

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 30 October 2008 has adopted the following

## **DECREE ON MANNER AND PROCEDURES OF ASSESSMENT OF CONFORMITY OF PRODUCTS WITH PRESCRIBED REQUIREMENTS<sup>1</sup>**

### **Subject –matter of the Decree**

#### **Article 1**

This Decree shall govern manner and procedures of conformity assessment of products with prescribed requirements, form, content and appearance of conformity marks, , the procedures of appointing and authorizing of conformity assessment bodies, and content and manner of keeping the register.

### **The Manner and the Procedures for the Conformity Assessment**

#### **Article 2**

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

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<sup>1</sup> Published in the Official Gazette of Montenegro No.71/08 on 21 November 2008

- 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.

#### **Article 4**

(1) Conformity assessment of products with the prescribed requirements shall be performed upon the application for the conformity assessment, which shall be submitted to the conformity assessment body.

(2) The application referred to in paragraph 1 of this Article shall include the following:

- 1) name or the corporate name of the applicant;
- 2) the name of the person representing the applicant;
- 3) the field and extent of the subject of the assessment;
- 4) title of the technical regulation setting the requirements.

(3) Attached to the application referred to in paragraph 2 of this Article shall be the proof of payment of costs for the conformity assessment.

#### **Article 5**

If the conformity assessment body determines that the product conforms to the technical regulation, it shall issue a document on conformity of the product with prescribed technical requirements.

#### **Article 6**

(1) A document referred to in Article 5 of this Decree, which certifies that the product conforms to the technical requirements shall be any of the following: certificate, report on examination of the product or declaration of conformity.

(2) The certificate and the report on examination of the product referred to in paragraph 1 of this Article shall be issued by the by the conformity assessment body.

### **Article 7**

Declaration of conformity shall be a document issued by the manufacturer or supplier, certifying that:

- 1) the manufacturer or supplier, as the case may be, performs control over all the activities that influence the safety of products;
- 2) it has appropriate documentation on examination, which, without any doubt, confirms the conformity of a product with technical requirements; and
- 3) the manufacturer or supplier, as the case may be, assumes responsibility for the safety of the product.

### **Article 8**

Declaration referred to in Article 7 of this Decree shall also include the following:

- 1) name or the corporate name, address and the corporate domicile of the person issuing a declaration;
- 2) identity of the subject of the declaration;
- 3) technical regulation to which the declaration refers;
- 4) number and the date of issuing of the examination report;
- 5) name of the state where the product was manufactured;
- 6) the place and the date of issuance and the signature of the person issuing the declaration.

## **Obligations of the Manufacturer**

### **Article 9**

- (1) The product that conforms to prescribed technical requirements must contain the type, series or a serial number, as well as any other information in accordance with the technical regulation, necessary for its identification.
- (2) The information referred to in paragraph 1 of this Article shall embossed in the product.
- (3) If, due to the nature of the product, it is not possible to emboss the information referred to in paragraph 1 of this Article, the information shall be included on the package in in the document accompanying the product.

## **Mandatory Conformity Marks**

### **Article 10**

Before placing it in the market or in use, the product that conforms to prescribed technical requirements shall be marked by the conformity mark:

- 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 11**

- (1) CE mark shall be placed by the producer or supplier, as the case may be.
- (2) The mark referred to in paragraph 1 of this Article may be accompanied by the pictogram (picture sign) or any other mark indicating special risk.
- (3) CE mark shall be placed on the visible place in a manner allowing it to stay permanently on the product and preventing it to be damaged.
- (4) 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 in accordance with the technical regulation.
- (5) CE mark shall be printed in **Annex 1** of this Decree and shall be integral part thereof.

### **Article 12**

- (1) Mark "E" for homologation of parts of motor vehicle shall be placed on the product in accordance with rules contained in technical regulations if so provided by technical regulations.
- (2) Other conformity marks shall be placed on the product in accordance with the technical regulation.

## **Procedure for Appointing Bodies**

### **Article 13**

- (1) The procedure for appointing body shall be initiated by submitting an application.

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

#### **Article 14**

- (1) The application 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) title of the technical regulation to which the application refers to;
  - 3) 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;
- (2) Attached to the application referred to in paragraph 1 of this Article shall be the accreditation paper or other documentation that demonstrates the technical competence and other conditions prescribed by the relevant technical regulation and the proof of registration in the Central Register of the Commercial Court.

