

Having regard to the article 20b paragraph 3 and article 17 of the Law on metrology (Official Gazette of the Republic of Macedonia No. 55/2002, 84/2007 and 120/2009), Minister of Economy adopted

RULEBOOK FOR THE PROCEDURES OF CONFORMITY ASSESSMENT OF NON-AUTOMATIC MEASURING INSTRUMENTS

CHAPTER I

COMMON PROVISIONS

Article 1

This Rulebook lays down the procedures of conformity assessment of non-automatic measuring instruments (hereinafter “instrument”) with the essential requirements, as well as their implementation in the process of conformity assessment, which should be met by the instruments before their placing on the market and putting in use.

Article 2

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

1. ‘Weighing instrument’ is a measuring instrument serving to determine the mass of a body by using the action of gravity on that body. A weighing instrument may also serve to determine other mass-related magnitudes, quantities, parameters or characteristics related to the mass.
2. ‘Non-automatic weighing instrument’ is a weighing instrument requiring the intervention of an operator during weighing.

Article 3

Only Non-automatic weighing instruments that meet the requirements of this Rulebook may be placed on the market.

Non- automatic weighing instruments can be placed on the market and put into use only if they meet the requirements of this rulebook and accordingly bear the ‘CE’ conformity marking, provided for in the Law on metrology and this rulebook as well.

Article 4

For the purposes of conformity assessment procedure, the following categories of use of non-automatic weighing instruments shall be distinguished:

1. determination of mass for commercial transactions;
2. determination of mass for the calculation of a toll, tariff, tax, bonus, penalty, remuneration, indemnity or similar type of payment;

3. determination of mass for the application of laws or regulations or for an expert opinion given in court proceedings
4. determination of mass in the practice of medicine for weighing patients for the purposes of monitoring, diagnosis and medical treatment;
5. determination of mass 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 prepackages;
7. all applications other than those listed in point 1, 2, 3, 4, 5 and 6 in this Article.

Article 5

Essential requirements that should be met by the non-automatic weighing instruments, used for the purposes listed in Article 4 of this Rulebook, are given in Annex 1 which is an integral part of this Rulebook.

In cases where non-automatic weighing instrument includes or is connected with devices not intended for use for the applications listed in Article 4 of this Rulebook, such devices are not subject to the essential requirements established by this Regulation.

Article 6

Non-automatic weighing instruments shall be considered to meet the essential requirements set out in Annex I in this rulebook, if they are projected and constructed in accordance to the harmonized standards.

Bibliographic data of the harmonized standards for non – automatic weighing instruments are published in the Official gazette of Republic of Macedonia.

Article 7

When put into use non automatic weighing instruments bearing the ‘CE’ conformity marking, if do not meet the requirements of this rulebook, those instruments shall be withdrawn from the market.

In such measure, the Ministry of economy shall be immediately informed, indicating the reasons for its decision and in particular whether non-compliance is due to:

- a) Failure to meet the essential requirements set out in Annex I, where instruments do not meet the harmonized standards referred to in Article 6 paragraph (1) of this rulebook;
- b) Incorrect application of the harmonized standards referred to in Article 6 paragraph (1) of this rulebook;
- c) Shortcomings in the technical specifications of the harmonized standards referred to in Article 6 paragraph (1) of this rulebook.

CHAPTER 2

CONFORMITY ASSESSMENT PROCEDURE

Article 8

The conformity of NAWI to the essential requirements set out in Annex I may be certified by either of the following procedures as selected by the applicant:

- (a) EC type examination as referred to in Annex II, point 1, followed either by the EC declaration of type conformity, based on the guarantee of production quality as referred to in Annex II, point 2, or by the EC verification as referred to in Annex II, point 3.

EC type examination shall not be compulsory for NAWI which do not use electronic devices and the load-measuring device of which does not use a spring to balance the load;

- (b) EC unit verification as referred to in Annex II, point 4 in this rulebook.

