

LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY ASSESSMENT

I. BASIC PROVISIONS

Subject

Article 1

This Law defines the manner of stipulating technical requirements for products, conformity assessment of the product with the stipulated technical requirements (hereinafter referred to as: product conformity assessment), obligations for product supplier, validation of certificates of compliance and compliance marks issued abroad, notification of technical regulations and conformity assessment procedures.

Application of the Law

Article 2

(1) This Law is not applied to the products for which the technical requirements are regulated by special laws.

(2) If the laws referred to in paragraph 1 of this Article do not define the issues pertaining to appointment and authorisation of the bodies for conformity assessment and validation of compliance certificates and marks issued abroad, provisions of this Law shall be applied.

(3) Provisions of this Law that define the registration procedure of the appointed body for the conformity assessment, keeping the register and notification, shall be applied to the products whose technical requirements are stipulated by special laws.

Definitions

Article 3

The terms used herein shall have the following meanings:

- 1) **product** is any product that is as a result of a process, or developed or otherwise obtained, regardless of the degree of its processing, and is intended for placing on the market or supply in the market;
- 2) **manufacturer** is a legal entity or a natural person, i.e. an entrepreneur who produces a product or a person that present himself as the manufacturer of the product by putting his business name, his name, stamp or some other recognizable trademark;
- 3) **representative** is a legal entity or an entrepreneur with the head office in Montenegro or that resides in Montenegro which the manufacturer authorised to act on his behalf regarding certain affairs related to placing the product on the market;
- 4) **importer** is a legal entity or a natural person, i.e. an entrepreneur with the head office in Montenegro, or with the place of residence in Montenegro, which imports the products for the purpose of placing them on the Montenegrin market;
- 5) **distributer** is a legal entity i.e. an entrepreneur with the head office or the place of

- 6) **supplier** is the manufacturer, representative, importer and distributor;
- 7) **placing on the market** is the first delivery of the product on the Montenegrin market;
- 8) **supply on the market** is any delivery of products for distribution, consumption or use on the market of Montenegro in the trading activities for payments or without payments;
- 9) **harmonised standard** is a European standard that is adopted based on the request of the European Commission and whose reference is published in the Official Journal of the European Union;
- 10) **conformity assessment** is a procedure that determines whether the requests that refer to the product, the process, the service, the system, the person or the body are met;
- 11) **review** is a regular or extraordinary checking of compliance of stipulated requests for safety of product during its life;
- 12) **conformity assessment body** is a legal entity that conducts conformity assessments, including calibration, testing, certification and control (of laboratories, certification bodies, control organisations, etc.);
- 13) **conformity mark** is a sign that manufacturer use to mark the product that is in compliance with the technical requirements that refer to it, in accordance with the technical regulation;
- 14) **appointment** is an approval by which the competent ministry appoints the body for conformity assessment of products that will perform conformity assessments for the needs of the manufacturers;
- 15) **authorisation** is an approval by which the competent ministry authorises the body for conformity assessment for performing conformity assessments for the needs of public administration bodies;
- 16) **appointed body for conformity assessment** is a legal entity that is appointed by the competent ministry to perform product conformity assessment affairs for the needs of the manufacturers;
- 17) **authorised body for conformity assessment** is a legal entity that is authorised by the competent ministry to perform product conformity assessment affairs for the needs of the public administration bodies;
- 18) **Notified Body** (Notified Body – NB) is a body for conformity assessment for products covered by the EU harmonised standards.

II. TECHNICAL REQUIREMENTS AND TECHNICAL REGULATIONS

Technical requirements

Article 4

The technical requirements for individual product, i.e. groups of products (hereinafter referred to as: technical requirements) are defined by the technical regulation, in the listed requirements in the text of the technical regulation or indirectly by referring to the standards.

Technical regulations

Article 5

(1) Technical regulation means any regulation, which, for a single product or product group regulates at least one of the following elements:

- 1) the technical requirements to be met by the products that are delivered to the market;
- 2) requirements for safety during the life of the product;
- 3) regular and extraordinary reviews over the life of the product;
- 4) requirements regarding packaging and labelling;
- 5) obligations of the suppliers that deliver the product the market;
- 6) conformity assessment procedures;
- 7) requirements to be fulfilled by conformity assessment body;
- 8) conformity certificates and technical documentation necessary for proving the compliance of product that must be made available to the competent bodies (instructions, data, etc.);
- 9) mark and manner of marking of the product.

