

## **PROPOSAL**

On the basis of Article 14 paragraph 3, 15 paragraph 3, 17 paragraph 3, 20 and 21 paragraph 2 of the Law on Technical Requirements for Products and Conformity Assessment of Products with Prescribed Requirements («Official Gazette of Montenegro», No. 14/08), the Government of Montenegro on the meeting held on \_\_\_\_\_2008 passed the following

### **DECREE ON MANNER AND PROCEDURES OF ASSESSMENT OF CONFORMITY OF PRODUCTS WITH PRESCRIBED REQUIREMENTS**

#### **I BASIC PROVISION**

##### **Article 1**

This Decree shall govern manner and procedures of conformity assessment of products with prescribed requirements, form, content and appearance of conformity marks, supervision of fulfillment of conditions that must be met by conformity assessment bodies, the procedures of appointing and authorizing, and content and manner of keeping the register.

#### **II MANNER AND PROCEDURES OF CONFORMITY ASSESSMENT**

##### **Conformity Assessment Methods**

##### **Article 2**

(1) Assessment of conformity of products with the prescribed requirements shall be conducted on the basis of:

- 1) self-assessment,
- 2) testing of type in accordance with EC (European Commission),
- 3) type conformity,
- 4) providing the quality of production,
- 5) providing the quality of the product,
- 6) verification of the product,
- 7) individual verification,
- 8) providing of comprehensive quality.

(2) Methods referred to in paragraph 1 of this Article (hereinafter referred to as: conformity assessment methods) shall be applied separately or combined in accordance with the technical regulation in question.

##### **Criteria for Selecting the Conformity Assessment Method**

##### **Article 3**

(1) Conformity assessment methods shall be specified in line with the technical regulation according to:

- 1) type of the product,
- 2) level of risk that may be caused by the product,

- 3) need for conformity assessment of the product by the third party,
- 4) choice of the producer regarding providing the quality of the production of the product,
- 5) selecting adequate methods corresponding to the recognized risks in accordance with the technical regulation.

(2) Where several technical regulations apply to one product, conformity assessment must be coherent.

### **III OBLIGATIONS OF SUPPLIER**

#### **Statement on Conformity**

##### **Article 4**

Where technical regulation prescribes that the producer undertakes the responsibility for fulfillment of requirements related to the product through a statement, such statement should contain all data connected to the technical regulations in question.

##### **Article 5**

(1) By issuing the statement, the producer shall undertake responsibility for conformity of the product.

(2) The statement shall be issued in accordance with the form enclosed in Annex 1 of this Decree, unless specified otherwise in the technical regulation.

#### **Obligations of Producers**

##### **Article 6**

(1) Producer shall specify its contact details on the product, as well as the type, series or serial number or any other mark for the purpose of their identification. If such is not possible due to size or nature of the product, data must be contained on the package or in the document accompanying goods.

(2) Producer shall keep technical documentation and statement after the product has been placed on the market for the period specified in the technical regulation.

### **IV CONFORMITY MARKS**

#### **Prescribing Conformity Marks**

##### **Article 7**

The obligation to mark the product shall be prescribed in the technical regulation in a manner that the fulfillment of prescribed requirements is indicated by conformity marks:

- 1) "CE" mark,
- 2) homologation mark for parts of motor vehicles "E",
- 3) other marks in accordance with technical regulation.

## **General Principles for Placing CE Mark**

### **Article 8**

CE mark shall be placed by the producer or its representative.

### **Article 9**

(1) CE mark shall be placed prior to placing the product on the market. It may be accompanied by the pictogram (picture sign) or any other mark indicating special risk or use.

(2) CE mark shall be placed on the visible place in a manner to stay permanently on the product and that it can not be damaged.

(3) If it is not possible to place the CE mark directly on the product due to the nature of the product, CE mark shall be placed on the package or documents accompanying the product, if the technical regulation in question provides for such documents.

### **Article 10**

CE mark shall be printed in Annex 2 of this Decree and represent integral part thereof.

## **General Principles for Placing Homologation Mark E**

### **Article 11**

Mark "E" for homologation of parts of motor vehicle shall be placed on the product in accordance with rules contained in technical regulations on homologation of vehicles or with rules contained in technical specifications referred to in technical regulations.