The conformity assessment procedure includes examination whether the technical documentation is prepared in accordance to the requirements referred to in Annex 3 of this rulebook.

The documents and correspondence relating to the procedures referred to in paragraph 1 shall be drafted by the producer or his representative in the official language of the country where the procedure is performed or in the language which is acceptable by the notified body.

Where the NAWI are subject to fulfillment of other requirements, the 'CE' conformity marking, referred to in Article 10 of this rulebook shall indicate that the non-automatic weighing instruments in question are also presumed to conform to those requirements.

The conformity assessment procedures are laid down in the Annex 2 in this rulebook.

CHAPTER 3 'CE' CONFORMITY MARKING AND INSCRIPTIONS

Article 9

The conformity assessment procedure of NAWI includes assessment whether the 'CE' conformity marking and the required supplementary data as described in Annex IV, point 1, are affixed in a clearly visible, easily legible and indelible form to instruments for which EC conformity has been established.

The inscriptions referred to in Annex IV, point 2, shall be affixed in a clearly visible, easily legible and indelible form to all other instruments.

Any other marking that can be affixed to the instrument shall not reduce visibility and legibility of the 'CE' conformity marking.

Article 10

In case where the 'CE' conformity marking has been affixed unduly, the manufacturer or his authorized representative shall be obliged to make the instrument conform as regards the provisions of this rulebook, concerning the 'CE' conformity marking.

Article 11

Where an instrument which is used for any of the applications referred to in Article 4 of this rulebook, 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 as laid down in Annex IV, point 3. That symbol shall be affixed to the devices in a clearly visible and indelible form.

IV. TRANSITIONAL AND FINAL PROVISIONS

Article 12

All non-automatic weighing instruments that are already in use by the day of entering into force of this rulebook, shall be verified only if they meet the requirement of maximum permissible error referred to in Annex I, table 3 of this rulebook.

Non-automatic weighing instruments, which until the day of entering into force have document for type approval, can be placed on the market and put into use, in accordance to the provisions of this rulebook until the day of expiring the validity of the document for the type approval of the instrument.

Article 13

Until the date of notification of the Bureau of metrology or any other body, the conformity of the non-automatic weighing instruments shall be certified in accordance to the provisions of the Rulebook for metrological requirements for NAWI with accuracy classes (I), (II), (III), (III) (Official Gazette of SFRJ No. 4/87) and with the procedure for conformity assessment referred to in OIML R76-1.

Article 14

Until the date of notification of the Bureau of metrology or any other body, the procedures of conformity assessment referred to in Annex 2, shall be applied.

Article 15

The provisions laid down in the article 9 paragraph 2 of this rulebook, shall be applied from the date of accession of the Republic of Macedonia in the European Union or signing the ACCA agreement for NAWI.

Article 16

From the date of notification of the Bureau of metrology or any other body, the following rulebooks will be repealed: Rulebook for metrological requirements for NAWI with accuracy classes (I), (II), (III), (III) (Official Gazette of SFRJ No. 4/87), Rulebook for road and rail weighing instruments (Official Gazette of SFRJ No. 31/87), Rulebook for cases for road and rail weighing instruments (Official Gazette of SFRJ No. 31/87)

Article 17

From the date of entering into force of this rulebook, the Rulebook on NAWI (Official Gazette of Republic of Macedonia No. 56/07) shall be considered as repealed.

Article 18

This rulebook enters into force on the eight day after its publishing into “Official Gazette of Republic of Macedonia”.

ANNEX I

ESSENTIAL REQUIREMENTS

Essential requirements which should be met by NAWI specified in Article 2 paragraph 2 of this rulebook are given in the text below.

The terminology used is that of the International Organisation of Legal Metrology.

