

LAW ON TECHNICAL REQUIREMENTS AND CONFORMITY ASSESSMENT OF
PRODUCTS WITH PRESCRIBED REQUIREMENTS

I. GENERAL PROVISIONS

Subject-matter of the Law
Article 1

This Law shall govern the manner of prescribing of technical requirements for products, procedures of conformity assessment of products with prescribed requirements (hereinafter referred to as the: conformity assessment), adoption of technical regulations, register of technical requirements for products originating outside Montenegro than the one applicable to domestic like products.

- (3) The standard processing period for each conformity assessment procedure shall be established by the law or a sub-legal act, and upon request, the applicant shall be informed of the anticipated processing period.
- (4) Products originating from a country signatory of

- 1) "Product" shall mean a result of a process (hardware, software, process material or a service) that was designed, manufactured or obtained in any other manner, regardless of the processing level and is intended for placing in the circulation or use;
- 2) "Technical regulation" shall mean a regulation that contains technical requirements, directly or by reference to Montenegrin standard, technical specification or the rules of practice, or a document that includes their contents, as well as conformity assessment procedures;
- 3) "Technical Requirement" shall mean document that prescribes characteristics of a product or a method of production or processing of such a product, including administrative provisions applicable to the product, that are obligatory and compliance with which is mandatory. Technical requirement may contain or exclusively refer to terminology, symbols, requirements with respect to packaging, marking or labeling, if applicable to a product, method of production or processing;
- 4) "Technical Specification" shall mean a part of the contract that defines technical requirements that products must fulfill;
- 5) "Placing a Product into Circulation" shall mean for the first time selling, offering for sale, or entering into any other commercial transaction involving a product;
- 6) "Use" shall mean the first use of a product by an end-user in Montenegro;
- 7) "Supplier" shall mean the manufacturer, its representative established in Montenegro, importer or any company, other legal person, entrepreneur or other natural person that places a product into circulation or makes it available for use;
- 8) "Conformity Assessment" shall mean any procedure used, directly or indirectly, to determine that prescribed requirements for products are fulfilled;
- 9) "Conformity Assessment Body" shall mean an independent laboratory, certification body, control authority, administration authority or other authority that performs a conformity assessment;
- 10) "Appointing" shall mean a procedure administered by the responsible ministry, for the purpose of assigning responsibility to a laboratory, certification body, control authority or any other subject to perform activities of conformity assessment for suppliers;
- 11) "Authorizing" shall mean a procedure administered by the responsible ministry, for the purpose of assigning responsibility to a conformity assessment body to perform activities of conformity assessment for the needs of state administration;

- 12) "Certificate of Conformity" shall mean a declaration, testing report, certificate or any other document attesting to the conformity of a product with the relevant technical regulation;
- 13) "Conformity Mark" shall mean a mark or indication affixed to a product indicating its compliance with a relevant technical regulation;
- 14) "Notification" shall mean providing to the relevant international organization the information required by international agreements binding on Montenegro, including the notification under the World Trade Organization Agreement on Technical Barriers to Trade;
- 15) "Interested Parties" shall be an interested member or the responsible authority of the member of international organizations, including the World Trade Organization, in accordance with the rules of international agreements.

II. PRESCRIBING TECHNICAL REQUIREMENTS

Responsibility Article 6

- (1) The ministry responsible for adoption of technical regulation (hereinafter referred to as: responsible ministry) shall adopt technical regulation in accordance with the principles established by Article 3 of this Law and in compliance with the obligations arising from bilateral and multilateral agreements on preventing and eliminating barriers to international trade.
- (2) The manner of preparation and adoption of technical regulations shall be governed by a regulation issued by the Government of Montenegro (hereinafter referred to as: the Government).
- (3) Technical regulations shall be published in the "Official Gazette of Montenegro" and shall become effective not earlier than six months after their publication.

Notification Article 7

- (1) Where a proposed technical regulation is not based on or is not in accordance with an international standard, and where such technical regulation may have a significant impact on international trade, the responsible ministry shall:
 - Notify interested parties of commencement of preparation of such a technical regulation, in accordance with the rules of international agreements;
 - At an early appropriate stage, notify interested parties of the products to be covered by the proposed technical regulation, together with an indication of its objectives and rationale;

- (3) The list of adopted technical specifications and the list of specifications that have ceased to apply shall be published in the „Official Gazette of Montenegro“, and the publications shall be available at the responsible ministry.
- (4) The manner of preparation and the basic content of technical specifications shall be prescribed in the regulation issued by the Government.

Article 11

In the course of preparing a technical regulation on the request of the responsible ministry, the Institute for Standardization of Montenegro shall provide information as to whether an appropriate Montenegrin standard exists or is pending adoption, or whether relevant European or international standard exists, the area to be governed by the technical regulation.

Protective Clause Article 12

Where it is determined that products conforming with technical regulations may jeopardize public interest, notably the safety of life, health of humans, animals and plants, environment and property, the responsible ministry shall undertake measures for withdrawing of such products from the market or order prohibition or restriction of their placing on the market and their use, as the case may be.