## **Other Mandatory Conformity Marks**

### **Article 12**

Technical regulations shall define rules related to the placement of other mandatory conformity marks.

## **V MANNER OF APPOINTING AND AUTHORIZING CONFORMITY ASSESSMENT BODIES**

### **Procedure for Appointing Bodies**

#### **Article 13**

(1) The procedure for appointing body shall be initiated by submitting the written request by the body in order to obtain a decision on appointing.

(2) The request referred to in paragraph 1 of this Article shall be submitted to the ministry that adopted the relevant technical regulation (hereinafter referred to as: the responsible ministry).

#### **Article 14**

The request referred to in Article 13 of this Decree shall contain in particular:

- 1) data on the applicant (name of the body and address, legal status, data on technical and personnel capacities and the like);
- 2) proof of registration with the Commercial Court;

- 3) title of the technical regulation to which the request refers to;
- 4) data on the area of conformity assessment (hereinafter referred to as: the area), scope of the appointing (hereinafter referred to as: the scope), as well as the types of products for which the request for appointing is submitted;
- 5) accreditation paper or other documentation that demonstrates the technical competence and other conditions prescribed by the relevant technical regulation.

#### **Article 15**

The Commission appointed by the minister of the responsible ministry (hereinafter referred to as: the responsible minister) shall determine the fulfillment of conditions for appointing conformity assessment bodies referred to in Article 13 of this Decree.

#### **Article 16**

Commission referred to in Article 15 of this Decree shall assess the need for additional control of conditions after considering the received request and documentation referred to in Article 14 of this Decree.

#### **Article 17**

The responsible ministry shall issue a decision on appointing on the basis of the facts determined in the procedure and on the basis of proposal of the Commission.

### **Decision on Appointing**

#### **Article 18**

- (1) Decision on appointing shall contain in particular:
  - 1) name and identification number of the appointed body;
  - 2) title of the technical regulation to which the decision refers to;
  - 3) area, scope and types of products to which the decision refers to;
  - 4) validity period of the decision;
  - 5) and other data relevant for the conformity assessment area.
- (2) Decision on appointing shall be issued for the validity period of the accreditation paper.
- (3) Decision on appointing shall be entered in the register referred to in Article 19 of this Decree upon request of the responsible ministry.

### **Register of Appointed Bodies**

#### **Article 19**

The ministry responsible for quality infrastructure (hereinafter referred to as: the Ministry) shall keep the Register of Appointed Bodies (hereinafter referred to as: the Register), which must contain:

- 1) identification number of the appointed body, name of the appointed body, corporate domicile, address and other data;
- 2) title of the technical regulation based on which the body has been appointed;
- 3) area, scope and types of products to which the appointing refers to;
- 4) number and date of the decision on appointing.

## **Abolishing of the Decision on Appointing**

### **Article 20**

(1) Decision on appointing shall be abolished if the appointed body ceases to meet the conditions referred to in Article 14 of this Decree, responsible minister shall issue a decision on abolishing of the decision on appointing of the body and deletion from the Register of Appointed Bodies.

(2) The responsible minister shall also issue a decision on abolishing of the decision on appointing of the body and deletion from the Register of Appointed Bodies where the appointed body informs the responsible ministry that it is can no longer perform tasks specified in the decision on appointing.

(3) The responsible ministry shall forward the copy of the decision on abolishing of the decision on appointing of the body and deletion from the Register with the notification to the Ministry for the purpose of deleting from the register.

## **Notification of the Appointed Body**

### **Article 21**

The Ministry shall notify the appointed body to the relevant international organization if such is provided for in the international agreement.

## **Manner of Authorizing Bodies**

### **Article 22**

(1) The procedure for authorizing bodies shall be initiated in accordance with the needs of the responsible ministry, which shall publish the public invitation.

(2) The public invitation shall contain:

- 1) title of the technical regulation to which the public invitation refers to,
- 2) area and scope of authorization and types of products,
- 3) number of necessary conformity assessment bodies,
- 4) conditions that should be met by applicants,
- 5) time limit for submitting the request.

(3) Bodies shall submit request for obtaining a decision on authorization on the basis of the public invitation referred to in paragraph 1 of this Article.

### **Article 23**

The provisions of Articles 14 to 20 shall apply *mutatis mutandis* to the procedure of authorization, decision on authorization and entry in the register.

