	10e	100	1 000

The minimum capacity is reduced to 5 e for instruments in accuracy classes II and III non-automatic weighing instrument for determining a conveying tariff.

## 2.2. Scale intervals (e)

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:  $1 \times 10^k$ ,  $2 \times 10^k$ , or  $5 \times 10^k$  mass units, and k is being any integer or zero.

2.2.2. For all instruments other than those with auxiliary indicating devices:

$$d = e.$$

2.2.3. For instruments with auxiliary indicating devices the following conditions apply:

$$e = 1 \times 10^k \text{ g},$$

$$d < e \leq 10 d,$$

except for instruments of class I with  $d < 10^{-4} \text{ g}$ , for which  $e = 10^{-3} \text{ g}$ .

## 3. Classification non-automatic weighing instruments

### 3.1. Instruments with one weighing range

Instruments equipped with an auxiliary indicating device shall belong to class I or class II.

For these instruments the minimum capacity lower limits are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If  $d < 10^{-4} \text{ g}$ , the maximum capacity of class I may be less than 50000 e.

### 3.2. Instruments with multiple weighing ranges

Multiple weighing ranges are permitted, provided they are clearly indicated on the instrument. Each individual weighing range is classified according to point 3.1. If the

weighing ranges fall into different accuracy classes the instrument shall comply with the severest of the requirements that apply for the accuracy classes in which the weighing ranges fall.

### 3.3. Multi-interval instruments

3.3.1. Instruments with one weighing range may have several partial weighing ranges where every partial weighing ranges have their scale intervals (multi interval instruments).

Multi-interval instruments shall not be equipped with an auxiliary indicating device.

3.3.2. Each partial weighing range (i) of multi-interval instruments is defined by:

—its verification scale interval  $e_i$  where is  $e_{(i+1)} > e_i$

—its maximum capacity  $Max_i$  where is  $Max_r = Max$

—its minimum capacity  $Min_i$  vwhere is  $Min_i = Max_{(i-1)}$  and  $Min_i = Min$

where:

$i = 1, 2, \dots, r,$

$i =$  partial weighing range number,

$r =$  the total number of partial weighing ranges.

All capacities are capacities of net load, irrespective of the value of any tare used.

3.3.3. The partial weighing ranges are classified according to Table 2. All partial weighing ranges shall fall into the same accuracy class, that class being the instrument's accuracy class.

Table 2: Non-automatic weighing instruments with multiple weighing ranges

Class accuracy	Verification scale intervals (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value (*) $n = Max_i/e_{(i+1)}$	Maximum value $n = Max_i/e_i$



I	$0,001 \text{ g} \leq e_i$ $0,001 \text{ g} \leq e_i \leq 0,05 \text{ g}$	$100 e_i$	50 000	-
II	$0,1 \text{ g} \leq e_i$	$20 e_i$ $50 e_i$	5 000 5 000	100 000 100 000
III	$0,1 \text{ g} \leq e_i$	$20 e_i$	500	10 000
IIII	$5 \text{ g} \leq e_i$	$10 e_i$	50	1 000
( *) For $i = r$ will be used applicable column of Table 1 and $e$ will be re putted with $e_r$				

$i = 1, 2, \dots r$

$i$  = partial weighing range number

$r$  = total number of partial weighing ranges

#### 4. Accuracy

4.1. On implementation of the procedures laid down in Article 8 of this Rulebook, the error of indication shall not exceed the maximum permissible error of indication as shown in Table 3. In case of digital indication the error of indication shall be corrected for the rounding error.

The maximum permissible errors apply to the net value and tare value for all possible loads, excluding preset tare values.

Table 3: Maximum permissible errors

Load				Maximum permissible error
Class I	Class II	Class III	Class IIII	
$0 \leq m \leq 50\,000 e$	$0 \leq m \leq 5\,000 e$	$0 \leq m \leq 500 e$	$0 \leq m \leq 50 e$	$\pm 0,5 e$
$50\,000 e \leq m \leq 200\,000 e$	$5\,000 e \leq m \leq 20\,000 e$	$500 e \leq m \leq 2\,000 e$	$50 e \leq m \leq 20 e$	$\pm 1 e$
$200\,000 e \leq m$	$20\,000 e \leq m \leq 200\,000 e$	$2\,000 e \leq m \leq 10\,000 e$	$200 e \leq m \leq 1\,000 e$	$\pm 1,5 e$

$m$  - load on the scale expressed in the number of verification scale intervals.