III. REGISTER OF TECHNICAL REGULATIONS

Article 13

- (1) The Ministry shall maintain the Register of Technical Regulations as a public record.
- (2) The contents and the manner of maintaining the Register of Technical Regulations shall be governed by a regulation issued by the Government.

IV. CONFORMITY ASSESSMENT PROCEDURES

Obligations of the Supplier Article 14

- (1) Technical regulations shall specify the products for which a supplier shall, before placing them into circulation or use:
 - 1) Ensure application of a conformity assessment procedure;
 - 2) Issue or provide a certificate of conformity;
 - 3) Prepare and maintain technical documentation in the prescribed volume, form and deadlines;
 - 4) Mark the products with prescribed conformity marks.

- (2) Conformity assessment procedures may be prescribed directly in technical regulations, or indirectly in standards to which technical regulations refer, or in technical specifications.
- (3) The manner of conformity assessment shall be governed by a regulation issued by the Government.

Methods of Conformity Assessment
Article 15

- (1) A conformity assessment referred to in Article 14, paragraph 2 of this Law may be accomplished by application of one procedure, a number of procedures or appropriate

Conformity Mark
Article 17

- (1) A conformity mark may be placed on products that conform to technical regulations.
- (2) Conformity marks must be placed on product for which an obligation of placing conformity mark has been prescribed.
- (3) Form, content and appearance of the conformity mark shall be governed by a regulation issued by the Government.

V. CONFORMITY ASSESSMENT BODY

Requirements for Conformity Assessment Body
Article 18

A technical regulation shall specify the conditions that must be fulfilled by a relevant conformity assessment body, notably:

- 1) professional competency of personnel;
- 2) equipment;
- 3) independence and impartiality in the conformity assessment procedure;
- 4) safeguard of commercial secrets;
- 5) accountability for the tasks performed;
- 6) other conditions, in accordance with law.

Issuing of a Decision
Article 19

- (1) Responsible ministry shall issue a decision on appointing or authorizing a conformity assessment body, which may be time limited.
- (2) The decision referred to in paragraph 155 Tw (818.4 on 859d. Tw (0004 T)()-5.5(c)5)2(a)4.1(

Article 20

The manner of appointing and authorizing a conformity assessment body and determining the fulfillment of conditions referred to in Article 18 of this Law shall be governed by a regulation issued by the Government.

Register
Article 21

(1) The Ministry shall maintain the Register of Appointed and Authorized Conformity

- order rectifying of determined deficiencies;
 - request marking of products with prescribed marks, or removal of illegal marks, as the case may be;
 - prohibit or restrict placing on the market or order removal from the market of non-conforming products and ensure that such prohibition is abided by;
 - inform the responsible state authority that has adopted the regulation applicable to specific product to take action in accordance with the regulation on mutual information;
 - order destruction of non-conforming products if it is necessary to protect human health and safety.
- (3) If the responsible inspection authority does not have necessary expertise and equipment to perform inspection and testing referred to in paragraph 2 of this Article, some of the activities of inspectorial supervision may be transferred to the institution which is capable of performing them.
- (4) The costs of inspectorial supervision (costs of testing and assessment of conformity of products and other costs related to inspectorial supervision) incurred in connection with

Equivalence
Article 25

- (1) Technical regulations of countries that are signatories to relevant international agreements, including the World Trade Organization Agreement on Technical Barriers to Trade, may be accepted as equivalent, even if these technical regulations differ from technical regulations of Montenegro.
- (2) Conditions for application of technical regulations referred to in paragraph 1 of this Article shall be prescribed by a regulation issued by the Government.

IX. PENAL PROVISIONS

Article 26

- (1) Any company, other legal person or entrepreneur that:
 - 1) places into circulation a product that is not in conformity with the prescribed technical requirements, if the conformity of the product is not assessed in accordance with the prescribed procedure, or if it is not marked in accordance with regulations, or not accompanied by prescribed documents (Article 8);

Article 28

- (1) Technical regulations valid on the day this Law comes into force shall be brought into compliance with this Law within two years from the date this Law comes into force.
- (2) Technical regulations adopted and taken over on the basis of the Law on Standardization ("FRY Official Gazette", No. 30/96, 59/98, 70/01 and 8/03) and the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements ("Official Gazette of Serbia and Montenegro", No. 44/05) shall apply until the adoption of technical regulations in accordance with this Law or other laws.

Article 29

- (1) Regulations for the implementation of this Law shall be adopted within four months as of the date this Law comes into force.
- (2) Until the enactment of regulations referred to in paragraph 1 of this Article, regulations issued under the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements ("Official Gazette of Serbia and Montenegro", No.44/05) shall apply, if they are not in contravention to this Law.

Article 30

On the date this Law becomes effective, the following shall cease to apply: Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements ("Official Gazette of Serbia and Montenegro", No.44/05), Regulation on Determining Authorities that Assume Responsibilities from the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements ("Official Gazette of the Republic of Montenegro", No.56/06) and the Regulation on Fines Prescribed by the Law on Metrology and the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements ("Official Gazette of the Republic of Montenegro", No.52/06), in part related to measures prescribed by the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements.

Article 31

This Law shall come into force on the eighth day after the day of its publication in the "Official Gazette of Montenegro".