## **VI TRANSITIONAL AND FINAL PROVISIONS**

### **Article 24**

Marking with CE mark as provided in Articles 8, 9 and 10 of this Decree shall apply in Montenegro from the day of signing the international agreement binding Montenegro to apply CE mark.

### **Article 25**

On the day of coming into force of this Decree, the Decree on the Manner of Authorizing Conformity Assessment Bodies, the Register of Authorized Conformity Assessment Bodies, Records on Certificates of Conformity, Conformity Marks and Conformity Assessment Bodies, and the Conditions for Application of Technical Regulations of Other Countries ("Serbia and Montenegro Official Gazette", No. 22/06) and the Decree on the Manner and Procedures of Conformity Assessment ("Serbia and Montenegro Official Gazette", No. 22/06) shall cease to apply, except in part related to the recognition of technical regulations of other countries.

### **Article 26**

This Decree shall come into force on the eighth day from the day of its publishing in the "Official Gazette of Montenegro".

**STATEMENT ON CONFORMITY**

**(1) Number:** \_\_\_\_\_

**(2) Name of supplier:** \_\_\_\_\_

**Street and number:** \_\_\_\_\_

**City:** \_\_\_\_\_

**Telephone number:** \_\_\_\_\_

**Fax:** \_\_\_\_\_

**Name and surname of responsible person:** \_\_\_\_\_

**(3) Certificate from court register and number:** \_\_\_\_\_

**(4) Name of the product:** \_\_\_\_\_

**Quantity:** \_\_\_\_\_

**Number of shipping document and date and/or number of customs declaration and date:**\* \_\_\_\_\_  
\_\_\_\_\_

**(5) Country of production:**\* \_\_\_\_\_

**(6) Testing report:**\*\* \_\_\_\_\_

**Number and date of testing report:**\*\* \_\_\_\_\_

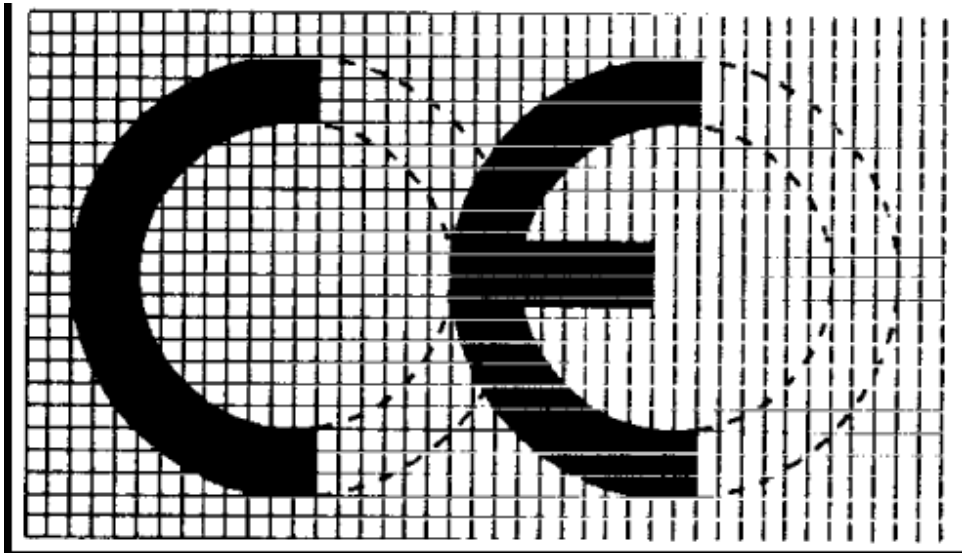
**(7) I state with full responsibility that the product from item 4, in the entire quantity specified in item 4, is safe for use and compliant with declared characteristics.**

**Responsible person:**

\_\_\_\_\_  
**(signature)**

\*only for importer or distributor  
\*\* only for the imported product

## ANNEX 2



If CE mark is reduced or increased, the proportions specified in the drawing rendered above must be observed. If the technical regulation does not prescribe dimensions, CE mark shall be at least 5 mm high.

CE mark shall be accompanied with the identification number of the conformity assessment body if such body participates in the production control stage. Identification number of such body shall be placed by the body itself or by the producer or its representative according to the instructions of the body.