(2) The technical regulations are adopted for the purpose of protection of public interest and particularly protection of life, health, and safety of people, animals, plants, environment and protection of property.

Adoption of technical regulations

Article 6

(1) The technical regulations for certain products or groups of products are prepared or adopted by the competent bodies of the public administration (hereinafter referred to as competent ministries).

(2) During preparation of the technical regulation the competent ministry shall particularly take into consideration the following:

- 1) prevention of unnecessary barriers for the trade;
- 2) the equality of domestic and foreign products on the market;
- 3) the use of Montenegrin standards that accept the international standards as the basis for preparation of the technical regulation;
- 4) setting of an appropriate deadline when the technical regulation shall come into force;
- 5) changed of circumstances occurring after the adoption of technical regulation, for the purpose of its amendment or abrogation;
- 6) meeting the objectives of the technical regulation in a manner that is least restrictive for the trade;
- 7) requirements that a product must meet primarily in terms of functional characteristics, and not in terms of design or descriptive characteristics of the product.

(3) The technical regulations referred to in Article 5 paragraph 1 of this Law, the competent ministries adopt with previously obtained opinion of the public administration body competent for quality infrastructure (hereinafter referred to as Ministry).

(4) The technical regulations that are adopted based on this Law are published in the "Official Gazette of Montenegro".

Assumption of Conformity
Article 7

IV. CONFORMITY ASSESSMENT BODIES

Requirements for the Conformity Assessment Bodies

Article 10

- (1) The bodies for conformity assessment shall fulfil at least the following requirements:
- 1) professional competence of persons conducting conformity assessment;
 - 2) appropriate equipment and premises;
 - 3) the independence and impartiality in the conformity assessment procedure;
 - 4) professional secrecy;
 - 5) liability insurance.
- (2) The technical regulation, in addition to the requirements referred to in paragraph 1 of this Article, may stipulate specific requirements that must be fulfilled by the conformity assessment bodies.
- (3) The conformity assessment body must not be: the supplier of the products that are being assessed, directly involved in designing, production, make, assembling, usage and maintenance of the product.

The Manner of Authorisation and Appointing

Article 11

- (1) The product conformity assessment for the needs of the public administration bodies may be performed by the conformity assessment body if that body fulfils the requirements from the technical regulation, based on the authorisation of the competent ministry.
- (2) The product conformity assessment for the needs of the manufacturer may be performed by the conformity assessment body if that body fulfils the requirements stipulated in the technical regulation based on the appointment decision of the competent ministry.
- (3) The decision on appointment referred to in paragraph 1 of this Article, is issued on the basis of public call initiated by the competent ministry.

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(8) The decisions referred to in paragraph 7 of this Article are final and an administrative dispute cannot be initiated against this decision.

Obligations of the authorised i.e. appointed bodies for conformity assessment

Article 12

(1) Authorised i.e. appointed body for conformity assessment of a product shall continuously fulfil the requirements from the technical regulations.

(2) The bodies referred to in paragraph 1 of this Article shall upon the request of the competent ministry deliver a report on the conducted conformity assessment for a product correspondingly to the authorisation, i.e. appointment, in Montenegro and abroad.

(3) Report referred to in the paragraph 2 of this Article shall be delivered within eight days from the day the request was received.

(4) A proof that the body referred to in paragraph 1 of this Article continuously fulfils the requirements stipulated by the technical regulations is a confirmation on regular or extraordinary supervision from the accreditation procedure.

(5) The competent ministry shall abolish the decision on appointment i.e. authorisation of the body for conformity assessment if the authorised i.e. appointed body for conformity assessment:

- 1) seizes the fulfil the stipulated requirements;
- 2) does not deliver the Report referred to in paragraph 2 of this Article;
- 3) does not act in accordance with the Article 10 paragraph 3 of this Law.

(6) The decision referred to in paragraph 5 of this Article is final and an administrative dispute cannot be initiated against this decision.

