

# 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) **distributor** is a legal entity i.e. an entrepreneur with the head office or the place of residence in Montenegro, and who is not a manufacturer or the importer and who is involved in the supply chain i.e. who delivers the product to the market during the pursuance of their activities;

- 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 that meets the requirements stipulated by the technical regulation and which a EU member country or a country that has concluded with the EU an agreement on conformity assessment and acceptance of industrial products (hereinafter referred to as: ACAA), reports to the EU Commission;
- 19) **certificate of conformity** is a declaration of conformity, report on testing, certificate, confirmation or a report on control, or another document that confirms the compliance of the product with the technical regulation;
- 20) **stakeholder** is a stakeholder of the members, i.e. competent body of the international organisations members;
- 21) **recall of product** is a measure aiming to return the product that is already delivered to the end user;
- 22) **withdrawal of product** is a measure aiming to prevent the product from the supply chain to be delivered to the market.

## 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**

(1) It is assumed that a product is in compliance with the technical regulations if it meets the requirements of the standard to which the technical regulation is referring to.

(2) Conformity of the product with the technical requirements is determined in accordance with the technical regulation.

(3) The Institute for Standardisation of Montenegro shall have the obligation, upon request of the competent ministry, to deliver opinion if for the product and/or groups of products there is a defined technical regulation, if there is an appropriate Montenegrin standard or is such standard to be adopted, i.e. is there an appropriate European or international standard.

(4) The list of standards referred to in paragraph 1 of this Article, to which the technical regulation is referring to, is published by the competent ministry in "Official Gazette of Montenegro".

### **III. CONFORMITY ASSESSMENT**

#### **Standardization of Conformity Assessment**

##### **Article 8**

(1) The obligation of conformity assessment for a product is determined by the technical regulation.

(2) Conformity assessment of the product with the technical regulations shall be determined prior to placing the product on the market or putting it in use.

(3) Conformity assessment referred to in paragraph 2 of this Article, in accordance with the technical regulations may perform:

- 1) manufacturer;
- 2) authorised i.e. appointed body for conformity assessment.

#### **Conformity assessment procedures**

##### **Article 9**

(1) The technical regulation or the standard to which the technical regulation is referring to, determines the procedure for a product conformity assessment.

(2) The conformity assessment referred to in paragraph 1 of this Article may be performed by conducting one or more procedures or by an appropriate combination of different procedures in accordance with the technical regulation.

## **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.
- (4) The decision on appointment referred to in paragraph 2 of this Article is issued on the basis of a request by the conformity assessment body that fulfils the requirements stipulated by the technical regulation for performing conformity assessment affairs.
- (5) The competent ministry shall establish whether the technical regulations requirements for conformity assessment affairs are fulfilled, prior to adopting a decision referred to in paragraphs 2 and 3 of this Article.
- (6) In the procedure of establishing the stipulated requirements referred to in the paragraph 5 of this Article, the competent ministry shall also assess the technical competence from the accreditation procedure or another equally important procedure.
- (7) The decision referred to in paragraphs 1 and 2 of this Article shall be issued for the period of four years.

(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 accreditation, when Decision referred to in Article 11 of this Law was adopted.

(2) The technical regulation may stipulate that in the conformity assessment procedures, certain affairs, instead of appointed body, may conduct the body for conformity assessment of the manufacturer that has got the accreditation certificate in accordance with the technical regulation.

### **Mutual relations**

#### **Article 14**

(1) The appointed body for conformity assessment performs the procedures for conformity based on the request of a manufacturer or its representative.

(2) Mutual relations and obligations of the appointed body for conformity assessment and the manufacturer or its representative are defined by a contract.

## **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 1 of this Article, shall be defined by the ordinance of the Government of Montenegro (hereinafter referred to as: the Government).

