

# REPUBLIC OF MACEDONIA

## LAW ON METROLOGY

### I. COMMON PROVISIONS

#### Article 1

This Law regulates: the metrological system in the Republic of Macedonia; the competencies of the Bureau for Metrology; legal measurement units; measurement standards; reference materials; placing on the market and use of measuring instruments; conformity assessment of type (pattern) of the measuring instruments; conformity assessment of the measuring instruments and the essential requirements; verification of measuring instruments; validity of the markings and the certificates for the conformity assessment of the type of measuring instruments and markings and seals or certificates for verification of foreign measuring instruments; metrological supervision of quantities and markings on quantities on pre-packages; supervision of the implementation of this Law, and other issues of importance to the metrological system for the purpose of ensuring measurement unity in the Republic of Macedonia and uniformity with the world.

#### Article 2

Specific terms used in this Law have the following meaning:

1. **Metrology** means the science for measurement;
2. **Measurement unit** means particular quantity, defined and adopted by a convention and having a numerical value equal to one (1);
3. **Legal measurement unit** means a unit of measurement, which usage is imposed and permitted by this Law;
4. **Measurement standard** (hereinafter: referred to as: standard) means a material measure, measuring instrument or measuring system intended to define, realize, conserve or reproduce a unit or one or more values of quantity to serve as reference;
5. **National measurement standard** means a reference measurement standard recognized by a decision of the Bureau to serve, in the Republic of Macedonia, as the basis for assigning values to other standards of the same quantity;
6. **Reference measurement standard** means a measurement standard, basically having the highest metrological quality and available at a given location or in a given organization, and used as the basis for measuring at a location or organisation respectfully;
7. **Calibration** means set of operations that, in specific circumstances, establish a relationship between values of quantities indicated by measuring instruments or measuring system, or values represented by a material measure or by reference material, and the corresponding values realized by measurement standards;
8. **Traceability** means a characteristic, which purpose is to relate measurements or measurement standards' results to laid down references, usually to national or international standards, through an unbroken chain of comparisons all having stated uncertainties;
9. **Reference material** means material or substance, for which features regarding physical characteristics or chemical composition are well enough determined to

- be used for the calibration of measurement standards and measuring instruments or for the assessment of a measurement method;
10. **Certified reference material** means reference material, accompanied by a certificate, for which features of physical characteristics or chemical composition, traceability is established with measurement units in which features are expressed of physical characteristics or chemical composition and for which the uncertainty of measurement is defined;
  11. **Measuring instrument** means a device or system, intended for measuring, either independently or together with other devices;
  12. **Category of measuring instruments** means measuring instruments that measure the same physical quantity;
  13. **Kind of measuring instruments** means measuring instruments for measurement of the same physical quantity on the same or similar principles;
  14. **Type (pattern) of measuring instruments** are measuring instruments of the same manufacturer, which have similar characteristics with respect to their purpose, use, principles of construction, shape, components, materials and metrological characteristics, and can differ in regards to the range of measurement and nominal values;
  15. **Verification** means a set of procedures performed by the Bureau for Metrology or a legal entity designated by the Minister of Economy, for the purpose of establishing and certifying that the measuring instrument is in conformity with the laid down metrological criteria for verification. The verification includes legal metrological control and sealing, i.e. issuing of verification certificate;
  16. **Metrological supervision** on quantities and markings of the quantities on the pre packages means metrological examination on quantities, manner of marking of quantities and permissible deviation of quantities and list of nominal quantities of pre-packages, regarding this Law and regulations adopted in accordance to this Law.
  17. **Sealing** means a set of procedures for the purpose of marking the measuring instrument to certify that the measuring instrument meets the regulations and other verification acts. Certain parts of the measuring instrument that may affect metrological characteristics are sealed for protection of any modification or manipulation after the verification;
  18. **Pre-packages** are the products in solid, liquid or gas condition in tested packaging, which are packed in absence of the consumer and which quantitative contents can not be changed without opening or changing the packaging. Liquids can be packed in bottles made from glass or other material with the same stability and hardness, as those which are used as measuring containers;
  19. **Manufacturer** means a person or legal entity which is responsible for the conformity of the measuring instrument to the articles of this Law and regulations adopted from this Law, while placing the measuring instrument on the market under its own name, or while putting in use for own purposes.
  20. **Authorized representative** means any person or legal entity which is registered in Republic of Macedonia or European Union and is authorized in written form by the manufacturer, to represent, as well as to act on behalf of his own name and on his interest when accomplishing certain tasks in accordance with this Law and regulations adopted from this Law.
  21. **Placing on the market** means an activity performed when a measuring instrument, intended for an end user, for the first time becomes available in Republic of

Macedonia or in European Union, whether with or without paying any compensation.

