

Pursuant to Article 6 § 1 of the Law on technical requirements and conformity assessment of products with prescribed requirements (*Official Gazette of Montenegro*, No. 12/08) and Decree on the manner of preparation and adoption of technical regulations and technical specifications and register of technical regulations (*Official Gazette of Montenegro*, No. 55/08), the Ministry of Maritime Affairs, Transportation and Telecommunications, issues the following

## REGULATION ON ELECTROMAGNETIC COMPATIBILITY

### CHAPTER I

#### GENERAL PROVISIONS

##### *Article 1*

##### **Subject matter and scope**

1. This Regulation regulates requirements of the electromagnetic compatibility, which must meet electrical and other technical equipment which has been manufactured, imported and placed on the market of Montenegro and presents technical regulations pursuant Decree on the manner of preparation and adoption of technical regulations and technical specifications and register of technical regulations (*Official Gazette of Montenegro*, No. 55/08). This Regulation It aims to ensure the functioning of the internal market by requiring equipment to comply with an adequate level of electromagnetic compatibility. This Regulation applies to equipment as defined in Article 2.

This regulations applies on the all equipment which is able to make electromagnetic disturbance and/or products which can be affected by interference.

2. This Regulation shall not apply to:

(a) equipment covered by Regulation which regulate R&TTE;

(b) aeronautical products, parts and appliances in the field of civil aviation;

(c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution and Convention of the ITU , unless the equipment is available commercially. Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

3. This Regulation shall not apply to equipment the inherent nature of the physical characteristics of which is such that:

(a) it is incapable of generating or contributing to electromagnetic emissions which exceed a level allowing radio and telecommunication equipment and other equipment to operate as intended; and

(b) it will operate without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use.

4. Where, for the equipment referred to in paragraph 1, the essential requirements referred to in Annex I are wholly or partly laid down more specifically by other Regulations, this Regulation shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those Regulations.

5. This Regulation shall not affect the application legislation regulating the safety of equipment.

## *Article 2*

### **Definitions**

1. For the purposes of this Regulation, the following definitions shall apply:

(a) 'equipment' means any apparatus or fixed installation;

(b) 'apparatus' means any finished appliance or combination thereof made commercially available as a single functional unit, intended for the end user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

(c) 'fixed installation' means a particular combination of several types of apparatus and, where applicable, other devices, which are assembled, installed and intended to be used permanently at a predefined location;

(d) 'electromagnetic compatibility' means the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment;

(e) 'electromagnetic disturbance' means any electromagnetic phenomenon which may degrade the performance of equipment. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself;

(f) 'immunity' means the ability of equipment to perform as intended without degradation in the presence of an electromagnetic disturbance;

(g) 'safety purposes' means the purposes of safeguarding human life or property;

(h) 'electromagnetic environment' means all electromagnetic phenomena observable in a given location.

j) "Ministry" means ministry responsible for electronic communications

2. For the purposes of this Regulation the following shall be deemed to be an apparatus within the meaning of paragraph 1(b):

(a) 'components' or 'sub-assemblies' intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;

(b) 'mobile installations' defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations.

### *Article 3*

#### **Placing on the market and/or putting into service**

Equipment can be placed on the market and/or put into service only if it complies with the requirements of this Regulation when properly installed, maintained and used for its intended purpose.

### *Article 4*

#### **Free movement of equipment**

1. It shall not be impeded, for reasons relating to electromagnetic compatibility, the placing on the market and/ or the putting into service of equipment which complies with this Regulation.

2. The requirements of this Regulation shall not prevent the application of the following special measures concerning the putting into service or use of equipment:

(a) measures to overcome an existing or predicted electromagnetic compatibility problem at a specific site;

(b) measures taken for safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

Ministry shall publish these special measures in the *Official Gazzette of the Montenegro*.

3. Ministry shall not create any obstacles to the display and/or demonstration at trade fairs, exhibitions or similar events of equipment which does not comply with this Regulation, provided that a visible sign clearly indicates that such equipment may not be placed on the market and/or put into service until it has been brought into conformity with this Regulation. Demonstration may only take place provided that adequate measures are taken to avoid electromagnetic disturbances.

### *Article 5*

#### **Essential requirements**

The equipment referred to in Article 1 shall meet the essential requirements set out in Annex I.

## Article 6

### **Harmonised standards**

1. 'Harmonised standard' means a technical specification adopted by a recognised European standardisation body for the purpose of establishing a European requirement and which can be accepted as Montenegrin pursuant with procedures laid down in Law on standardization (*Official Gazette of Montenegro*, No. 13/08). Compliance with a 'harmonised standard' is not compulsory.
2. The compliance of equipment with the relevant harmonised standards whose references have been published in the *Official Gazette of the Montenegro* shall raise a presumption of conformity with the essential requirements referred to in Annex I to which such standards relate. This presumption of conformity is limited to the scope of the harmonised standard(s) applied and the relevant essential requirements covered by such harmonised standard(s).
3. Where a Ministry considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the ministry responsible for market and Institute for standardization, stating its reasons.