4.2. The maximum permissible errors non-automatic weighing instruments in service are twice the maximum permissible errors fixed in Section 4.1.

5. Weighing results of an instrument shall be repeatable, and shall be reproducible by the other indicating devices used and in accordance with other methods of balancing used.

6. The instrument shall react to small variations in the load.

7. Influence quantities and time

7.1. Instruments of classes II, III and IV, liable to be used in a tilted position, shall be sufficiently insensitive to the degree of tilting that can occur in normal use.

7.2. The instruments shall meet the metrological requirements within the temperature range specified by the manufacturer. The value of this range shall be at least equal to:

- 5 °C for an instrument in class I,
- 15 °C for an instrument in class II,
- 30 °C for an instrument in class III or IV.

In the absence of a manufacturer's specification, the temperature range of – 10 °C to + 40 °C applies.

7.3. Instruments operated from a mains power supply shall meet the metrological requirements under conditions of power supply within the limits of normal fluctuation.

Instruments operated from battery power shall indicate whenever the voltage drops below the minimum required value and shall under those circumstances either continue to function correctly or be automatically put out of service.

7.4. Electronic instruments, except those in class I and in class II if  $e$  is less than 1 g, shall meet the metrological requirements under conditions of high relative humidity at the upper limit of their temperature range.

7.5. Loading an instrument in class II, III or IV for a prolonged period of time shall have a negligible influence on the indication at load or on the zero indication immediately after removal of the load.

7.6. Under other conditions the instruments shall either continue to function correctly or be automatically put out of service.

## **DESIGN AND CONSTRUCTION**

8. General requirements

8.1. Design and construction of the instruments shall be such that the instruments will preserve their metrological qualities when properly used and installed and when used in an environment for which they are intended. The value of the mass must be indicated.

8.2. When exposed to disturbances, electronic instruments shall not display the effects of significant faults, or shall automatically detect and indicate them.

Upon automatic detection of a significant fault, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the fault disappears.

8.3. The requirements of points 8.1 and 8.2 shall be met on a lasting basis during a period of time that is normal in view of the intended use of such instruments.

Digital electronic devices shall always exercise adequate control of the correct operation of the measuring process, of the indicating device, and of all data storage and data transfer.

Upon automatic detection of a significant durability error, electronic instruments shall provide a visual or audible alarm that shall continue until the user takes corrective action or the error disappears.

8.4. When external equipment is connected to an electronic instrument through an appropriate interface the metrological qualities of the instrument shall not be adversely influenced.

8.5. The instruments shall have no characteristics likely to facilitate fraudulent use, whereas possibilities for unintentional misuse shall be minimal. Components that may not be dismantled or adjusted by the user shall be secured against such actions.

#### 9. Indication of weighing results and other weight values

The indication of the weighing results and other weight values shall be accurate, unambiguous and non-misleading and the indicating device shall permit easy reading of the indication under normal conditions of use.

The names and symbols of the units referred to in point 1 of this Annex shall comply with the provisions of metrological requirements, with the addition of the symbol for the metric carat which shall be the symbol "ct".

Indication shall be impossible above the maximum capacity (Max), increased by 9 e.

An auxiliary indicating device is permitted only to the right of the decimal mark. An extended indicating device may be used only temporarily, and printing shall be inhibited during its functioning.

Secondary indications may be shown, provided that they cannot be mistaken for primary indications.

#### 10. Printing of weighing results and other weight values

Printed results shall be correct, suitably identified and unambiguous. The printing shall be clear, legible, non-erasable and durable.

#### 11. Leveling

When appropriate, instruments shall be fitted with a leveling device and a level indicator, sufficiently sensitive to allow proper installation.

#### 12. Zeroing

Instruments may be equipped with zeroing devices. The operation of these devices shall result in accurate zeroing and shall not cause incorrect measuring results.

### 13. Tare devices and preset tare devices

The instruments may have one or more tare devices and a preset tare device. The operation of the tare devices shall result in accurate zeroing and shall ensure correct net weighing. The operation of the preset tare device shall ensure correct determination of the calculated net value.

14. Instruments for direct sales to the public, with a maximum capacity not greater than 100 kg, additional requirements:

Instruments for direct sale to the public shall show all essential information about the weighing operation and, in the case of price-indicating instruments, shall clearly show the customer the price calculation of the product to be purchased.