### **Other Obligations of the Manufacturer**

#### **Article 22**

- (1) The manufacturer shall provide continuous conformity of the product of the serial production, taking into consideration the changes in the making or the changes in product characteristics, as well as the changes in the standards or changes in the technical regulations with which the products comply.
- (2) The manufacturer shall put on the product the type number, batch or series, or another information that enables identification of the product in accordance with the technical regulation.



(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 of this Law to his representative.

### **Obligations of the Importer**

#### **Article 24**

(1) The importer shall place on the market only the product that is in compliance with the technical regulations that apply to that product.

(2) The importer shall guarantee, when the product is being placed on the market, that the manufacturer has conducted the stipulated procedure for conformity assessment, that they have developed the technical documentation, put the conformity mark on the product in accordance with the regulation, that the stipulated documents are enclosed with the product, as well as that the requirements referred to in Article 22, paragraphs 2 and 3 of this Law are met;

(3) The importer shall keep the copy of conformity declaration in accordance with the technical regulation that refers to the product and enable accessibility at the request of the competent inspection bodies.

(4) The importer shall make sure that the storage or transportation conditions do not endanger compliance of the product with the stipulated requirements, until the moment the product is delivered to the market.

(5) If the importer suspects that the product is not in compliance with the technical requirements that are applied to that product, that product may be placed on the market after it is made in compliance with technical requirements.

(6) If the product referred to in paragraph 5 of this Article presents a risk, the importer shall inform the manufacturer and the competent inspection bodies.

## **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 compliance of the product with the stipulated requirements, until the moment the product is delivered to the market.
- (3) If the distributer suspects that the product is not in compliance with the technical requirements applied to the product, they may place that product on the market after it has made it in compliance with the technical requirements.
- (4) If the product referred to in paragraph 3 of this Article presents a risk, the distributer shall inform the manufacturer or the importer as well as the competent inspection bodies.

## **Mutual Obligations of the Manufacturers, Importers and Distributors**

### **Article 26**

- (1) If the manufacturer, importer, or distributer have a reason to doubt that the product that they have placed i.e. delivered to the market is not in compliance with the technical regulations that apply to that product, they shall without delay take measures to comply the product with the stipulated requirements (corrective measures) or to check whether the corrective measures are already taken or to withdraw or recall the product.
- (2) If the product that the manufacturer, the importer or the distributer placed on the market presents the risk they shall without delay inform the competent inspection bodies, particularly about the identified incompliances and taken corrective measures referred to in paragraph 1 of this Article.
- (3) The manufacturer, the importer or the distributer shall, at the request of the competent inspection body:
  - 1) provide all the information and the documents in Montenegrin language necessary for proving the product compliance;
  - 2) monitor carrying out of the corrective measures with the aim to eliminate the risk that the product, that they placed or delivered to the market presents.
- (4) More detailed contents of the information referred to in paragraph 2 of this Article shall be defined by the ordinance of the Ministry.

## **Mutual Obligations of the Manufacturer and Importer**

### **Article 27**

- (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 incompliant 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 incompliant 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 of this Law is adopted on previously obtained opinion of the Ministry.

(2) The manner for recognising the conformity certificates and marks referred to in Article 30 paragraph 2 of this Law shall be defined by the ordinance of the Government.

## VIII. REGISTERS AND NOTIFICATION

### Registers

#### Article 32

(1) The ministry shall keep the register of:

- 1) valid technical regulations and technical regulations that are being drafted;
- 2) appointed i.e. authorised bodies for conformity assessment;
- 3) foreign conformity certificates and marks referred to in the Article 30 paragraphs 1 and 2 of this Law.

(2) The contents and the manner of keeping the registers referred to in paragraph 1 of this Article shall be defined by the ordinance of the Ministry.