## CHAPTER II

### **APPARATUS**

## Article 7

### **Conformity assessment procedure for apparatus**

1. Compliance of apparatus with the essential requirements referred to in Annex I shall be demonstrated by means of the procedure described in Annex II (internal production control).
2. Manufacturer or of his authorised representative in the Montenegro, the procedure described in Annex III may also be followed.

## Article 8

### **'CE' marking**

1. Apparatus whose compliance with this Regulation has been established by means of the procedure laid down in Article 7 shall bear the 'CE' marking which attests to that fact. The affixing of the 'CE' marking shall be the responsibility of the manufacturer or his authorised representative in the Montenegro. The 'CE' marking shall be affixed in accordance with Annex V.
2. Ministry shall take the necessary measures to prohibit the affixing to the apparatus, or to its packaging, or to the instructions for its use, of marks which are likely to mislead third parties in relation to the meaning and/or graphic form of the 'CE' marking.

3. Any other mark may be affixed to the apparatus, its packaging, or the instructions for its use, provided that neither the visibility nor the legibility of the 'CE' marking is thereby impaired.

4. Without prejudice to Article 10, if a competent authority establishes that the 'CE' marking has been unduly affixed, the manufacturer or his authorised representative in the Montenegro shall bring the apparatus into conformity with the provisions concerning the 'CE' marking under conditions imposed by the Ministry.

#### *Article 9*

#### **Other marks and information**

1. Each apparatus shall be identified in terms of type, batch, serial number or any other information allowing for the identification of the apparatus.

2. Each apparatus shall be accompanied by the name and address of the manufacturer and, if he is not established within the Montenegro, the name and address of his authorised representative or of the person in the Montenegro responsible for placing the apparatus on the Montenegrin market.

3. The manufacturer shall provide information on Montenegrin or English language on any specific precautions that must be taken when the apparatus is assembled, installed, maintained or used, in order to ensure that, when put into service, the apparatus is in conformity with the protection requirements set out in Annex I, point 1.

4. Apparatus for which compliance with the protection requirements is not ensured in residential areas shall be accompanied by a clear indication of this restriction of use, where appropriate also on the packaging.

5. The information, on Montenegrin and English language, required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be contained in the instructions accompanying the apparatus.

#### *Article 10*

#### **Safeguards**

1. Where a Ministry ascertains that apparatus bearing the 'CE' marking does not comply with the requirements of this Regulation, it shall take all appropriate measures to withdraw the apparatus from the market, to prohibit its placing on the market or its putting into service, or to restrict the free movement thereof.

2. The Ministry shall immediately inform the public of any such measure, indicating the reasons and specifying, in particular, whether non-compliance is due to:

(a) failure to satisfy the essential requirements referred to in Annex I, where the apparatus does not comply with the harmonised standards referred to in Article 6;

(b) incorrect application of the harmonised standards referred to in Article 6;

(c) shortcomings in the harmonised standards referred to in Article 6.

3. The Ministry shall consult the parties concerned as soon as possible, following which it shall inform domestic and foreign public whether or not it finds the measure to be justified.
4. Where the measure referred to in paragraph 1 is attributed to a shortcoming in harmonised standards, the Ministry, the ministry responsible for market and Institute for standardization.
5. Where the non-compliant apparatus has been subject to the conformity assessment procedure referred to in Annex III, the Ministry shall take appropriate action in respect of the author of the statement referred to in Annex III, point 3, and shall inform the public accordingly.

#### *Article 11*

#### **Decisions to withdraw, prohibit or restrict the free movement of apparatus**

1. Any decision taken pursuant to this Regulation to withdraw apparatus from the market, prohibit or restrict its placing on the market or its putting into service, or restrict the free movement thereof, shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Ministry in question and of the time limits to which such remedies are subject.
2. In the event of a decision as referred to in paragraph 1, the manufacturer, his authorised representative, or any other interested party shall have the opportunity to put forward his point of view in advance, unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular with respect to public interest requirements.