The Role of Accreditation

Article 13

(1) The body for conformity assessment that has a certificate of accreditation is considered to have fulfilled all the stipulated requirements to the extent these requirements are entailed in the scope of

Notification about the Body for Conformity Assessment

Article 15

(1) The ministry at the proposal of the competent ministry shall notify the appropriate international organisation about the appointed bodies for conformity assessment.

(2) The manner of notification referred to in paragraph 1 of this Article shall be stipulated by the Ministry.

V. COMPLIANCE OF THE PRODUCTS AND PROTECTIVE CLAUSE

Compliance of the Products

Article 16

The product may be delivered to the market only if it fulfils the technical requirements stipulated by the technical regulations, if its compliance is assessed according to the stipulated procedure, if it is marked in accordance with those regulations and if it has got all the required documents.

Protective Clause

Article 17

If it is established that the products that are in compliance with the technical regulations may endanger the public interest, and particularly the life, the health of people, animals and plants, the environment and property, the competent inspection body shall take measures for withdrawal of such products from the market, i.e. it will prohibit or limit their supply to the market.

VI. OBLIGATIONS OF THE PRODUCT SUPPLIER

Obligations of the Manufacturer

Article 18

When placing the product on the market, the manufacture shall:

- 1) provide that the product is made in accordance with the prescribed requirements that refer to the product;
- 2) conduct or ensure the conformity assessment procedure in accordance with the technical regulation;
- 3) draft the technical documentation and keep it for a specified period of time;
- 4) draft or provide the certificate on conformity in accordance with the technical regulation and keep it for the specified period of time;
- 5) place the conformity mark in accordance with the Article 20 and the Article 21 paragraph 2 of this Law, if that is stipulated by the technical regulation.

Conformity Declaration

Article 19

(1) The manufacturer shall make the conformity declaration when that is stipulated by the technical regulation.

(2) The declaration referred to in paragraph 1 of this Article, shall comprise the elements stipulated by the technical regulations that refer to that product.

- (3) In the declaration referred to in paragraph 1 of this Article it is stated that all the technical requirements from technical regulations that refer to that product are fulfilled.
- (4) The declaration referred to in paragraph 1 of this Article must be made in Montenegrin language.

Conformity Mark

Article 20

- (1) The conformity mark is put on the products that are in compliance with all the technical regulations that apply to them, prior to placement of the product on the market.
- (2) The conformity sign shall not be put on the product for which that mark is not prescribed, and neither on the product that is not in compliance with all the regulations that apply to it.
- (3) If because of the nature of the product it is not possible to put conformity mark on the product or on its name plate, the conformity mark is placed on the package and additional documents if they are anticipated by the regulations.
- (4) It shall be prohibited to put other marks, signs or labels whose content or form might mislead the third parties that it is a conformity mark.
- (5) Other marks may be put on the product, providing they do not diminish the visibility and readability of the conformity mark.

Mandatory Conformity Marks

Article 21

- (1) The conformity marks referred to in Article 20 paragraph 1 of this Law are:
 - 1) "CE" mark,
 - 2) other signs in accordance with the technical regulations.
- (2) The shape, the contents and the features of the conformity mark referred to in paragraph 1 item

(3) If due to the nature of the product (the size or other characteristics of the product) it is not possible to insert the information referred to in paragraph 2 of this Article, the information shall be listed on the package or in the documents that are enclosed with the product.

Representatives

Article 23

(1) The representative shall fulfil the obligations that were delegated to him by the manufacturer through a written authorisation, and they shall particularly:

- 1) keep the conformity declaration in accordance with the technical regulations and keep the technical documentation for the specified time period and present them to the competent inspection body;
- 2) provide all the information and documents necessary for proving the product compliance, at the request of the inspection body
- 3) upon the request of the competent inspection bodies take measures to eliminate the risk that the product presents.

(2) The manufacturer shall not delegate the obligations referred to in the Article 18 item 1 oAre D1gate e the.