### Notification

#### Article 33

(1) When the proposed technical regulation does not have a basis or is not in compliance with the international standards, and it may have a significant influence on the foreign trade, the Ministry shall:

- 1) deliver notification on initiating of drafting of the technical regulation to the stakeholders in accordance with the rules of the international agreements;
- 2) during preparation of the draft of the technical regulation inform the stakeholders on the products to which the proposed technical regulation shall apply, and shall provide them with description of its objectives with an explanation;
- 3) at the request of the stakeholders, provide copies of the proposed technical regulation, and when possible, identify the parts that in essence deviate from the appropriate international standard;
- 4) ensure a reasonable deadline to the stakeholders to deliver the comments and opinions in writing.

(2) the provisions referred to in paragraph 1 of this Article shall not apply when a danger emerges or there is a threat to the security and health of people, animals, plants and environment.

(3) the ministry shall, in cases referred to in paragraph 2 of this Article, after adopting a technical regulation:

- 1) without delay notify the stakeholders about the technical regulation (its objectives, purpose and the nature of the problems);
- 2) provide, at the request of stakeholders, the copies of the technical regulation;
- 3) provide a reasonable deadline for the stakeholders to deliver the comments and opinions in writing, and shall consider the comments and the opinions.

(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.

(2) A fee amounting to the real costs shall be paid for delivery of information and copies of documents referred to in the paragraph 1 of this Article.

(3) The fee referred to in paragraph 2 of this Article shall be the revenue of the Budget of Montenegro

### **IX. INSPECTION**

#### **Article 35**

(1) The inspection of implementation of provisions of this Law and regulations adopted based on this Law, shall be conducted by the competent inspection bodies through the inspectors in accordance with the law.

(2) When conducting the inspection, in addition to the measures that the competent inspector is authorised to take through other regulations, he/she shall have to authorisation to:

- 1) request all the necessary information and the insight into conformity certificates and stipulated technical documentation from the supplier;
- 2) perform appropriate check-ups, take samples of the products and sends them for testing in order to check the compliance of the product with the stipulated technical requirements;
- 3) check if the reviews that confirm the safety of the product during its life had been conducted;
- 4) establish removal of identified incompliances during a foreseen deadline;
- 5) demand that the products are marked with the stipulated conformity marks, i.e. that the prohibited signs are removed;
- 6) determine the measures aiming to provide the conditions for storage and transport of product that will not endanger its compliance with the prescribed requirements;
- 7) limit or prohibit the delivery of product to the market and to take additional measures, in accordance with the law, that will ensure the limitation or prohibition are adhered;
- 8) determine withdrawal or recall of the products that are not in compliance with the prescribed requirements;
- 9) notify the competent ministry that has adopted the technical regulation that refers to the certain product in order to take appropriate measures;

- 10) determine destruction of non-compliant products if they present a serious risk for security for lives of people, animals, and plants, as well as for the environmental protection.
- (3) The competent inspector in performing the inspection is authorised to check the business premises and facilities of the supplier and owner.
- (4) If the competent inspection body does not have the necessary expert knowledge or equipment for checking or testing referred to in paragraph 2 of this Article, it may delegate the check-ups and tests to an appropriate body for conformity assessment.
- (5) The costs for checkups and tests for product compliance, as well as other costs that emerge during the inspection, shall be paid by the supplier if it is determined that the product is not in compliance with the prescribed requirements.
- (6) A complaint against the decision, that inspector issued for enforcement of measures referred to in paragraph 2. of this Article, shall not delay the enforcement of the decision.

## **X. PENAL PROVISIONS**

### **Article 36**

A legal entity shall be punished with a fine amounting between 2.000 and 20.000 euro for an infringement if it:

- 1) does not ensure making of the product in accordance with the specified requirements (Article 18 paragraph 1 line 1);
- 2) does not perform or ensure performance of conformity assessment procedure in accordance with the technical regulation (Article 18 paragraph 1 line 2);
- 3) does not develop technical documentation or does not keep in the specified time period (Article 18 paragraph 1 line 3);
- 4) does not develop or obtain a conformity certificate in accordance with the technical regulation and does not keep them in the specified time period (Article 18 paragraph 1 line 4);
- 5) does not put the conformity mark when that is stipulated in accordance with the Article 20 and Article 21, paragraph 2 of this law (Article 18 paragraph 1 line 5);
- 6) does not make the label on the product conformity (Article 19 paragraphs 1 and 2);
- 7) does not ensure that there are elements that enable identification (number of type, batch, series, etc.) on the product, on the package or in the other documents, in accordance with the technical regulation (Article 22 paragraphs 2 and 3);
- 8) does not meet the obligations that have been delegated to them by the manufacturer through a written authorisation, and which are stipulated in the authorisation in accordance with the Article 23 paragraph 1;
- 9) places on the market a product that is not in compliance with the technical regulations (Article 24 paragraph 1);
- 10) does not act in accordance with the Article 24 paragraph 2;
- 11) does not keep the copies of the conformity certificate and does not present it to the competent inspection bodies at their request (Article 24 paragraph 3);

- 12) does not ensure that the storage and transportation conditions do not endanger compliance of the product with the specified requirements up to the moment of delivery to the market (Article 24 paragraph 4 and Article 25 paragraph 2);
- 13) places or delivers to the market a product for which they suspect is incompliant with the technical requirements, before making the product compliant with the technical requirements (Article 24 paragraph 5 and Article 25 paragraph 3);
- 14) does not act in accordance with the Article 24 paragraph 6;
- 15) does not act in accordance with the Article 25 paragraph 4;
- 16) did not identify that the product is compliant with the technical regulations (Article 25 paragraph 1);
- 17) does not act in accordance with the Article 26;
- 18) does not ensure that the specified documentation is enclosed with the product (Article 27 paragraph 1 line 1)
- 19) does not ensure that on the product, on the package or in the enclosed documents there are the information referred to in the Article 27 paragraph 1 line 2.;
- 20) does not act in accordance with the Article 27 paragraph 2;
- 21) does not act in accordance with the Article 28;
- 22) does not act in accordance with the Article 29.

(2) For the infringement referred to in paragraph 1 of this Article, a responsible person in the legal entity and natural person shall be punished with a fine amounting between 500 and 4.000 euro.

(3) For the infringement referred to in paragraph 1 of this Article, an entrepreneur shall be punished with a fine amounting between 2.000 and 12.000 euro.

#### **Article 37**

- (1) In case it fails to act in accordance with the Article 10, paragraph 3, a legal entity shall be punished for infringement with a fine amounting between 2.000 and 20.000 euro.
- (2) For the infringement referred to in paragraph 1 of this Article, a responsible person in the legal entity shall be punished with a fine amounting between 1.000 and 4.000 euro.

### **XI. TRANSITIONAL AND FINAL PROVISIONS**

#### **Secondary Legislation**

##### **Article 38**

(1) The secondary legislation for enforcement of this Law shall be adopted within one year from the day this Law comes into force.

(2) Before the regulations referred to in paragraph 1 of this Article are adopted, the regulations adopted on the basis of the Law on Technical Requirements for Products and Conformity Assessment of Products with the Specified Requirements shall be applied ("Official Gazette of Montenegro", Number 14/08).

#### **Initiation of Registration of the Appointed Bodies**

##### **Article 39**

(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.

### **Termination of Validity of the Law**

#### **Article 40**

On the day this Law comes into force, the Law on Technical Requirements for Products and Conformity Assessment of Products shall become null and void ("Official Gazette of Montenegro", Number 14/08).

### **Coming into Force**

#### **Article 41**

This Law shall come into force on the eight day from the day of publishing in the "Official Gazette of Montenegro".