22. **Putting into use** means the first usage of the measuring instrument, by an end user, in the Republic of Macedonia or European Union, in accordance with its intended usage.
23. **Harmonized standard** means technical specification which is used as a support for fulfilling the essential requirements of the Guidelines of the New approach, and which is adopted by the European committee for standardization (CEN), European Committee for electro technical standardization (CENELEC) or European Institute for standardization in the area of Telecommunications (ETSI) ( hereinafter: European organizations for standardization), two or all of these organizations, on request of the European Commission, and in accordance with the 98/34/EC Directive of the European Parliament and the Council, on June 22, 1988 for establishment of procedure for exchange and giving information in the area of the technical standards and regulations and Rules for services in informatics society, with the amendments of the 98/48/EC Directive and which is prepared according to General Guidelines agreed between the Commission and one or more of the European organizations for standardization.
24. **Normative document** means a document containing technical specifications, adopted by the International Organizations for Legal Metrology (OIML), in accordance with the Directive 2004/22/EEC of the European Parliament and the Council, from March 31 2004, for the measuring instruments ( hereinafter: MI Directive) and procedures laid down in article 16.1 of the MI Directive.
25. **Legal metrological control** means control of the measurement tasks in the field of application of measuring instruments, according to this Law and regulations adopted on the basis of this Law, due to protection of the public interest, public health and public order, protection of the environment, protection of the customers, public taxes collection, as well as fair ( lawfully) trade.
26. **Conformity assessment body** means authorized body to perform services for conformity assessment, therefore it is subject of accreditation.
27. **Conformity marking** means marking which is used or is established in accordance with the regulations of certified system, and shows that particular process, product or service complies with particular standard or technical regulation.

### Article 3

The objective of this Law is to ensure:

- Protection of public interest;
- Protection of public order;
- Protection of human's health
- Protection of environment;
- General technical safety;
- Collecting Taxes and other demands;
- Fair trade.

Due to achievement of the objective referred to in paragraph 1 from this article, traceability for all measuring instruments should be defined and ensured. .

## II. BUREAU OF METROLOGY

### Article 4

For the purpose of performing professional and other duties in the field of metrology defined with this and other Laws, a Bureau of Metrology is established (hereinafter: Bureau), as body of the Ministry of Economy.

The Bureau is a legal entity, managed by a Director.

### Article 5

For the purpose of maintaining and development of the metrological system in the Republic of Macedonia, the Government of the Republic of Macedonia approves Annual Programs upon proposals of the Ministry of Economy.

For the purpose of implementation of the Program referred to in paragraph 1 of this article, the Ministry of Economy shall submit a report to the Government of the Republic of Macedonia at least twice a year.

### Article 6

The Bureau shall carry out duties and tasks in the field of metrological system of the Republic of Macedonia concerning:

- Expert supervision of usage and manner of writing the legal measurement units;
- Ensuring traceability, realization, conservation and maintenance of national measurement standards and certified reference materials;
- Ensuring traceability of the reference measurement standards;
- Calibration of measurement standards and instruments;
- Conformity assessment of measuring instruments with the essential requirements;
- Supervision of the work of legal entities authorized to perform particular activities in the field of metrology, as per this Law;
- Conformity assessment of the type (pattern) of measuring instruments;
- Verification of the measuring instruments;
- Registration procedures for recognition of the time validity of markings and certificates for conformity of the type of measuring instruments, markings and seals, i.e. certificates for verification of foreign measuring instruments;
- Metrological supervision of quantities and markings on quantities of pre-packages;
- Professional supervision of the implementation of this Law and of regulations based on this and other laws;
- Permanent training and education of the employees of the Bureau and of the authorised legal entities;
- Definition of duties and tasks of the Metrological Council and participation in their work;
- Consulting services for the needs of individuals and legal entities who trade with or use measuring instruments;
- Participation in the drafting of the Laws and regulations in the field of the metrology;
- Cooperation with other inspection bodies, and

- Other duties and tasks related to the implementation of this Law and regulations issued in accordance with this Law.

#### **Article 7**

The Bureau shall be a member of and shall represent the Republic of Macedonia in the international and regional organizations in the field of metrology, shall cooperate with them and participate in their work.

#### **Article 7**

Bureau of metrology cooperates with all interested parties for the OIML ( International Organization of Legal Metrology) work, related to the provisions of this Law and regulations adopted in accordance to this Law.

Bureau is the authorized body in Republic of Macedonia for cooperation and information exchange about measuring instruments, with the authorized bodies from the member states of European Union and European Commission.

#### **Article 8**

The Minister of Economy shall found the Metrological Council (hereinafter:: Council), which will act like a professional and advising body to the Bureau in the field of metrology.

The Council shall consist of a President and members, officially designated by the Minister of Economy, by the principle of professional competency and equitable representation of all parties interested in the field of metrology.

The President and members of the Council shall be designated for a period of four years.

The President and members shall be entitled to a certain allowance for their work in the Council, which shall be laid down by the Minister of Economy.

The Council shall submit a report on their activities to the Minister of Economy at least once a year.

#### **Article 9**

The Bureau shall be issuing a Bulletin in which the following shall be published:

- The Certificates for conformity assessment of the type (pattern) of measuring instruments issued in accordance with this Law by the Bureau or authorised legal entities for conformity assessment of type (pattern) of measuring instruments;
- The Certificates issued by the Minister of Economy authorising legal entities to carry out the professional duties as per this Law;
- Bureau's Certificates on recognition of reference measuring standards for national measuring standards;
- The Register (List) of recognition of validity of the markings and certificates for conformity of the type of measuring instruments and markings and seals, i.e. certificates for verification of foreign measuring instruments;
- Professional and scientific articles in the field of metrology;
- Other information in the field of metrology.

### **III. MEASUREMENT UNITS**

#### **Article 10**

In the Republic of Macedonia, Legal Units of Measurement are in use.