Obligations of the Distributer

Article 25

- (1) Prior to delivering the product to the market, the distributer shall check and establish that:
 - the conformity sign is put on the product in accordance with the technical regulation;
 - the prescribed documents are enclosed with the product as well as the other documents and information on the safety of product in accordance with the technical regulation in Montenegrin language;
 - the manufacturer and importer have fulfilled the requirements referred to in Article 22 paragraphs 2 and 3 and Article 27 paragraph 1 line 2 of this Law.
- (2) The distributer shall ensure that the conditions of storage and transport will not endanger the

- (1) The manufacturer and the importer shall, in accordance with the technical regulations, ensure that:
 - 1) the instruction, and other specified technical documentation and information on safety of the product in Montenegrin language are enclosed and in accordance with the technical regulation;
 - 2) on the product, i.e. package or in the enclosed documentation a title i.e. a name of the manufacturer or importer is indicated (registered trade name) or the trademark and the address where the product is available.
- (2) If the product presents a risk, the manufacturer and the importer shall, when needed, test the samples of the products placed on the market, keep the register of complaints, of noncompliant products, withdrawn or recalled products, of taken corrective measures, by order or in cooperation with the competent bodies, with the aim to eliminate the risk that the noncompliant product presents and they shall inform the distributors.

Obligations of the Product Owners

Article 28

The owner of the technically complex product shall conduct regular and extraordinary check-ups of the product with the aim to confirm the safety of the product during its life, in accordance with the technical regulation.

Cases in which the Obligations of the Manufacturer shall apply to the Importers and the Distributors

Article 29

If the importer or the distributor place the product on the market under their name or trademark, i.e. they alter the product, that is already placed on the market, to the extent that affects the compliance of the product with the technical regulations they shall be considered manufacturers and responsible for the obligations referred to in Articles 18, 20, 21 and 22 of this Law.

VII. VALIDITY OF CERTIFICATES AND CONFORMITY MARKS ISSUED ABROAD

Validity of Conformity Certificates issued by a Foreign Body

Article 30

- (1) The conformity certificates issued by a foreign body for conformity assessment and conformity marks issued abroad (hereinafter referred to as: foreign certificates and marks), if issued in accordance with the confirmed international agreements, shall be valid in Montenegro.
- (2) At the request of the supplier or by virtue of the office, the competent ministry may recognise the validity of foreign certificates and conformity marks that confirm the compliance of the product with the foreign technical regulation, providing that the conditions from that regulation ensure at least the same degree of protection of security of life and health of people, animals, plants, environment, protection of consumers and property that are stipulated by the technical regulations in Montenegro.

Manners for Recognising Validity of Conformity Certificates and Marks

Article 31

(1) The act on recognition of conformity certificates and marks referred to in Article 30 paragraph 2

(4) The manner and procedure of notification about technical regulations, standards, regulations for information society services and conformity assessment procedure shall be defined by a Government's ordinance.

**Informing
Article 34**

(1) The ministry shall at the request of the stakeholders and suppliers provide the information and provide:

- the text of the technical regulation that is adopted or proposed in Montenegro;
- list of procedures for conformity assessment that are applied in Montenegro;
- the information about the membership of Montenegro in the international and regional systems for conformity assessment or in the bilateral and multilateral agreements that refer to the technical regulations.

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10) determine destruction of noncompliant products if they present a serious risk for security for lives of people, animals, and plants, as well as for the environmental protection.

(1) Registration of the appointed bodies referred to in Article 15 paragraph 1 of this Law shall be made on the day of accession to the European Union.

(3) Notification referred to in Article 33 of this Law shall be done from the day of accession to the European Union.

In the accession process for the World Trade Organisation, which Montenegro is currently undergoing, the member countries demand from the country that accedes to incorporate into its legislation all the provisions of the appropriate agreements, some even literally. Having in mind that the WTO is "a member driven organisation" a country that accedes must previously meet the requirements of all the member countries, and when that is completed, the country may become a full member. This Law contains all the provisions that are related to the WTO Agreement on Technical Barriers to Trade that establishes the rules and the principles in the field of standardization and technical regulations.

The adoption of law provides a high level of protection of life, health and security of people, animals and plants, and environmental protection, protection of consumers and other users, protection of property, and protection of other public interests, on one hand, and on the other hand it provides the legal framework for stipulating technical requirements, transposing of the EU directives (directives of New and Sectoral approach), that will not create unnecessary barriers for the trade. This can be achieved by organising the market by through stipulating the technical requirements for the products that will ensure that on Montenegrin market only the products that are in compliance with the specified technical requirements are placed i.e. delivered. Furthermore, the Law ensures demonopolisation in the field of quality infrastructure, through authorisation, appointment and registration of the bodies for conformity assessment and provides transparency in the process of adoption of the technical regulations.