## **EXPLANATION**

### **I. CONSTITUTIONAL GROUNDS FOR ADOPTION OF LAW ON TECHNICAL REQUIREMENTS FOR PRODUCTS AND CONFORMITY ASSESSMENT**

The constitutional grounds for adoption of Law on Technical Requirements for Products and Conformity Assessment can be found in Article 16, paragraph 1, item 5 of the Constitution of Montenegro, which stipulates that the Law, in accordance with the Constitution, defined the matters of interest for Montenegro.

### **II. REASONS FOR ADOPTION OF LAW**

In 2008 Montenegro adopted the Law on Technical Requirements for Products and Compliance Assessment of Products with the specified requirements ("Official Gazette of Montenegro", number 14/08) that will be made null and void with this Law. The main reason for adoption of a new law in this field is a „New package of measures for improvement of trade of products“. The European Commission that the EU is using to create new harmonisation in the field of market surveillance, accreditation and the technical legislation as a whole. The proposal of the new law encompasses the measures that are harmonised in this package.

The obligation of harmonising laws, other regulations and general acts with the legal order of the European Union (*acquis communautaire*) in the accession process of Montenegro, results from the Stabilisation and Association Agreement between the European communities and their member countries, on one side and Montenegro on the other side. Furthermore, the adoption of the new Law on Technical Requirements for the Products and Conformity Assessment is anticipated in the National Programme for Integration of Montenegro into EU and the working programme of the Government of Montenegro for 2011.



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**

Decision (EC) No 768/2008 of the European Parliament and of the Council of 9 July 2008 on a Common Framework for the marketing of products and repealing Decision (EEC) No 93/465, OJ L 218, 13.08.2008.

**partly harmonized**

c) Compliance of draft/proposal of the regulation with the other sources of the European Union law  
There is no source of the EU law of this kind, that the proposal of the regulation could be compared with for the purpose of establishing the level of its compliance.

#### **IV EXPLANATION OF THE BASIC LEGAL INSTITUTES**

The proposal of the law on technical requirements for the products and conformity assessment contains the provisions that stipulate in more detail the prescribing of the technical requirements for the products and conformity assessment, and they are divided into eleven chapters: Basic Provisions, Technical Requirements for the Products and Technical Regulations, Conformity Assessment, Conformity Assessment Bodies, Compliance of the Product and the Protective Clause, Obligations of the Product supplier, Validity of Certificates and Conformity Marks issued Abroad, Informing and Notification, Inspection, Penal Provisions and Transitional and Final Provisions.

##### **General provisions (Articles 1-3)**

The provisions from Articles 1-3 of the proposal of Law define the subject, the scope of application and meaning of certain expressions used in this Law. This Law stipulates the technical requirement for the products, conformity assessment of the products with the stipulated requirements, obligations of the product supplier, validity of conformity certificates and marks issued abroad, notifications about the technical regulations and conformity assessment procedures. As regards the application, it is necessary to emphasise that this Law presents an umbrella law for defining technical requirements, but the technical requirements may be defined also by the special laws for certain product groups.

If the certain technical requirements are stipulated based on the special laws, and if those laws do not define matters that refer to the appointment i.e. authorisation of bodies for conformity assessment, and conformity certificates and marks issued abroad, the provisions of this Law shall apply. The provisions of this Law that refer to registration of the appointed bodies for conformity assessment, keeping of register, notification about technical regulations, standards, procedures for conformity assessment in accordance with the international obligations, will be applied also to for the products whose technical requirements are defined by the special laws.

In Article 3 of the proposal of law that deals with the terminology and expressions used in this Law, the definitions from the referent EU documents have been used, with necessary amendments and adaptations to the contents and needs of this Law.

##### **Technical requirements and technical regulations (Articles 4-7)**

Articles 4-7 of the proposal of the law refer to the specifying i.e. establishment of the technical requirements, purposes for adoption of technical regulations, as well as to the possible elements

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 competencies. Furthermore, in this Article the principles for adoption of technical regulations that must be taken into consideration are listed, in order to avoid the unnecessary barriers in the trade.