The Legal Measurement Units are:

- 1) Units of the International System of Units SI (System Internationale d' Unites) (hereinafter:: SI);
- 2) Decimal multiples and sub-multiples of Units;
- 3) Other Units;
- 4) Compound Units formed by combining the Units from points 1, 2 and 3 of this article.

Use of the Legal Units of Measurement referred to in paragraph 1 of this article is mandatory when using:

- 1) Measuring standards, measuring instruments and reference materials;
- 2) Results of performed measurements; and
- 3) Indication of measurement quantities expressed in measurement units, in the field of humans, animals and plants health and life protection, protection of environment and nature, common technical safety of products, goods and services production and placement on the market, education, standardization, and in judicial and administrative procedures.

#### **Article 11**

The Minister of Economy prescribes the definitions, names and symbols and the field and manner of implementation, obligation of usage and manner of writing the legal units of measurement.

### **IV. MEASUREMENT STANDARDS**

#### **Article 12**

The Bureau shall realize, conserve and maintain the National measurement standards and with calibration or by inter-laboratorial comparison ensure their traceability.

The Bureau may officially recognize any standard that has been realized, conserved and maintained by a legal entity as a National measurement standard.

#### **Article 13**

The Minister of Economy prescribes detailed criteria concerning the realization, conservation and maintenance of the National measurement standards, as well as the conditions for recognition of the Reference measurement standards as national standards.

#### **Article 14**

If the Bureau finds out that the criteria for recognizing a measurement standard as national measurement standard or conditions for realization, conservation and maintenance of a national standard are no longer met; it will revoke its decision for recognizing a measurement standard as a national measurement standard.

An appeal against the decision referred to in the previous paragraph shall be submitted to the Minister of Economy.

The appeal shall not cause delay on executing of the decision.

## **V. REFERENCE MATERIALS**

### **Article 15**

Certified reference materials may be realized, conserved and maintained by the Bureau or by a legal entity, which can provide traceability (for their physical characteristics or chemical composition) with measurement units in which the values of their physical characteristics or chemical composition are expressed.

### **Article 16**

The Minister of Economy prescribes (lays down) the manner and procedure of realization, conservation and maintenance of certified reference materials.

## **VI. MEASURING INSTRUMENTS**

### **1. Placing on the market and usage of measuring instruments**

#### **Article 17**

In the Republic of Macedonia, measuring instruments which do not fulfil the requirements defined by this or other Law and the regulations adopted in accordance to this or other Law for conformity assessment of the type of measuring instruments or which do not fulfil metrological and associated technical regulations (hereinafter: essential requirements), defined by this or other Law and with the regulations adopted in accordance to this or other Law, cannot be placed on market.

#### **Article 17a**

In the Republic of Macedonia, measuring instruments cannot be placed on the market or put in usage if:

- They do not fulfil the essential requirements, or
- The manufacturer have not verified the conformity of the measuring instrument with the essential requirements, in accordance to the procedures laid down in this Law and regulations adopted in accordance to this Law and
- The measuring instrument does not bear "CE" marking, supplementary metrological marking and identification number of the notified body designated to carry out the procedure for conformity assessment of the measuring instrument, with the essential requirements.

On fairs, exhibitions, public presentations and similar manifestations, the organizer can expose measuring instruments which do not fulfil the essential requirements, laid down by this Law and the regulations adopted in accordance to this Law, on condition to have clear marking to signify inconformity for placing on the market or putting in usage, until their conformation with the essential requirements.

In Republic of Macedonia could not be prevented, prohibited or restrict placing on market or putting in usage measuring instruments with EEC marking for type approval of measuring instrument and/or with marking for first EEC verification.

Minister for Economy prescribes the essential requirements which should be fulfilled by particular measuring instruments before their placing on the market or putting in usage, type of measuring instruments, marking of the measuring instruments, first EEC verification, supplementary conditions which should be fulfilled by the bodies that are involved in the procedure for conformity assessment of the measuring instruments, type of documents enclosed to the measuring instrument to be placed on market or put in usage, usage of harmonized standards, normative documents and technical specifications, contents of the necessary technical documentation and the manner of information about putting the measuring instruments in usage.

#### **Article 17b**

Manufacturer respectively natural or legal person is responsible for placing on the market or putting in usage of the measuring instruments, to fulfil the essential requirements laid down by this Law and regulations adopted in accordance to this Law.

Manufacturer provides data in the technical documentation, for fulfilling the essential requirements, as well as relevant data for particular procedures for conformity assessment, for the needs of the body which carries out the conformity assessment.

Manufacturer is obligated to keep technical documentation for ten years period, starting from the day of manufacturing the last measuring instrument from the exact type, as well as to put the documentation on disposal to the Bureau for expert supervision duties.

### **2. Conformity assessment**

#### **2.1 Conformity assessment of the type of measuring instruments**

##### **Article 18**

By the procedure of conformity assessment of the types of measuring instruments, their conformity with criteria laid down by this Law and regulations approved in accordance with it and other Laws and capability for their usage is assessed.

The usage of measuring instruments that meet the conditions referred to in paragraph 1 of this article shall not be limited in the Republic of Macedonia.

##### **Article 19**

The Minister of Economy shall prescribe the mode and procedure of conformity assessment of the type (pattern) of the measuring instruments, as well as the method, several methods or an appropriate combination of methods for assessment of conformity of the type of measuring instruments, and the contents and form of certificates for conformity of the type (pattern) of measuring instruments.