#### **Article 15**

- (1) The Commission appointed by the minister of the responsible ministry shall determine the fulfillment of conditions for appointing conformity assessment bodies referred to in Article 13 of this Decree.
- (2) The Commission referred to in paragraph 1 of this Article shall determine whether the applicant fulfils the conditions for appointment based on the document submitted and the facts established.
- (3) The conformity assessment body shall be appointed by the decision issued by the responsible ministry, upon the proposal of the Commission referred to in paragraph 1 of this Article.

#### **Article 16**

- (1) Decision on appointing of the conformity assessment body 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; and
  - 5) any 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 communicated to the ministry responsible for the quality infrastructure (hereinafter referred to as: the Ministry) for the purpose of registering it in the register referred to in Article 17 of this Decree.

### **Register of Appointed Conformity Assessment Bodies**

#### **Article 17**

The Ministry shall maintain the Register of Appointed Bodies (hereinafter referred to as: the Register), which shall contain, in particular:

- 1) identification number of the appointed body, name of the appointed body, corporate domicile and address;
- 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.

### **Notification of the Appointed Body**

#### **Article 18**

The Ministry shall notify the appointed body to the relevant international organization in accordance with the international agreement.

### **Manner of Authorizing Bodies**

#### **Article 19**

- (1) The authorizing of bodies shall be performed upon 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, and
  - 6) the documentation that should be submitted with the application.
- (3) Public invitation referred to in paragraph 1 of this Article shall be made by the Ministry.

## **Article 20**

- (1) Public invitation procedure shall be administered by the Commission for the Administration of the Public Invitation (hereinafter referred to as: the Commission), appointed by the responsible minister, which shall determine fulfillment of conditions for authorization of conformity assessment bodies.
- (2) The conformity assessment body shall be authorized by the decision issued by the responsible ministry, upon the proposal of the Commission referred to in paragraph 1 of this Article.

## **Article 21**

- (1) Decision on authorizing of the conformity assessment body shall contain in particular:
  - 1) name and identification number of the authorized 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; and
  - 5) any other data relevant for the conformity assessment area.
- (2) The decision on authorization of the conformity assessment body shall be issued for the validity period of the accreditation paper.
- (3) Decision on authorizing of the conformity assessment body shall be communicated to the Ministry for the purpose of registering it.

## **Article 22**

The Ministry shall maintain the Register of Authorized Bodies, which shall contain, in particular:

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

## **Final Provision**

### **Article 23**

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

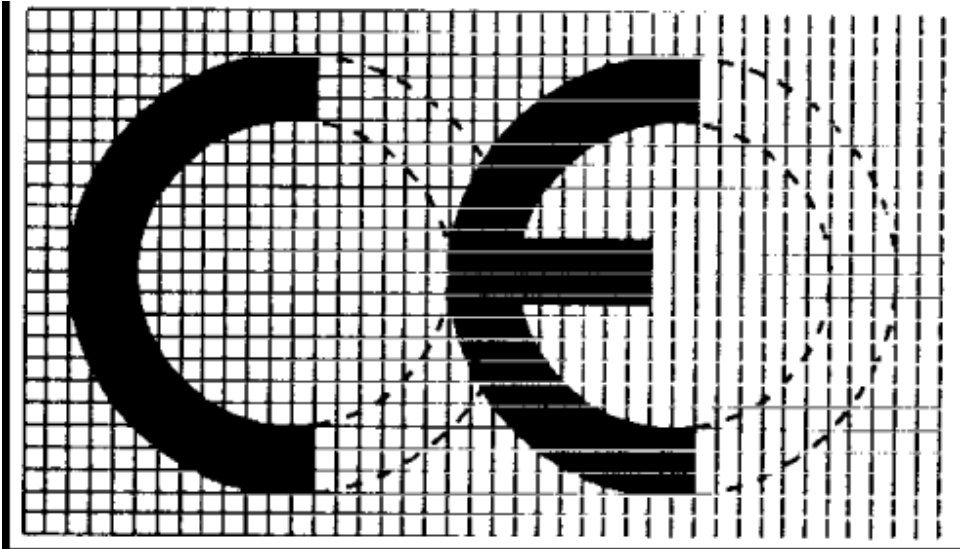
Conformity Assessment ("Serbia and Montenegro Official Gazette", No. 22/06) shall cease to apply.

#### **Article 24**

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



## ANNEX 1



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.