Preliminary observation

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

1. Units of mass

The units of mass used shall be the legal units referred to in Rulebook for the definitions, terms, symbols and scope of application, commitment for the use and manner of writing of legal measuring units (Official Gazette of Republic of Macedonia No. 104/ 2007)

Subject to compliance with this condition, the following units are permitted:

— SI units: kilogram, microgram, milligram, gram, tone

— other non-SI unit: metric carat, if weighing precious stones.

For instruments that make use of the imperial unit of mass referred to above, the relevant essential requirements specified below shall be converted to that unit, using simple interpolation.

2. Accuracy classes

2.1. The following accuracy classes have been defined:

I special

II high

III medium

IIII ordinary

The specifications of these classes are given in Table 1.

Table 1

Accuracy classes					
Class	Verification scale interval (e)		Minimum capacity (Min)	Number of verification scale intervals $n = \frac{\text{Max}}{e}$	
			minimum value	minimum value	maximum value
I	0,001	$g \leq e$	100 e	50 000	—
II	0,001	$g \leq e \leq 0,05 \text{ g}$	20 e	100	100 000
	0,1	$g \leq e$	50 e	5 000	100 000
III	0,1	$g \leq e \leq 2 \text{ g}$	20 e	100	10 000
	5	$g \leq e$	20 e	500	10 000
IIII	5	$g \leq e$	10 e	100	1 000

The minimum capacity is reduced to 5 e for instruments in classes II and III for determining a conveying tariff

2.2. Scale intervals

2.2.1. The actual scale interval (d) and the verification scale interval (e) shall be in the form:

$1 \times 10 \text{ k}$, $2 \times 10 \text{ k}$, or $5 \times 10 \text{ k}$ mass units,

k 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:

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

$d < e \leq 10 d$,

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

3. Classification

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 for these two classes are obtained from Table 1 by replacement in column 3 of the verification scale interval (e) by the actual scale interval (d).

If $d < 10 - 4$ g, the maximum capacity of class I may be less than 50 000 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 (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 with $e_{(i+1)} > e_i$

— its maximum capacity Max_i

with $Max_r = Max$

— its minimum capacity Min_i

with $Min_i = Max_{(i-1)}$ and $Min_1 = Min$

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

Multi-interval instruments

Class	Verification scale interval (e)	Minimum capacity (Min)	Number of verification scale intervals	
		Minimum value	Minimum value ⁽¹⁾ $n = \frac{Max_i}{e_{(i+1)}}$	Maximum value $n = \frac{Max_i}{e_i}$
I	0,001 g $\leq e_i$	100 e ₁	50 000	—
II	0,001 g $\leq e_i \leq 0,05$ g	20 e ₁	5 000	100 000
	0,1 g $\leq e_i$	50 e ₁	5 000	100 000
III	0,1 g $\leq e_i$	20 e ₁	500	10 000
IIII	5 g $\leq e_i$	10 e ₁	50	1 000

⁽¹⁾ For $i = r$, the corresponding column of Table 1 applies, with e replaced by e_r .

4. Accuracy

4.1. On implementation of the procedures laid down in Article 9, 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 III	
$0 \leq m \leq 50\,000\ e$	$0 \leq m \leq 5\,000\ e$	$0 \leq m \leq 500\ e$	$0 \leq m \leq 50\ e$	$\pm 0,5\ e$
$50\,000\ e < m \leq 200\,000\ e$	$5\,000\ e < m \leq 20\,000\ e$	$500\ e < m \leq 2\,000\ e$	$50\ e < m \leq 200\ e$	$\pm 1,0\ e$
$200\,000\ e < m$	$20\,000\ e < m \leq 100\,000\ e$	$2\,000\ e < m \leq 10\,000\ e$	$200\ e < m \leq 1\,000\ e$	$\pm 1,5\ e$

4.2. The maximum permissible errors 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.

The weighing results shall be sufficiently insensitive to changes in the position of the load on the load receptor.

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

7. Influence quantities and time

7.1. Instruments of classes II, III and IIII, 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 IIII.

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 IIII 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 non-automatic weighing 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.