The price to pay, if indicated, shall be accurate.

Price-computing instruments shall display the essential indications long enough for the customer to read them properly.

Price-computing instruments may perform functions other than per-article weighing and price computation only if all indications related to all transactions are printed clearly and unambiguously and are conveniently arranged on a ticket or label for the customer.

Instruments shall bear no characteristics that can cause, directly or indirectly, indications the interpretation of which is not easy or straightforward.

Instruments shall safeguard customers against incorrect sales transactions due to their malfunctioning.

Auxiliary indicating devices and extended indicating devices are not permitted.

Supplementary devices are permitted only if they cannot lead to fraudulent use.

Instruments similar to those normally used for direct sales to the public which do not satisfy the requirements of this Section must carry near to the display the indelible marking "Not to be used for direct sale to the public".

### 15. Price labeling instruments

Price labeling instruments shall meet the requirements of price indicating instruments for direct sale to the public, as far as applicable to the instrument in question. The printing of a price label shall be impossible below a minimum capacity.

## **ANNEX II**

### **CONFORMITY ASSESSMENT PROCEDURES**

#### 1. EU type-examination

1.1. EU type-examination is the procedure whereby a notified body verifies and certifies that an instrument, representative of the production envisaged, meets the requirements of this Rulebook that apply to it.

1.2. The application for EU type-examination shall be lodged with a single notified body by the manufacturer or his authorized representative established.

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,
  - a written declaration that the application has not been lodged with any other notified body,
  - the design documentation, as described in Annex III.
- The applicant shall place at the disposal of the notified body an instrument, representative of the production envisaged, hereinafter the "type".

1.3. The notified body shall:

- 1.3.1. examine the design documentation and verify that the type has been manufactured in accordance with that documentation;
- 1.3.2. agree with the applicant on the location where the examinations and/or tests shall be carried out;
- 1.3.3. perform or have performed the appropriate examinations and/or tests to check whether the solutions adopted by the manufacturer meet the essential requirements where the harmonized standards referred to in Article 9 have not been applied;
- 1.3.4. perform or have performed the appropriate examinations and/or tests to check whether, where the manufacturer has chosen to apply the relevant standards, these standards have been applied effectively, thereby assuring conformity with the essential requirements.

1.4. Where the type complies with the provisions of this Rulebook, the notified body shall issue an EU type-approval certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions (if any) for its validity, the necessary data for identification of the approved instrument and, if relevant, a description of its functioning. All the relevant technical elements such as drawings and layouts shall be annexed to the EU type-approval certificate.

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

In the event of fundamental changes to the design of the instrument, e.g. as a result of the application of new techniques, the validity of the certificate may be limited to two years and extended by three years.

1.5. Each notified body shall periodically make available to all states in which is implemented 2009/23/EC Directive the list of:

- requirements received for EU type-examination,
- EU type-approval certificates issued,
- requirements for type-certificates refused,
- additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the states forthwith of withdrawals of EU type-approval certificates.

Each state in which is implemented 2009/23/EC Directive shall make this information available to the bodies which it has notified.

1.6. The other notified bodies may receive a copy of the certificates together with the annexes to them.

1.7. The applicant shall keep the notified body that has issued the EU type-approval certificate informed of any modification to the approved type.

Modifications to the approved type must receive additional approval from the notified body that issued the EU type-approval certificate where such changes influence conformity with the essential requirements of this Rulebook or the prescribed conditions for use of the instrument. This additional approval is given in the form of an addition to the original EU type-approval certificate.

## 2. EU declaration of type conformity (guarantee of production quality)

2.1. The EU declaration of type conformity (guarantee of production quality) is the procedure whereby the manufacturer who satisfies the obligations of point 2.2 declares that the instruments concerned are, where applicable, in conformity with the type as described in the EU type-approval certificate and that they satisfy the requirements of this Rulebook.

The manufacturer or his authorized representative shall affix the "CE" conformity marking to each instrument and the inscriptions provided for in Annex IV and shall draw up a written declaration of conformity.

The "CE" conformity marking shall be accompanied by the identification number of the notified body responsible for the EU surveillance referred to in point 2.4.

2.2. The manufacturer shall have adequately implemented a quality system as specified in point 2.3 and shall be subject to EU surveillance as specified in point 2.4.

