

MINISTRY OF ECONOMY

**Law on Prescribing Technical Requirements for Products
and Conformity Assessment
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Law on Prescribing Technical Requirements for Products and Conformity Assessment

I. General Provisions

Article 1

This Law regulates the method of prescribing technical requirements which the products must conform to before they are placed on the market or otherwise put into service; the procedures for product conformity assessment according to the prescribed technical requirements; the validity of foreign certificates and marks of conformity, and the surveillance of the compliance with the requirements prescribed with the regulations.

Article 2

The regulations prescribing technical requirements for products are issued, in particular, for the purposes of:

- realization and protection of public interests;
- protection of human, animal and plant health and life;
- environment and nature protection and promotion, and protection of the consumers and other users of the products.

The development of the technical regulations shall be based on most up-to-date scientific and professional achievements, while taking due account of the specific needs and possibilities of the economy of the Republic of Macedonia, as well as the commitments undertaken by the Republic of Macedonia under the ratified international agreements.

Article 3

Some of the terms used in this law, shall mean as follows:

1. **Product** shall mean any product as a result of specified processing activities;
2. **Technical regulation** shall mean a regulation that prescribes the characteristics of a product directly or by referring to the standard, technical specification or code of good practice.
3. **Technical specification** shall mean a document that prescribes the technical requirements, which the product has to fulfil.
4. **Placing on the market** shall mean the initial action of making a product available for use or distribution in the Republic of Macedonia, for payment or free of charge;
5. **Putting into service** shall mean first use of a product by the end user in the Republic of Macedonia;
6. **Supplier** shall mean natural or legal person who had placed the product on the market or ensured its putting into service;
7. **Conformity assessment procedure** shall mean procedure applied, directly or indirectly, to determine that the specified requirements are fulfilled;
8. **Conformity assessment body** shall mean body involved in conformity assessment procedure;
9. **Conformity certificate** shall mean a document issued in compliance with the rules of the certification system, by which confidence is provided that the certain process, product or service is in compliance with specified standard or regulation;
10. **Certification mark** shall mean a mark of conformity, used or issued in compliance with rules of certification system, shows that a product, process or service is in conformity with specified standard or regulation;
11. **Accreditation** shall mean expert procedure by which, the national body for accreditation determines whether certain body fulfils necessary conditions for performing certain activities in the area of conformity assessment.

II. Method of prescribing technical regulations

Article 4

Technical regulations, which are issued for certain products or group of products, prescribe:

1. Technical requirements for the products;
2. The procedures, the method and the conditions for assessment of conformity with the prescribed requirements;
3. Requirements for the bodies participating in the procedures for conformity assessment (hereinafter: conformity assessment bodies);
4. Documents that should accompany a product when placed on the market or put into service;
5. Obligation and method of marking of the products.

The Minister, who is in charge of the things connected to the production, placing on the market and putting in to service certain products, issues technical regulations.

Article 5

If a technical regulation for certain products or group of products refers to Macedonian standards, it will be considered that the products or the group of products are in conformity with the technical requirements assigned in the technical regulation if they are in conformity with the standards.

In the cases of paragraph 1 of this article, technical regulation shall declare a list of standards on the basis of which the conformity assessment is being determined.

Article 6

Mandatory use of technical specifications may be prescribed by technical regulations.

Technical specifications shall be issued by the Minister responsible for issuing technical regulations, upon proposal of the committee comprised of important scientists and experts from suitable field.

The Minister responsible for prescribing technical regulation shall appoint committee of paragraph 2 of this Article.

Constitutional part of the technical regulation of paragraph 1 of this Article is the list of technical specifications.

III. Placing on the market

Article 7

The domestic or imported products may only be placed on the market or put into service if they conform to the prescribed technical requirements, if they have been assessed according to the prescribed procedure, if they are marked in accordance with the regulation, and if they are followed with the prescribed documentation.

Article 8

Technical regulations shall specify the products for which, prior to placing them on the market or putting them into service, the supplier is required to:

1. Ensure implementation of the procedures for assessment of conformity with the prescribed technical requirements;
2. Issue or provide a certificate of conformity;
3. Produce and keep technical documentation within the prescribed form and scope, and keep this documentation within the prescribed manner and time limits;
4. Implement prescribed marks of conformity.

IV. Conformity assessment procedure

Article 9

Prescribed conformity assessment procedures may be specified directly, in technical regulation, or indirectly, in technical specification or standard adopted by Macedonian Standardization Institute.

Article 10

The requirements to be fulfilled by conformity assessment body, shall be laid down in technical regulation and they shall refer to:

- Professionally trained staff, space and technical equipment;
- Independence and impartiality in relation to the legal or natural persons directly or indirectly connected with the product;
- Business confidentiality;
- Liability insurance for the work done,
- Other conditions ensuring appropriate implementation of prescribed procedure.

Article 11

If it is assessed that the conditions for obtaining status of conformity assessment body, prescribed in technical requirement, are fulfilled, the Minister responsible for issuing technical regulations with previously obtained opinion of the Macedonian Accreditation Institute, shall authorise, by decision, the legal or natural person to perform conformity assessments and shall define the time limitation of this decision.

National body of accreditation is responsible, during evaluation of the opinion of paragraph 1 of this Article to respect the statements of technical regulation as well as the suitable accreditation criteria.