##### **Article 20**

The conformity assessment procedure is performed by the Bureau or a legal entity designated by the Minister of Economy.

Technical regulations, brought by the Minister of economy, or the Minister in whose authority laid down by the Law, are the tasks related to certain categories of measuring instruments, specify the criteria which should be fulfilled by the legal entities that perform conformity assessment procedures.



Legal entity is presumed that fulfils the conditions for performing conformity assessment procedure, specified in technical regulations, when its qualification is approved with previously accomplished procedure for accreditation. Certificate for accreditation issued by the Institute for accreditation of Republic of Macedonia is considered as a proof of technical qualification as a conformity assessment body.

The Minister of Economy shall prescribe the additional requirements, , the procedure of designating a legal entity, the tasks of the designated legal entity, and the assessment of the level of fulfilling authorisation criteria.

When ascertained, that criteria from the paragraph 4 of this article, as well as criteria for performing conformity assessment specified in technical regulation, the Minister of economy, on proposal of the Bureau, with decree authorizes the legal entity for performing conformity assessment.

With the decree from the paragraph 5, the legal entity becomes authorized to perform conformity assessment procedures, whereupon the decree contains the expiry date of authorization, range and tasks to be performed by the conformity assessment body.

Dissatisfied party can appeal against the decision from the paragraph 5, within 15 days from the day of the reception of the Decree, to the Commission, within the Government of the Republic of Macedonia, for questions for legal affairs of higher stage from the area of economy.

Conformity assessment bodies are obligated continuously to fulfil criteria from the paragraphs 2 and 4 of this article.

Conformity assessment bodies that meet the criteria laid down standards adopted by the Institute for standardization of the Republic of Macedonia, which transpose the relevant harmonised standards, the references of which have been published in the *Official Gazette of the Republic of Macedonia*, shall be presumed to meet the criteria .laid down in paragraph 2 and 4 of this article.

Conformity assessment bodies have duty to inform the Bureau for issued certificates and their withdrawn, for quality systems and for the procedures for conformity assessment.

### **Article 20a Abolishment of the Decree for authorization**

When Minister of economy, endorses that the conformity assessment body does not fulfill certain criteria from the article 20 paragraph 4 from this Law or any criteria specified with the technical regulation from article 20 paragraph 2 of this Law, will reach decision of abolishment of the Decree for authorization.

Against the decision from the paragraph 1 of this article, within 15 days, one can appeal, to the Commission, within the Government of the Republic of Macedonia, for questions for legal affairs of higher stage from the area of economy.

Appeal from the paragraph 2 of this article does not delay accomplishing of the decision.

For the action taken, whereas the conformity assessment body is designated ( notified) in the European Commission, the Minister of economy should inform the European Commission,

## **2.2. Conformity assessment of measuring instruments with the essential requirements**

### **Article 20b**

With the procedure of conformity assessment of measuring instrument with the essential requirements, compliance of the measuring instrument with the essential requirements laid down in this Law and regulations adopted in accordance to this Law, is approved, as well as their intended usage.

Conformity assessment of the measuring instrument with the appropriate essential requirements is performed with application of one of the procedures for conformity assessment or appropriate combination of procedures for conformity assessment. Minister for Economy, prescribes the manner for performing conformity assessment procedure of measuring instrument with the essential requirements, as well as application of the procedures (modules) for conformity assessment.

## **3. Conformity Marking**

### **Article 20c**

The Conformity of a measuring instrument with the essential requirements is indicated by the presence of CE marking and supplementary metrology marking. Manufacturer can affix any other markings, provided that the visibility and legibility of the CE marking and supplementary metrology marking is not thereby reduced.

The 'CE' marking and supplementary metrology marking shall be affixed by the manufacturer or notified body under the responsibility of, the manufacturer. Those markings can be affixed on the measuring instruments during the fabrication, if justified considering the characteristics of the measuring instrument or economic reasons.

Manufacturer or notified body under behalf of the manufacturer can not affix markings on a measuring instrument that are likely to deceive third parties as to the meaning and/or form of the 'CE' marking and the supplementary metrology marking.

Where the measuring instrument is subject to measures adopted under other Directives covering other aspects which require the affixing of the 'CE' marking, the marking shall indicate that the instrument in question is also presumed to conform to

the requirements of those other Directives. In such a case, the publication reference of the said Directives, in the *Official Gazette of the Republic of Macedonia*, should be given in the documents, notices or instructions required by those Directives and accompanying the measuring instrument.

#### **4 Informing for the conformity assessment bodies**

##### **Article 20d**

Ministry for Economy, by official duty shall notify to the other Member states of the European Union and the European Commission, bodies under their jurisdiction, which have gained attribute of a conformity assessment bodies and designated to carry out the tasks pertaining to the modules for conformity assessment, along with the identification numbers assigned from the European Commission, for the type of measuring instruments for which each body has been designated and in addition accuracy class of the instruments, the measuring range, the measurement technology and any other characteristics of the measuring instruments limiting the scope of the notification.

#### **5 Verification of measuring instruments**

##### **Article 21**

Measuring instruments referred to in article 3 of this Law shall be subject to initial, periodical and extraordinary verification.

##### **Article 22**

The manufacturer of the measuring instruments shall be in charge of their initial verification.

##### **Article 23**

The owner of the measuring instruments shall be in charge of the periodical verification.