2.3.1. The manufacturer shall lodge an application for approval of his quality system with a notified body.

The application shall include:

- an undertaking to carry out the obligations arising from the approved quality system,
- an undertaking to maintain the approved quality system to ensure its continuing suitability and effectiveness.

The manufacturer shall make available to the notified body all relevant information, in particular the quality system's documentation and the design documentation of the instrument.

2.3.2. The quality system shall ensure conformity of the instruments with the type as described in the EU type-approval certificate and with the requirement(s) 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 rules, procedures and instructions. This quality system documentation shall ensure a proper understanding of the quality programs, plans, manuals and records.

It shall contain in particular an adequate description of:

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

- the manufacturing process, the quality control and assurance techniques and the systematic measures that will be used,
- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
- the means to monitor the achievement of the required product quality and the effective operation of the quality system.

2.3.3. The notified body shall examine and evaluate the quality system to determine whether it satisfies the requirements referred to in point 2.3.2. It shall presume conformity with these requirements in respect of quality systems that implement the corresponding harmonized standard.

It shall notify its decision to the manufacturer and inform the other notified bodies thereof. The notification to the manufacturer shall contain the conclusions of the examination and, in the event of refusal, the justification for the decision.

2.3.4. The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any updating of the quality assurance system in relation to changes brought about by, e.g. new technologies and new quality concepts.

2.3.5. Any notified body that withdraws approval of a quality system shall so inform the other notified bodies.

#### 2.4. EU surveillance

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

2.4.2. The manufacturer shall grant the notified body access for EU inspection purposes to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the design documentation,
- the quality records, e.g. the inspection reports and tests and calibration data, reports on the qualifications of the personnel concerned, etc.

The notified body shall periodically carry out audits in order to ensure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report.

In addition, the notified body may carry out unscheduled visits to the manufacturer. During such visits, the notified body may carry out full or partial audits. It shall provide the manufacturer with a report on the visit, and, where appropriate, an audit report.

2.4.3. The notified body shall ensure that the manufacturer maintains and applies the approved quality system.

### 3. EU verification

3.1. EU verification is the procedure whereby the manufacturer or his authorized representative and declares that the instruments which have been checked in accordance with point 3.3 are, where applicable, in conformity with the type described in the EU type-examination certificate and that they satisfy the requirements of this Rulebook.

3.2. The manufacturer shall take all necessary measures in order that the manufacturing process ensures conformity of the instruments, where applicable, with the type as described in the EU type-examination certificate and with the requirements of this Rulebook which apply to them. The manufacturer or his authorized representative shall affix the EU conformity marking to each instrument and draw up a written declaration of conformity.

3.3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of this Rulebook by examination and testing of every instrument, as specified in point 3.5.

3.4. For instruments not subject to EU type-approval, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body should the latter so request.

3.5. Verification by checking and testing of each instrument

3.5.1. All instruments shall be individually examined and appropriate tests, as set out in the relevant harmonized standards referred to in Article 7, or equivalent tests, shall be carried out in order to verify their conformity, where applicable, with the type as described in the EU type-examination certificate and the requirements of this Rulebook.

3.5.2. The notified body shall affix, or cause to be affixed, its identification number on each instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity relating to the tests carried out.

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

4. EU unit verification

4.1. EU unit verification is the procedure whereby the manufacturer or his authorized representative ensures and declares that the instrument, generally designed for a specific application, which has been issued with the certificate referred to in point 4.2 conforms to the requirements of this Rulebook that apply to it. The manufacturer or his authorized representative shall affix the "CE" conformity marking to the instrument and shall draw up a written declaration of conformity.

4.2. The notified body shall examine the instrument and carry out the appropriate tests, as set out in the relevant harmonized standard(s) referred to in Article 9, or equivalent tests, in order to ensure its conformity with the relevant requirements of this Rulebook.

The notified body shall affix, or cause to be affixed, its identification number to the instrument the conformity of which to requirements has been established, and shall draw up a written certificate of conformity concerning the tests carried out.

4.3. The aim of the technical documentation relating to the design of the instrument, as referred to in Annex III, is to enable conformity with the requirements of this Rulebook to be assessed and the design, manufacture and operation of the instrument to be understood. It must be accessible to the notified body.