#### *Article 12*

#### **Notified bodies**

1. Ministry shall notify of the bodies which they have designated to carry out the tasks referred to in Annex III. When determining the bodies to be designated, Ministry shall apply the criteria laid down in Annex VI. Such notification shall state whether the bodies are designated to carry out the tasks referred to in Annex III for all apparatus covered by this Regulation, and/or the essential requirements referred to in Annex I or whether the scope of designation is limited to certain specific aspects and/or categories of apparatus.
2. Bodies which comply with the assessment criteria established by the relevant harmonised standards shall be presumed to comply with the criteria set out in Annex VI covered by such harmonised standards. The Ministry shall publish in the *Official Gazette of the Montenegro* the references of those standards.
3. The Ministry shall publish in the *Official Gazette of the Montenegro* a list of notified bodies. The Ministry shall ensure that the list is kept up to date.

## CHAPTER III

### FIXED INSTALLATIONS

#### *Article 13*

##### **Fixed installations**

1. Apparatus which has been placed on the market and which may be incorporated into a fixed installation is subject to all relevant provisions for apparatus set out in this Regulation.

However, the provisions of Articles 5, 7, 8 and 9 shall not be compulsory in the case of apparatus which is intended for incorporation into a given fixed installation and is otherwise not commercially available. In such cases, the accompanying documentation shall identify the fixed installation and its electromagnetic compatibility characteristics and shall indicate the precautions to be taken for the incorporation of the apparatus into the fixed installation in order not to compromise the conformity of that installation. It shall furthermore include the information referred to in Article 9(1) and (2).

2. Where there are indications of non-compliance of the fixed installation, in particular, where there are complaints about disturbances being generated by the installation, inspector or supervisor concerned may request evidence of compliance of the fixed installation, and, when appropriate, initiate an assessment.

Where non-compliance is established, the inspector or supervisor may impose appropriate measures to bring the fixed installation into compliance with the protection requirements set out in Annex I, point 1.

3. Ministry shall set out the necessary provisions for identifying the person or persons responsible for the establishment of compliance of a fixed installation with the relevant essential requirements.

## CHAPTER IV

### FINAL PROVISIONS

#### *Article 14*

##### **Transitional provisions**

Ministry shall not impede the placing on the market and/ or the putting into service of equipment which is in compliance with the provisions of EMC Regulation (*Official Gazette of Montenegro*, No. 21/05) and which was placed on the market before 31 December 2009.

#### *Article 15*

##### **End of validity**

On the day of entry into force of this Regulation, previous Regulation is not valid anymore.

*Article 17*

**Entry into force**

This Regulation shall enter into force on 01.01.2010. and shall be in the *Official Gazette of the Montenegro*.

## *ANNEX I*

### **ESSENTIAL REQUIREMENTS REFERRED TO IN ARTICLE 5**

#### **1. Protection requirements**

Equipment shall be so designed and manufactured, having regard to the state of the art, as to ensure that:

(a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

#### **2. Specific requirements for fixed installations**

Installation and intended use of components

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out in Point 1. Those good engineering practices shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the relevant national authorities for inspection purposes for as long as the fixed installation is in operation.

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## ANNEX II

### CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7

#### (internal production control)

1. The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the protection requirements set out in Annex I, point 1. The correct application of all the relevant harmonised standards whose references have been published in the *Official Gazzette of the Montenegro* shall be equivalent to the carrying out of the electromagnetic compatibility assessment.
2. The electromagnetic compatibility assessment shall take into account all normal intended operating conditions.  
Where the apparatus is capable of taking different configurations, the electromagnetic compatibility assessment shall confirm whether the apparatus meets the protection requirements set out in Annex I, point 1, in all the possible configurations identified by the manufacturer as representative of its intended use.
3. In accordance with the provisions set out in Annex IV, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Regulation.
4. The manufacturer or his authorised representative in the Montenegro shall hold the technical documentation at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured.
5. The compliance of apparatus with all relevant essential requirements shall be attested by an EC declaration of conformity issued by the manufacturer or his authorised representative in the Community.
6. The manufacturer or his authorised representative in the Montenegro shall hold the EC declaration of conformity at the disposal of the competent authorities for a period of at least ten years after the date on which such apparatus was last manufactured.
7. If neither the manufacturer nor his authorised representative is established within the Montenegro, the obligation to hold the EC declaration of conformity and the technical documentation at the disposal of the competent authorities shall lie with the person who places the apparatus on the Montenegro market.
8. The manufacturer must take all measures necessary to ensure that the products are manufactured in accordance with the technical documentation referred to in point 3 and with the provisions of this Regulation that apply to them.
9. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Annex IV.