8.6. NAW Instruments shall be designed to permit ready execution of the statutory controls laid down by this Rulebook.

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 the Rulebook for the definitions, terms, symbols and scope of application, commitment for the use and manner of writing of legal measuring units 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. Levelling

When appropriate, instruments shall be fitted with a levelling 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. EC type-examination

1.1. EC 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

1.2. The application for EC type-examination shall be lodged with a single notified body by the manufacturer or his authorized representative established within the Community. 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 6 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 EC 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 EC 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 case 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 Member States the list of: — applications received for EC type-examination,

- EC type-approval certificates issued,
- Applications for type-certificates refused,
- Additions and amendments relating to documents already issued.

Each notified body shall moreover inform all the Member States forthwith of withdrawals of EC type-approval certificates.

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 EC 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 EC 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 EC type-approval certificate.

2. EC declaration of type conformity (guarantee of production quality)

2.1. The EC 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 EC type-approval certificate and that they satisfy the requirements of this Rulebook.

The manufacturer or his authorized representative established within the Community 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 EC 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 EC surveillance as specified in point 2.4.

2.3. Quality system

2.3.1. The manufacturer shall submit 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 EC type-approval certificate and with the 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 rules, procedures and instructions. This quality system documentation shall ensure a proper understanding of the quality programmes, plans, manuals and records.

It shall contain in particular an adequate description of:

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

2.4.1. The purpose of EC 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 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. EC verification

3.1. EC verification is the procedure whereby the notified body shall carry out the control in order to check the conformity with the type described in the EC type-examination certificate and that they satisfy the requirements of this rulebook. Notified body affixes the conformity marking to each instrument.

3.2. Each instrument shall be individually examined and appropriate tests, as set out in the relevant harmonized standards referred to in Article 6, or equivalent tests, shall be carried out in order to verify their conformity with the essential requirements of this rulebook.

3.3. 'CE' conformity marking from 3.1 of this Annex shall be accompanied with marking for identification of the notified body.

3.4. For instruments not subject to EC type-approval, the documents relating to the design of the instrument, as set out in Annex III, must be accessible to the notified body, as long as it is required.

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 6, or equivalent tests, shall be carried out in order to verify their conformity, where applicable, with the type as described in the EC 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. EC unit verification

4.1. EC unit verification is the procedure whereby the notified body examines and declares that the instrument, projected for particular purpose, meets the requirements of this rulebook. Notified body affixes the CE conformity marking to the instrument.

4.2. The instrument is examined and the appropriate tests carried out, as set out in the relevant harmonized standard(s) referred to in Article 6, or equivalent tests, in order to ensure its conformity with the relevant requirements of this Rulebook.

4.3 'CE' conformity marking from 3.1 of this Annex shall be accompanied with marking for identification of the notified body.

4.4. The technical documentation relating to the design of the instrument, as referred to in Annex III, must be accessible to the notified body.

5. Common provisions

5.1. The EC declaration of type conformity, based on the guarantee of production quality, the EC verification, and the EC unit verification may be carried out at the manufacturer's premises 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. If the gravity zones are established on the territory of Republic of Macedonia, the expression 'at the place of use of the instrument' may be read as 'in the gravity zone 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.

5.2.3. A manufacturer who has opted for the EC declaration of type conformity based on the 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 EC 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

DESIGN - 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 6, 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 6 have not been applied,
- results of design calculations made and of examinations, etc.,
- test reports,
- the EC 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 EC conformity assessment procedure

1.1. These instruments must bear:

- (a) — the ‘CE’ conformity marking comprising the ‘CE’ symbol as described in Annex VI,
 - the identification number(s) of the notified body/bodies that has/have carried out the EC surveillance or the EC verification.

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

- (b) a green sticker at least 12,5 mm × 12,5 mm square bearing a capital letter ‘M’ printed in black;

(c) the following inscriptions:

- the number of the EC 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.