The Article 7 of the proposal of law defines the assumption of compliance, it is assumed that the product is compliant, if it corresponds to the requirements of the standard to which the technical regulation is referring to, but the compliance of a product can also be established in a different way. Moreover, this Article stipulates the obligation of the Institute for Standardization to deliver the list of standards that refer to the product group at the request of the competent ministry. This Article also stipulates the obligation of the competent ministries to publish the list of Montenegrin standards to which this regulation is referring to.

### **Conformity assessment (Articles 8-9)**

The provisions of Article 8 define that the obligation of conformity assessment of a product is stipulated by the technical regulation. After the technical requirements for products are established it is necessary to establish the conformity assessment procedures, as well as the entities that will conduct or take part in conformity assessment. The conformity assessment is conducted before the product is placed on the market or put in use, and conformity assessment may conduct the manufacturer or the authorised, i.e. appointed body for compliance assessment. The Article 9 defines that the procedures of conformity assessment are stipulated by the technical regulations for products or groups of products, and that for conformity assessment one or more procedures, or combinations of different procedures may be used, in accordance with the technical regulations.

### **Conformity assessment bodies (Articles 10- 15)**

The Articles 10-15 define the requirements for the conformity assessment bodies, the manner of authorisation and appointment, obligations of the authorised, i.e. appointed conformity assessment bodies, the role of accreditation, mutual relations, registration of bodies for conformity assessment. The Article 10 of the proposal of law defines the minimum requirements for conformity assessment bodies, while the special technical regulation may stipulate the specific requirements for those bodies. Also, the Article 10 paragraph 3 defines that the body for conformity assessment cannot be the supplier for the products they are assessing, nor they can be involved directly into design, production or make, placement on the market and/or management, installation, use or maintenance of those products.

The Article 11 of the proposal of the law defines the manner for authorising i.e. appointment of conformity assessment bodies. This Article defines that the conformity assessment body may perform conformity assessment tasks, if it meets the requirements specified by the technical regulation. For the needs of the public administration bodies, the body that meets the specified requirements performs the conformity assessment tasks based on the decision on authorisation (sectoral approach: cosmetic products, chemicals, etc.), while for the needs of the manufacturers, the conformity assessment body that meets the specified requirements performs the conformity assessment tasks based on the decision on appointment. The decision on authorisation is issued on the basis of a public call initiated by the competent ministry, while the decision on appointment

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 requirements defined by the technical regulations, if its compliance is assessed in accordance with the specified procedure, if it is marked in accordance with those regulations and if the specified certificates are enclosed, while the Article 18 defines that if established that the product that are in compliance with the technical regulations may endanger the health and/or safety of users or other persons, the competent ministry shall take measures for withdrawal of such products of the market, i.e. for prohibition or limitation of their placement on the market or their use.

#### **Obligations of the supplier (Articles 18-29)**

In the meaning of this Law, the supplier is considered to be a manufacturer, representative, importer and distributor. In this chapter there are defined obligations of all the entities that place or deliver the products to the market. Furthermore, the obligations of the owners of the product, when it comes to products in use, are also entailed here. This opens the possibility to use regular or extraordinary reviews to check if the product is meeting the requirements related to the safety, during its life.

The Articles 20 and 21 refer to the mark or marks of conformity that must be placed on the product, which is defined by the special regulations, the mark must be placed on the product before the product is placed on the market, and that conformity mark must not be put on the products for which the regulations do not stipulate that. Moreover, if it is not possible to put the mark on the product, the mark must be put on the package and in the enclosed documents, if for such products is necessary to enclose the documents. Putting the marks or inscriptions on the products that might mislead the consumers to believe those are conformity marks is prohibited. The Article 11 defines the mandatory conformity marks in Montenegro, and stipulates that the secondary legislation will define the shape, contents and appearance of the mark(s) of conformity.

#### **Validity of certificates and marks of conformity issued abroad (Articles 30-31)**

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.