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

5. Common provisions



5.1. The EU declaration of type conformity (guarantee of production quality), the EU verification, and the EU unit verification may be carried out at the manufacturer's works or any other location if transport to the place of use does not require dismantling of the instrument, if the putting into service at the place of use does not require assembly of the instrument or other technical installation work likely to affect the instrument's performance, and if the gravity value at the place of putting into service is taken into consideration or if the instrument's performance is insensitive to gravity variations. In all other cases, they shall be carried out at the place of use of the instrument.

5.2. If the instrument's performance is sensitive to gravity variations the procedures referred to in point 5.1 may be carried out in two stages, with the second stage comprising all examinations and tests of which the outcome is gravity-dependent, and the first stage all other examinations and tests. The second stage shall be carried out at the place of use of the instrument.

5.2.1. Where a manufacturer has opted for execution in two stages of one of the procedures mentioned in point 5.1, and where these two stages will be carried out by different parties, an instrument which has undergone the first stage of the procedure shall bear the identification number of the notified body involved in that stage.

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

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

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

5.2.3. A manufacturer who has opted for the declaration of type conformity (guarantee of production quality) in the first stage may either use this same procedure in the second stage or decide to continue in the second stage with the verification.

5.2.4. The "CE" conformity marking shall be affixed to the instrument on completion of the second stage, along with the identification number of the notified body which took part in the second stage.

## **ANNEX III**

### **TECHNICAL DOCUMENTATION**

The technical documentation must render the design, manufacture and operation of the product intelligible and enable an assessment to be made of its conformity with the requirements of this Rulebook.

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

- a general description of the type,
- conceptual designs and manufacturing drawings and plans of components, sub-assemblies, circuits, etc.
- descriptions and explanations necessary for the understanding of the above, including the operation of the instrument,

- a list of the harmonized standards referred to in Article 9, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements where the harmonized standards referred to in Article 8 have not been applied,
- results of design calculations made and of examinations, etc.
- test reports,
- the EU type-approval certificates and the results of relevant tests on instruments containing parts identical to those in the design.

## ANNEX IV

### **"CE" CONFORMITY MARKING AND INSCRIPTIONS**

1. Instruments subject to the conformity assessment procedure must bear:

1) the "CE" conformity marking comprising the "CE" symbol and the identification number(s) of the notified body/bodies that has/have carried out the EU surveillance or the EU verification.

The above mentioned marking and inscriptions shall be affixed to the instrument and distinctly grouped together;

2) a green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter "M" printed in black;

3) the following inscriptions:

- the number of the type-approval certificate, where appropriate,
- the manufacturer's mark or name,
- the accuracy class, enclosed in an oval or in two horizontal lines joined by two half circles,
- maximum capacity, in the form Max ...,
- minimum capacity, in the form Min ...,
- verification scale interval, in the form  $e = \dots$ ,
- the last two digits of the year in which the "CE" conformity marking was affixed, plus, when applicable:
  - serial number,
  - for instruments consisting of separate but associated units: identification mark on each unit,
  - scale interval if it is different from  $e$ , in the form  $d = \dots$ ,
  - maximum additive tare effect, in the form  $T = + \dots$ ,
  - maximum subtractive tare effect if it is different from Max, in the form  $T = - \dots$ ,
  - tare interval if it is different from  $d$ , in the form  $d_T = \dots$ ,
  - maximum safe load if it is different from Max, in the form Lim ...,
  - the special temperature limits, in the form ... °C/... °C,
  - ratio between load receptor and load.

The instruments shall have adequate facilities for the affixing of the "CE" conformity marking and/or inscriptions. These shall be such that it shall be impossible to remove the marking and inscriptions without damaging them, and that the marking and inscriptions shall be visible when the instrument is in its regular operating position.

Where a data plate is used it shall be possible to seal the plate unless it cannot be removed without being destroyed. If the data plate is sealable it shall be possible to apply a control mark to it.

The inscriptions Max, Min, e, and d, shall also be shown near the display of the result if they are not already located there.

Each load measuring device which is connected or can be connected to one or more load receptors shall bear the relevant inscriptions relating to the said load receptors.

## 2. Other instruments

The other instruments must bear:

- the manufacturer's mark or name,
- maximum capacity, in the form Max ....

Those instruments may not bear the stickers provided for in point 1.1(b) of this Annex.

## 3. Restrictive use symbol specified in Article 10

That symbol shall be constituted by a capital letter "M" printed in black on a red background at least 25 mm × 25 mm square with two intersecting diagonals forming a cross.