Notwithstanding paragraph 1 of this article is the regular verification of thermal energy meters, electric energy meters, measuring transformers, time switches, water meters, fuel dispensers for motor vehicles, gas meters, correctors and parking meters, for which the legal entities and individuals that sell thermal energy, electric energy, water, gas, fuel and which let parking lots, regardless of who owns those measuring instruments.

##### **Article 24**

Periodical verification of a measuring instrument shall be made in the year when the validity of verification markings and seals expires, i.e. of the certificate of verification of a measuring instrument.

##### **Article 25**

Extraordinary verification shall be mandatory for measuring instruments, which have been withdrawn from service for malfunction or other technical shortcomings.

The extraordinary verification shall determine whether the measuring instrument continues to comply with the approved type (pattern), i.e. with the requirements defined in accordance with this law.

A legal entity that has repaired or re-modelled the measuring instrument shall ensure its extraordinary verification.

#### **Article 26**

The Minister of Economy shall specify the mode and procedure of measuring instruments verification referred to in articles 22, 23 and 25 of this Law.

#### **Article 27**

The Minister of Economy shall determine the categories and kinds of measuring instruments for which the verification shall be mandatory, as well as verification procedures, time limits of the periodical verification, and categories and kinds of measuring instruments for which authorisation for verification may be obtained.

#### **Article 28**

If the verification procedure finds that a measuring instrument is in compliance with the approved type, i.e. with the laid down metrological requirements for verification, it shall be marked with markings and seals for verification, i.e. a certificate of verification shall be issued.

If the verification procedure finds that a measuring instrument is not in compliance with the approved type, i.e. the laid down metrological requirements for verification, it shall not be marked and sealed with verification mark and seal, i.e. a verification certificate shall not be issued.

#### **Article 29**

The Minister of Economy shall prescribe the types and formats of markings and seals used in measuring instruments verifications, as well as the contents and format of verification certificate.

The markings and seals, as well as the certificate of verification shall cease to be valid as follows:

- When their validity has expired;
- When they have been altered, damaged or removed (this refers to markings and seals only);
- When they have been obliterated; and
- When the measuring instrument has been repaired or re-modelled.

A measuring instrument lacking markings and seals, i.e. a verification certificate, or which markings and seals, i.e. verification certificate have ceased to be valid shall not be used.

### **Article 30**

The verification shall be performed by the Bureau or by a legal entity designated by the Minister of Economy.

The Minister of Economy, following a proposal of the Bureau, shall designate a legal entity which competency has been verified in accordance with the accreditation rules or rules equivalent to those of accreditation in compliance with the Law on accreditation, and which meet additional requirements for verification of particular kinds of measuring instruments.

The Minister of Economy shall prescribe the additional requirements referred to in paragraph 2 of this article, the procedure of designating a legal entity, the tasks of the designated legal entity, and the assessment of fulfilment of designation requirements.

## **6 Harmonized standards and normative documents**

### **Article 30a**

Conformity with the essential requirements, will be presumed, if the measuring instrument complies with the elements ( standards adopted by the Institute for standardization of the Republic of Macedonia) that correspond to those elements of this European harmonised standards, the references in respect of which have been published in the *Official Gazette of the Republic of Macedonia by the Ministry for Economy*

Where a measuring instrument complies only in part with the elements of the paragraph 1 of this article, conformity with the essential requirements corresponding to the elements of the national standards with which the instrument complies, will be presumed.

Conformity with the essential requirements will be presumed, in respect of a measuring instrument that complies with the elements of the normative documents, whose references have been published in the *Official Gazette of the Republic of Macedonia by the Ministry of Economy*.

Where a measuring instrument complies only in part with the normative document conformity with the essential requirements corresponding to the normative elements with which the measuring instrument complies will be presumed

The references of the normative document referred to in the paragraph 3 of this article should be assumed from corresponding documents which have been published by European Commission, in the Official Gazette of the European Union.

### **Article 30b**

Bureau acts in accordance to the procedures for informing of the European Commission for adopting technical and non-harmonized regulations, technical specifications and standards, where considered, that a harmonised standard as referred to in Article 30a paragraph 1 in this Law, does not fully meet the essential requirements

referred to in this Law and the regulations adopted in accordance to this Law, in respect of particular measuring instrument, Bureau of metrology, without delay will inform Institute for standardization of the Republic of Macedonia. Institute for standardization of the Republic of Macedonia (as a competent body for relations with the Standing Committee of the European Union set up under Article 5 of Directive 98/34/EC), without delay to the Standing Committee, giving its reasons for doing so.

When European Commission, informs the Institute for standardization of Republic of Macedonia, that the standard adopted by the Institute, by which the harmonized European standard is undertaken, does not fully complies with the essential requirements and regulations adopted by this Law, Institute for standardization of RM without delaying shall deliver, through the Ministry of economy, that information to the Bureau.

Ministry of Economy, after it has been informed by the European Commission, without delaying will publish withdraws of particular standard from the list of standards, published in the Official Gazette of Republic of Macedonia.

### **Article 30c**

Where considered, that a normative document from Article 30a paragraph 3, of this Law, does not fully meet the essential requirements concerning particular type of measuring instrument, and regulations adopted in accordance to this Law concerning particular type of measuring instrument, Ministry of Economy on proposal of Bureau, shall bring the matter before the measuring instruments Committee, giving its reasons for doing so.