After the adoption of the Law, the secondary legislation will establish the procedures in detail, and the competent bodies of Montenegro will act upon them, in accordance with the rules enforced on the common European Union market, which are the obligation of WTO membership and are the best international practice.

The adoption of this law and secondary legislation in the field of technical legislation provides, along with other laws, a high level of legal security for doing business in Montenegro and creation of favourable conditions for foreign investments in the Montenegrin economy, in its development and full acceptance of the market economy model.

III COMPLIANCE WITH THE EUROPEAN LEGISLATION

a) Compliance of draft/proposal of the regulation with the primary sources of the European Union law:

Treaty on the functioning of the EU, Title I, Internal market, article 26

fully harmonized

b) Compliance of draft/proposal of the regulation with the secondary sources of the European Union law

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.08.2008.

partly harmonized

that can be defined by the technical regulations. The technical requirements may be defined by a technical regulation or by referring to the standards. The Article 6 paragraph 1 defines that the technical regulations are adopted by the competent ministries within the scope of their

is issued based on the request of a manufacturer. Prior to adoption of a decision on authorisation/appointment the competent ministry will establish if the body meets the prescribed requirements and it will particularly appreciate the technical competence in the field of accreditation. The Article 12 defines the obligation for reporting on continuous fulfilment of requirements, that the body for conformity assessment is obliged to deliver at the request of the competent ministry, and it also defines the cases in which the competent ministry will abolish the decision on appointment i.e. authorisation. The provisions of Article 13 refer to the role of accreditation for adoption of decisions on authorisation i.e. appointment – the conformity assessment body that has got the certificate on accreditation meets the stipulated requirements to the extent these requirements are encompassed with the scope of accreditation. Furthermore, it is defined that in the conformity assessment procedure, instead of the appointed body, the accredited body of the manufacturer may perform certain activities. Article 14 of the proposal of the Law stipulates that mutual relations of conformity assessment bodies and manufacturers or representatives are defined by a contract. The Article 15 refers to the obligation of Montenegro, to register the appointed conformity assessment bodies in the European Commission, after the accession to the EU.

Compliance of the product and the protective clause (Articles 16- 17)

The Article 17 defines that the product may be delivered to the market if it fulfils the technical

The Articles 30 and 31 define the issues related to recognition of certificates of conformity and conformity marks issued abroad in accordance with international agreements that Montenegro has signed.

Register and notification (Articles 32-34)

The Article 32 refers to the register that is kept by the ministry competent for the affairs of quality infrastructure, and refers to the data that are inserted in the register, while the contents and manner of keeping of register will be defined by a regulation of the ministry.

The Article 33 stipulates that the ministry competent for quality infrastructure conducts the notification procedure in the part that refers to technical regulations, standards, regulations for services of information society and conformity assessment procedures in accordance with the international agreements. When the proposed technical regulation does not have the grounds in the international standard or is not in accordance with it, and when it can have a significant influence on the foreign trade, the competent ministry will inform on the technical regulation in accordance with the obligations that result from the appropriate international agreements.

The provisions of Article 34 stipulate that the ministry competent for quality infrastructure provides information related to the technical regulations and procedures for conformity assessment, in accordance with the obligations resulting from the appropriate international agreements.

Inspection (Article 35)

The Article 35 defines that the supervision of performance of certain provisions from the law will be done by the competent inspections and there are listed authorisations of inspections for taking action in cases of infringements of provisions of this Law.

Penal provisions

The Articles 36 and 37 stipulate the fines for infringements identified in the Law.

Transitional and final provisions (Articles 38-42)

This chapter defines the deadline for adoption of secondary legislation, termination of the existing Law on Technical Requirements for the Products and Conformity Assessment for Products with the Specified Requirements, making the out-dated technical regulations null and void, transitional period for entering into force of the certain Articles that refer to the obligations of Montenegro after the EU accession and the date this Law will come into force.

V ESTIMATION OF FINANCIAL RESOURCES FOR ENFORCEMENT OF LAW

For enforcement of this Law it is not necessary to provide additional budget resources in the Budget of Montenegro for 2011.