### *ANNEX III*

#### **CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 7**

1. This procedure consists of applying Annex II, completed as follows:
  2. The manufacturer or his authorised representative in the Montenegro shall present the technical documentation to the notified body referred to in Article 12 and request the notified body for an assessment thereof. The manufacturer or his authorised representative in the Montenegro shall specify to the notified body which aspects of the essential requirements must be assessed by the notified body.
  3. The notified body shall review the technical documentation and assess whether the technical documentation properly demonstrates that the requirements of the Regulation that it is to assess have been met. If the compliance of the apparatus is confirmed, the notified body shall issue a statement to the manufacturer or his authorised representative in the Montenegro confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.
  4. The manufacturer shall add the statement of the notified body to the technical documentation.
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## ANNEX IV

### TECHNICAL DOCUMENTATION AND EC DECLARATION OF CONFORMITY

#### 1. Technical documentation

The technical documentation must enable the conformity of the apparatus with the essential requirements to be assessed. It must cover the design and manufacture of the apparatus, in particular:

- a general description of the apparatus;
- evidence of compliance with the harmonised standards, if any, applied in full or in part;
- where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of the Regulation, including a description of the electromagnetic compatibility assessment set out in Annex II, point 1, results of design calculations made, examinations carried out, test reports, etc.;
- a statement from the notified body, when the procedure referred to in Annex III has been followed.

#### 2. EC declaration of conformity

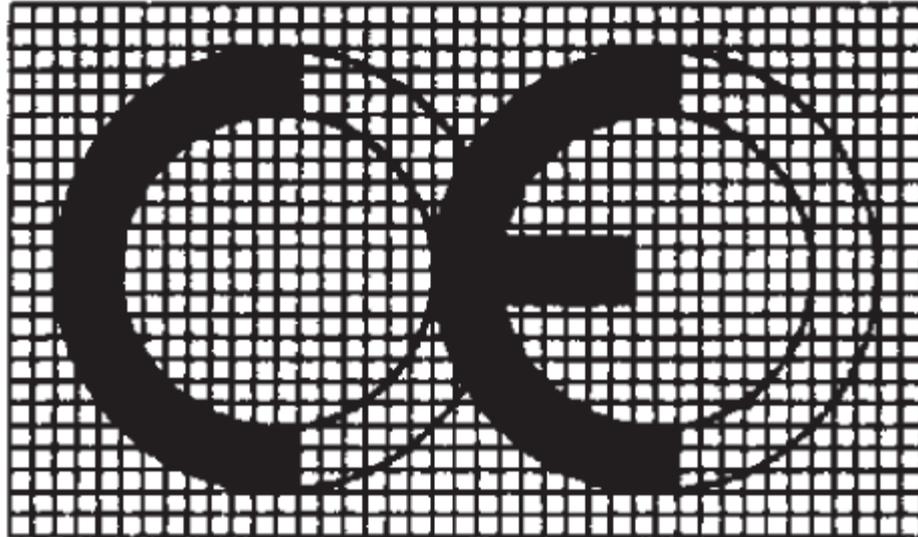
The EC declaration of conformity must contain, at least, the following:

- a reference to this Regulation,
  - an identification of the apparatus to which it refers, as set out in Article 9(1),
  - the name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Montenegro,
  - a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Regulation,
  - the date of that declaration,
  - the identity and signature of the person empowered to bind the manufacturer or his authorised representative.
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ANNEX V

**'CE' MARKING REFERRED TO IN ARTICLE 8**

The 'CE' marking shall consist in the initials 'CE' taking the following form:



The 'CE' marking must have a height of at least 5 mm. If the 'CE' marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

The 'CE' marking must be affixed to the apparatus or to its data plate. Where this is not possible or not warranted on account of the nature of the apparatus, it must be affixed to the packaging, if any, and to the accompanying documents.

Where the apparatus is the subject of other Regulations covering other aspects and which also provide for the 'CE' marking, the latter shall indicate that the apparatus also conforms with those other Regulations.

However, where one or more of those Regulations allow the manufacturer, during a transitional period, to choose which arrangements to apply, the 'CE' marking shall indicate conformity only with the Regulations applied by the manufacturer.

In that case, particulars of the Regulations applied, as published in the *Official Gazette of the Montenegro*, must be given in the documents, notices or instructions required by the Regulations and accompanying such apparatus.

## *ANNEX VI*

### **CRITERIA FOR THE ASSESSMENT OF THE BODIES TO BE NOTIFIED**

1. The bodies notified by the Ministry shall fulfil the following minimum conditions:
    - (a) availability of personnel and of the necessary means and equipment;
    - (b) technical competence and professional integrity of personnel;
    - (c) independence in preparing the reports and performing the verification function provided for in this Regulation;
    - (d) independence of staff and technical personnel in relation to all interested parties, groups or persons directly or indirectly concerned with the equipment in question;
    - (e) maintenance of professional secrecy by personnel;
    - (f) possession of civil liability insurance unless such liability is covered by the Ministry under national law.
  2. Fulfilment of the conditions laid down in point 1 shall be verified at intervals by the competent authorities of the Ministry.
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