When European Commission informs Member States of the European Union, that withdrawing of a bibliographic data of a normative document published in the Official Gazette of EU, is necessary, Ministry of Economy, without delaying shall deliver the information for withdrawing of a normative document from the list of normative documents, published in the Official Gazette of the Republic of Macedonia.

## **6. Measures in case of non-fulfilment the essential requirements**

### **Article 30d.**

Where Bureau establishes that all or part/parts, although are regularly Installed in the measuring instrument of a particular model that bear the 'CE' marking and the supplementary metrology marking do not satisfy the essential requirements and regulations adopted in accordance to this Law on its proposal, inspection authorities, shall take all appropriate measures to withdraw these instruments from the market, prohibit or restrict their further being placed on the market, or prohibit or restrict their further being used. The Bureau of metrology shall establish whether the nature of the non-compliance is systematic (essential or systematic) or incidental (non-essential or incidental). Where the Bureau has established that the non-compliance is of a systematic nature, it shall immediately, through the Ministry of economy, inform the European Commission for the measures taken, indicating the reasons for its decision.

The inspection authority in cooperation with the Bureau, through the Ministry of Economy, shall inform European Commission and relevant authorities in the Member States, for the appropriate actions against any person who affixes the markings not in accordance with this Law and regulations adopted in accordance to this Law.

## **7. Unduly fixed markings and cooperation**

### **Article 30e**

Where the Bureau establishes that the 'CE' marking and supplementary metrology marking have been affixed unduly, it shall inform Ministry of Economy or inspection authorities to take action, the manufacturer or his authorised representative, legal entity or person, which puts on market or in usage measuring instruments and shall take actions for restricting their activities for unduly affixing of CE markings and to take appropriate measures to make the instrument conforms with the provisions concerning the 'CE' marking and supplementary metrology marking.

Where Bureau establishes that the nonconformities from paragraph 1 of this article still persist or encored, on its proposal Ministry of Economy or relevant inspection authority takes action to withdraw the measuring instrument in question from the market, restrict or prohibit placing it on the market or its further use. Inspection authorities, shall ensure that any decision entailing the withdrawal from the market of a measuring instrument, or prohibiting or restricting the placing on the market or putting into use of an instrument, shall state the exact legal grounds on which it is based and the decision shall be notified forthwith to the party concerned (legal entity or person).

### **Article 30f.**

In Republic of Macedonia, measuring instruments that undergo on metrological supervision can not be placed on the market or put into use, , if they do not meet the essential requirements, laid down in this Law and regulations adopted according to this Law.

## **VII. VALIDITY OF MARKINGS AND CERTIFICATES OF CONFORMITY ASSESSMENT OF TYPE OF MEASURING INSTRUMENTS, AND MARKINGS AND SEALS, I.E. CERTIFICATES OF VERIFICATION OR CALIBRATION OF FOREIGN MEASURING INSTRUMENTS**

### **Article 31**

In the Republic of Macedonia, the following shall be recognized as valid:

- Markings and certificates of conformity assessment of the type of measuring instruments from domestic or foreign origin; and
- Markings and seals, i.e. certificates of verification or calibration of foreign measuring instruments, which have been issued in compliance with international, as well as with bilateral or multilateral agreements concluded and ratified, or acceded by Republic of Macedonia.

### **Article 32**

The Bureau shall keep a Register of markings and certificates of conformity assessment of measuring instruments types and markings and seals, i.e. verification certificates of foreign measuring instruments issued in compliance with article 31 of this Law.

The registration in the Register referred to in paragraph 1 of this article shall be made on request of an interested legal entity and/or an individual.

The Bureau shall issue a certificate for registration of the data of paragraph 1 of this article in the Register.

An appeal against the Certificate for rejection of registration in the Register may be lodged to the Minister of Economy.

The Minister of Economy shall prescribe the format, contents and mode of keeping the Register referred to in paragraph 1 of this article, as well as the formats and contents of certificates referred to in paragraphs 3 and 4 of this article.

## **VIII. METROLOGICAL SUPERVISION ON QUANTITIES AND MARKINGS ON QUANTITIES OF PRE-PACKAGES**

### **Article 33**

The quantities and markings of quantities of pre-packages on the market are subject to metrological supervision.

In the Republic of Macedonia, pre-packages shall be allowed on the market only when their quantity is accurately, clearly and unambiguously indicated, and when their actual quantity is within the permitted deviation from the indicated quantity.

### **Article 34**

Metrological supervision of pre-packages shall be carried out by the Bureau or by a designated legal entity.

The Minister of Economy, following a proposal of the Bureau, may issue a certificate designating a legal entity which competence has been verified in accordance with the accreditation rules or rules equivalent to those of accreditation in compliance with the Law on accreditation, and which meets additional requirements for metrological supervision of pre-packaged articles.

The Minister of Economy shall prescribe the additional requirements referred to in paragraph 2 of this article, the procedure of designating legal entity, the tasks of the designated legal entity, and the supervision of the fulfilment of designation requirements.

### **Article 35**

The Minister of Economy shall define the method and procedure of metrological supervision and the requirements to be met by pre-packaged articles in terms of quantities, method of indication of quantities and permitted deviations of actual quantities from the indicated quantities and essential requirements for bottles which are used as measuring vessels.

### **Article 36**

Should the metrological supervision find that pre-packaged articles do not bear the stated quantity, or that the quantity is vaguely or ambiguously stated, or that the



permitted deviation of actual quantity has been exceeded, the Bureau shall issue a decision banning their placement on the market.