The decision of paragraph 1 of this Article shall be published in "Official Journal of the Republic of Macedonia".

Article 12

The subject designated as conformity assessment body shall permanently meet and maintains the requirements prescribed by technical regulation and relevant accreditation criteria defined by Macedonian Accreditation Institute.

If the competent inspection body finds that the body of paragraph 1 of this Article fail to meet particular requirement prescribed by technical regulation, the inspection body shall propose to the Minister responsible for issuing technical regulation to announce decision for withdraw the decision of paragraph 1 of Article 11 of this Act.

V. Certificate of conformity

Article 13

Conformity assessment body shall issue certificate of conformity on the base of the request submitted by the interested domestic or foreign legal or natural person.

If conformity assessment body assesses that for a particular product cannot be issued certificate of conformity, a decision for refusing the request shall be issued.

Appeal against the decision of paragraph 2 of this Article can be submitted to the Minister responsible for Issuing technical regulation.

The Ministry in charge shall keep a record and publish in the Official Journal the list of conformity assessment bodies.

Article 14

The amount and the method of payment expenses for issuing certificate of conformity, the issues concerning the maintenance of certification mark, as well as the other mutual relations between the conformity assessment body and the customer, shall be settled by a contract.

Conformity assessment bodies shall conclude a contract with every legal or natural person wishing to obtain a certificate of conformity.

Article 15

In the Republic of Macedonia are valid certificates and certification marks of foreign origin issued in compliance with international, as well as bilateral and multilateral agreements entered into by the Republic of Macedonia.

The Minister responsible for issuing technical regulations, will also recognize the validity of certificates or certification marks of foreign origin, if:

- Such certificates or certification marks conform with the requirements for the products prescribed in the technical regulations in force in Republic of Macedonia,
- The conformity assessment bodies issuing the certificates or certification marks pursuant to item 1 of this paragraph, satisfy the conditions prescribed for such types of bodies by regulations in the Republic of Macedonia.

Article 16

Products which are non-conforming to the prescribed technical requirements, as well as the products which are exempted from marking with marks of conformity, shall not be marked with any mark of conformity or other marks whose similarity with the prescribed marks of conformity would be such that they could create confusion on the market and mislead the consumers.

VI. SURVEILLANCE

Article 17

The ministries responsible for issuing technical regulations, through their inspection bodies shall survey the implementation of the provisions of this law, regulations made on the base of this and other laws.

In addition to the authorities and measures based on particular regulations concerning their work, competent inspectors are hereby authorized to perform supervision of the certificates of conformity, as well as the technical documentation,

which the supplier is obliged to provide for examination and use, upon inspector's request.

If during inspection procedure is necessary to make some checks, the inspector may take samples of the products aiming of checking their conformity with regulations.

Article 18

If the inspector, during the inspection procedure, realizes that the provisions of this law or the technical regulations issued pursuant to it are disrespected, he/she shall:

a) Order:

1. Withdrawal of certificates of conformity for non-conforming products;
2. Elimination of non-conformances with time limit;
3. Marking of products with the prescribed marks, or removal of illicit marks;
4. Destruction of non-conforming products, if it is essential for the protection of health and safety of people, environment and nature;
5. Cessation of use of non-conforming products;

b) Ban:

1. Placing on the market, or restrict circulation of non-conforming products;
2. Putting into service, or restrict use of non-conforming products;
3. Temporary any supply, offer to supply or exhibition of products in order to make various checks and tests;
4. Use of non-conforming products;
- 5.

Appeal against the decision of the paragraph 1 of this article can be submitted to the Minister in charge 15 days after the receipt of the decision.

Appeals against decisions in paragraph 1 of this Article, shall not withhold their execution.

Article 19

During inspection procedure, the inspector may take statements from responsible persons in the legal person or natural person, from witnesses, may take samples for making analyses in connection with undertakings referred to Article 18 of this law.

When analysing samples, the inspector may use the services of authorised institutions.

If the results of the analyses show non-conformity of products with requirements of particular certificates and certification marks, costs of analyses shall be paid by the legal or natural person on which the supervision is performed.

VII. Penalty Provisions

Article 20

A fine of 80 000 to 250 000 denars shall be imposed on a legal person which:

1. Places on the market or put into service products inconsistently with Article 7 of this law;
2. Places on the market or put into service products which are not in conformity with technical requirements, places on the market or put into service products which are not marked on a proper way, marks the products with marks whose similarity to the marks of conformity could create a confusion on the market or could mislead the consumers (article 16):

A fine of 15 000 to 45 000 denars shall be imposed on the responsible person of the legal person for the activities of paragraph 1 of this Article.

In addition to the fine mentioned in paragraph 1 of this Article, safety measure of forbidding performing activities of one to three years should be imposed to the legal person.

In addition to the fine pursuant to paragraph 2 of this Article, safety measure of forbidding activities of six months to one-year shall be imposed to the responsible person in the legal person.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 21

Regulations that prescribe technical requirements for products, procedures for assessment of conformity with technical regulations, marking of products as well as required documentation following the products, which are adopted or implemented on the basis of the Law on Standardization (“Official Journal of the Republic of Macedonia” 23/95) or on the basis of other laws, shall apply until issuing regulations on the basis of this law.

Article 22

This law shall enter into force on the eighth day after its publication in the Official Journal of the Republic of Macedonia.