1.2. 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.

1.3. 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.

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

1.5. 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 11

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.

ANNEX V

The minimum criteria to be applied when designating bodies for the carrying-out of tasks pertaining to the procedures referred to in article 9

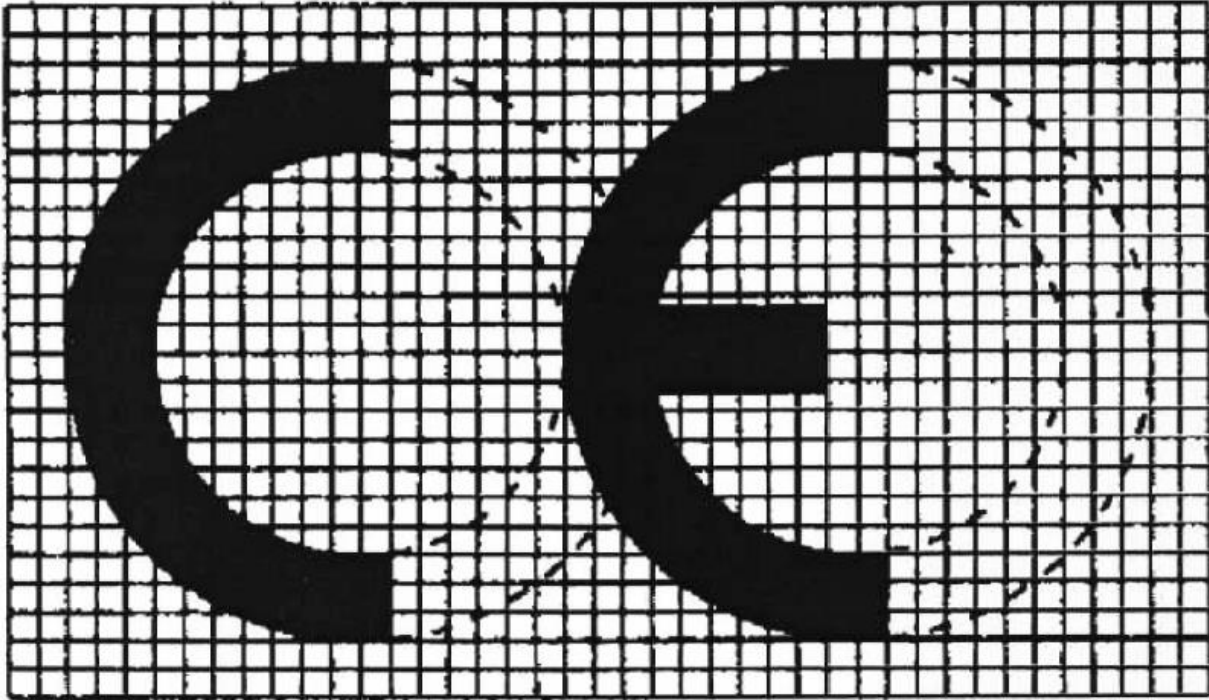
1. The bodies shall have at their disposal the necessary personnel, means and equipment.
2. The personnel of the bodies shall have technical competence and professional integrity.
3. The bodies shall work independently of all circles, groups or persons having a direct or indirect interest in non-automatic weighing instruments as regards the carrying-out of the tests, the preparation of the reports, the issuing of the certificates and the surveillance required by the Law on metrology and this Rulebook.
4. The personnel of the bodies shall respect professional confidentiality.
5. The bodies shall take out civil liability insurance if their civil liability is not covered by the State under national law.

The fulfillment of the conditions under points 1 and 2 of this Annex shall be periodically verified by the Ministry in charge.

ANNEX VI

'CE' CONFORMITY MARKING

The 'CE' conformity marking shall consist of the initials 'CE' taking the following form:



If the 'CE' conformity marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The various components of the 'CE' conformity marking must have substantially the same vertical dimension, which may not be less than 5 mm.