An appeal against the decision referred to in the previous paragraph may be lodged to the Minister of Economy.

The appeal shall not restrain the implementation of the decision referred to in paragraph 2 of this article.

## **IX. COSTS OF SERVICES**

### **Article 37**

For the services provided by the Bureau and a designated legal entity referring to:

- Calibration of measurement standards;
- Inter-laboratory comparison of measurement standards;
- Conformity assessment of type of measuring instruments;
- Conformity assessment of measuring instruments with the essential requirements;
- Examination of types of measuring instruments;
- Verification of measuring instruments;
- Supervision of the fulfilment of criteria for designation of legal entities;
- Supplying of the markings and certificates of conformity assessment of type of measuring instruments;
- Supplying of markings and seals, i.e. certificates of verification of measuring instruments;
- Registration of markings and certificates of conformity assessment of the type of measuring instruments and markings and seals, i.e. certificates of verification of foreign measuring instruments;
- Metrological supervision of quantities of markings of pre-packaged articles; and
- Consulting and training, fees shall be charged.

The Government of the Republic of Macedonia shall prescribe the amount and manner of charging the fees referred to in paragraph 1 of this article.

## **X. SUPERVISION**

### **Article 38**

The Ministry of Economy shall supervise the implementation of provisions of this Law and other regulations adopted in accordance with this and other Laws.

### **Article 39**

Inspectoral supervision of the implementation of provisions of this Law and regulations adopted as per this and other Laws referring to the use of legal measurement units and placement on the market and use of measuring instruments shall be performed by the body in charge of the work of market inspection.

### **Article 40**

The Bureau shall carry out the expert supervision of the implementation of provisions of this Law and regulations adopted as per this and other Laws referring to: use legal measurement units; fulfilment of criteria for realization, conservation and maintenance of the National measurement standards; placement on the market and use of measuring instruments; and the work of legal entities designated in accordance with this Law;

#### **Article 41**

The Minister of Economy shall prescribe the manner and procedure of the expert supervision.

#### **Article 42**

Staff performing duties and tasks of expert supervision are obliged to possess an identity card proving their official job position, and are obliged to present it if they are asked to.

The Minister of Economy shall issue the official identity card.

The Minister of Economy shall prescribe the format and manner of issuing and revoking the official identity card.

#### **Article 43**

Should violations be found of provisions of this Law and regulations adopted as per this and other Laws referring to the use of legal measurement units and their placement on the market and use, the body in charge of the work of market inspection shall take a decision on banning, i.e. the Bureau shall suggest to them to officially ban the following:

- Use of measurement units which are not laid down with this Law;
- Placement on the market and use of measuring instruments referred to in article 3 paragraph 1 of this Law, that do not meet the criteria defined in this Law and in regulations adopted in accordance with this and other Laws.

An appeal against the decision referred to in paragraph 1 of this article may be lodged to the Minister of Economy.

The appeal shall not restrain the implementation of the decision.

#### **Article 44**

Should violations be found of provisions of this Law and of regulations adopted as per this and other Laws referring to fulfilment of conditions for realisation, conservation and maintenance of national measurement standards, to the work of legal entities designated in accordance with this Law, the Bureau shall make an official decision for:

- revoking the certificate for recognition of a measurement standard as a national measurement standard;
- a proposal to the Minister of Economy to revoke the decision on designating the legal entity.

An official complaint may be lodged to the Minister of Economy against the decision referred to in paragraph 1 of this article. The complaint shall not delay the implementation of the decision.

## **XI. PUNITIVE PROVISIONS**

### **Article 45**

A fine of 80.000 to 240.000 denars shall be imposed upon a legal entity in case of the following violations:

- 1) For using measurement units which are not laid down by this Law, i.e. by regulations made as per this Law (paragraph 3 of article 10);
- 2) For placing on the market or using the measuring instruments referred to in paragraph 1 of article 3 of this Law, which do not meet the requirements defined in this Law and in the regulations made as per this and other Laws referring to the conformity assessment of the type (pattern) and for verification of the measuring instruments (article 17);
- 3) For not having clear marking to signify inconformity for placing on the market or putting in usage of measuring instruments, exposed on fairs, exhibitions, public presentations and similar manifestations (article 17a, paragraph 2);
- 4) For not keeping technical documentation of a measuring instrument for period of ten years after the production and for not putting on disposal to the Bureau (article 17b, paragraph 3);
- 5) For limitation of using the measuring instruments (article 18, paragraph 2);
- 6) For affixing marking other than conformity 'CE' marking and the supplementary metrology marking, that reduces visibility and readability of the 'CE' marking and the supplementary metrology marking (article 20v, paragraph 1);
- 7) For affixing markings that are likely to deceive third parties as to the meaning and/or form of the 'CE' marking and the supplementary metrology marking (article 20v, paragraph 3);
- 8) For not acting in accordance with article 20v, paragraph 4 of this law;
- 9) For disregarding the initial verification (article 22);
- 10) For disregarding the periodical verification (article 23);
- 11) For disregarding the extraordinary verification (article 25, paragraph 3);
- 12) For using a measuring instrument which markings and seals, i.e. verification certificates have ceased to be valid (article 29, paragraph 2);
- 13) for using a measuring instrument that lacks markings and seals, i.e. verification certificates (article 29, paragraph 3);
- 14) For placing on the market pre-packaged articles which quantity is not accurately, clearly and unambiguously indicated and when their actual quantity exceeds the permitted deviations from the indicated quantity (article 33, paragraph 2);
- 15) For disregarding the decision for banning the placement of the pre-packaged articles on the market (article 36, paragraph 1);
- 16) For disregarding the decision for banning the use of measurement units not laid down with this Law, i.e. with regulations issued in accordance with this Law (article 43, paragraph 1, alignment 1); and
- 17) For disregarding the decision for banning the placement on the market and use of measuring instruments referred to in paragraph 1 of article 3 of this Law, and which do not meet the criteria defined in this Law and in the regulations made as

per this and other Laws for the conformity assessment of the type (pattern) and for verification of the measuring instruments (article 43, paragraph 1, alignment 2).

A fine of 15.000 to 45.000 denars shall also be imposed on the responsible person of the legal entity who has committed an offence as per paragraph 1 of this article.

In addition to the fine referred to in paragraph 1, alignment 2, 3,4,6,7, 8, 12,13 and 16 of this article, a security measure shall be imposed – confiscation of measuring instruments with which the violation has been made.

#### **Article 46**

A fine of 15.000 to 45.000 denars shall be imposed on an individual for violations referred to in article 45, paragraph 1, alignments 1,3,4,6,7,8,11,12,13,14,15 and 16 . In addition to the fine referred to in article 45, paragraph 1, alignments 2,3,4,6,7,8,12,13 and 16 , a security measure shall be imposed – confiscation of measuring instruments with which the violation has been made.

**Article 46a** Violations referred to in article 45 and 46 of this law, are subject to a procedure and sanction for the violation, taken by the particular responsible Court.

#### **Article 46b**

For the violations referred to in article 45 and 46 of this Law, the authority responsible for the tasks of the trade inspection, should offer to the person that committed the violation, a procedure of alignment, before taking legal action against him.

When the committed the violation agrees to the procedure of alignment, the responsible authority for the tasks of the trade inspection, assembles protocol, which contains the essential elements for the violation, time, place and way of commitment of the violation, description of the action of violation and persons that happened to be at the place of violation, as well as the way of removing the damage from the violation. The authority responsible for the tasks of the trade inspection, on behalf of the procedure of alignment, shall give a warrant for payment.

When the person receives the warrant for payment, he is obligated to sign it. Receiving of the warrant for payment, should be noticed in the protocol.

When the commitment of the violation is done by a legal entity, the protocol and the warrant for payment is signed by an employee or authorised person that happened to be on the place at the time of control or other employee or authorised person which has stated to have rights to sign the protocol and to receive the warrant for payment.

Statement from the paragraph 4 of this Article is noticed in the protocol.

The authority responsible for the tasks of the trade inspection, is obligated to keep evidence for the taken procedures for alignment, as well as the results from them.

## **XII. TRANSITIONAL AND FINAL PROVISIONS**

#### **Article 47**

The regulations issued in accordance with the Law on Units of Measurement and Measuring Instruments ("Official Gazette of the Republic of Macedonia", No. 23/95), as well as the regulations implemented according to this Law, shall be in force until the regulations as per this Law are adopted.

#### **Article 48**

The markings and certificates of conformity assessment of type of measuring instruments (decision approving a type of measuring instruments), as well as markings and seals and certificates of measuring instruments verification (seals, i.e. certificates of good functioning of a measuring instrument), which were issued before this Law has become effective, shall remain in force under conditions and time limits defined in the regulations according to which they have been issued, up to a point when regulations shall be issued as per this Law, with the manner, procedures and criteria of their issuing shall be defined.

#### **Article 49**

Government of the Republic of Macedonia shall, for the purpose of efficient performance of duties and tasks in the field of metrology, provide premises for the Bureau's work.

Capital goods, equipment and archive referring to the work of metrology shall be re-assigned to the Bureau from the Office of Standardisation and Metrology.

Employees of the Office of Standardisation and Metrology performing duties and tasks in the field of metrology shall continue to perform those duties and tasks in the Bureau.

#### **Article 50**

The Office of Standardisation and Metrology shall continue to work as a Bureau for Metrology within the Ministry of Economy.

#### **Article 51**

Until the constituting of the Bureau, the Office of Standardisation and Metrology shall perform the duties in the field of metrology.

#### **Article 52**

On the day when this Law shall enter into force, the Law on Units of Measurement and Measuring Instruments ("Official Gazette of Republic of Macedonia", No. 23/95) shall cease to be valid.

#### **Article 53**

This Law shall become legally binding on the eighth day after its publication in the "Official Gazette of the Republic of Macedonia".

#### **Article 23**

Regulations regarding to this law will be adopted within 18 months from the day of entering of this law into force.

Until the day of entering into force of regulations laid down in paragraph 1 of this article, existing regulations will be implemented.

**Article 2**

Provisions of article 20a paragraph 3, 30b, 30v and 30g of this law, will be implemented from the day of joining of the Republic of Macedonia the European Union or with entering into force of particular international agreement with European Community, for reports of examinations and procedures of conformity assessment.

**Article 25**

Commission for legislative and legal affairs of the Parliament of Republic of Macedonia, is authorized to ratify fair copy of the Law on metrology.

**Article 26**

This law enters into force on the eight day of the day after its publication in the "Official Gazette of the Republic of Macedonia".