

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 Article 85 of the Law on Electronic Communications (*Official Gazette of Montenegro*, No. 50/08), the Ministry of Maritime Affairs, Transportation and Telecommunications, issues the following

## REGULATION ON RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT AND THE RECOGNITION OF THEIR CONFORMITY

### *Article 1*

#### **Scope and aim**

1. This Regulation establishes a regulatory framework for the placing on the market, free movement and putting into service in the Montenegro of radio equipment and telecommunications terminal equipment and presents technical regulation 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. 71/08).

2. This regulations applies on the all radio equipment and telecommunication terminal equipment.

Where apparatus as defined in Article 2(a) incorporates, as an integral part, or as an accessory:

- a) a medical device within the meaning of regulation concerning medical devices, or
- b) an active implantable medical device relating to active implantable medical devices,

the apparatus shall be governed by this Regulation, without prejudice to the application of regulations to medical devices and active implantable medical devices

3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of regulation relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning regulation relating to the type-approval of two or three-wheel motor vehicles, the apparatus shall be governed by this Regulation without prejudice to the application of regulations.

4. This Regulation shall not apply to equipment listed in Annex I.

5. This Regulation shall not apply to apparatus exclusively used for activities concerning public security, defence, State security (including the economic well being of the state in the case of activities pertaining to state security matters) and the activities of the state in the area of criminal law.

## Article 2

### Definitions

For the purpose of this Regulation the following definitions shall apply:

- a) 'apparatus' means any equipment that is either radio equipment or telecommunications terminal equipment or both;
- b) 'telecommunications terminal equipment' means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);
- c) 'radio equipment' means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/ space radiocommunication;
- d) 'radio waves' means electromagnetic waves of frequencies from 9 kHz to 3 000 GHz, propagated in space without artificial guide;
- e) 'interface' means
  - i. a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or
  - ii. an air interface specifying the radio path between radio equipment and their technical specifications;
- f) 'equipment class' means a class identifying particular types of apparatus which under this Regulation are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;
- g) 'technical construction file' means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;
- h) 'harmonised standard' means a technical specification adopted by a recognised standards body for the purpose of establishing a European requirement and which might be accepted as Montenegrin standards pursuant procedures laid down in Law on standardization (*Official Gazette of Montenegro*, No. 13/08), compliance with which is not compulsory.
- i) "harmful interference" means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Montenegrin regulations.
- j) "Ministry" means ministry responsible for electronic communications

k) "Agency" means Agency for electronic communications and postal services, regulatory body.

### *Article 3*

#### **Essential requirements**

1. The following essential requirements are applicable to all apparatus:

a) the protection of the health and the safety of the user and any other person, pursuant to the Law on general product safety (*Official Gazette of Montenegro*, No. 48/08) including the objectives with respect to safety requirements contained in regulation relating to electrical equipment designed for use within certain voltage limits, but with no voltage limit applying;

b) the protection requirements with respect to electromagnetic compatibility contained in regulation relating to electromagnetic compatibility.

2. In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.

3. In accordance with the procedure laid down in Article 15, the Ministry may decide that apparatus within certain equipment classes or apparatus of particular types shall be so constructed that:

a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Montenegro; and/or that

b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

d) it supports certain features ensuring avoidance of fraud; and/or that

e) it supports certain features ensuring access to emergency services; and/or that

f) it supports certain features in order to facilitate its use by users with a disability.

### *Article 4*

#### **Notification and publication of interface specifications**

1. Agency shall notify the interfaces which they have regulated to the Ministry insofar as the said interfaces have not been notified under the provisions of Law on standardization (*Official Gazette of Montenegro*, No. 13/08) . After consulting the Commission, the Telecommunication Conformity Assessment and Market Surveillance Commission (TCAM), in accordance with the procedure set out in Article 15, the Ministry, on the proposal of Commission, shall establish the

equivalence between notified interfaces and assign an equipment class identifier, details of which shall be published in the Official Gazette of the Montenegro.

2. Agency shall notify the types of interface offered in Montenegro by operators of public telecommunications networks. Operators shall publish accurate and adequate technical specifications of such interfaces before services provided through those interfaces are made publicly available, and regularly publish any updated specifications. The specifications shall include all the information necessary to allow manufacturers to carry out, at their choice, the relevant tests for the essential requirements applicable to the telecommunications terminal equipment.

#### *Article 5*

### **Harmonised standards**

1. Where apparatus meets the relevant Montenegrin standards ( whose list with reference numbers have been published by Ministry in the Official Gazette) for which are basis for accepting have been harmonized standards or parts thereof shall be presumed compliance with those of the essential requirements referred to in Article 3 as are covered by the said harmonised standards or parts thereof, Ministry assess conformance of device and its interaction with technical-technological environment.

2. Where the Ministry considers that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3 which the said standard is intended to cover, the Ministry shall bring the matter before the Commission.

3. In the case of shortcomings of harmonised standards with respect to the essential requirements, the Ministry may, after consulting the Commission and in accordance with the procedure laid down in Article 14, publish in the Official Gazette of the Montenegro guidelines on the interpretation of harmonised standards or the conditions under which compliance with that standard raises a presumption of conformity. After consultation of the Commission and in accordance with the procedure laid down in Article 14, the Ministry may withdraw harmonised standards by publication of a notice in the Official Gazette of the Montenegro.

#### *Article 6*

### **Placing on the market**

1. Apparatus may be placed on the market only if it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Regulation when it is properly installed and maintained and used for its intended purpose.

Before placing on the market, manufacturer or person responsible for the placing on the market of Montenegro is obligated to get approval for import and placing on the market RTTE equipment by the Ministry.

2. In taking a decision regarding the application of essential requirements under Article 3(3), the Ministry shall determine the date of application of the requirements. If it is determined that an equipment class needs to comply with particular essential requirements under Article 3(3), any apparatus of the equipment class in question which is first placed on the market before the date

of application of the Ministry's determination can continue to be placed on the market for a reasonable period. Both the date of application and the period shall be determined by the Ministry in accordance with the procedure laid down in Article 14.

3. Ministry shall ensure that the manufacturer or the person responsible for placing the apparatus on the market provides information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the apparatus the Ministry or the geographical area within a Ministry where the equipment is intended to be used and shall alert the user by the marking on the apparatus referred to in Annex VII, paragraph 5, to potential restrictions or requirements for authorisation of use of the radio equipment in certain Ministry. Where it concerns telecommunications terminal equipment, such information shall be sufficient to identify interfaces of the public telecommunications networks to which the equipment is intended to be connected. For all apparatus such information shall be prominently displayed.

4. In the case of radio equipment using frequency bands whose use is not harmonised throughout the EU or is not in compliance with Allocation Plan , the manufacturer or his authorised representative established within the Montenegro or the person responsible for placing the equipment on the market shall notify the Agency of the intention to place such equipment on its national market. This notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or V.

#### *Article 7*

#### **Putting into service and right to connect**

1. Apparatus may be put into service for its intended purpose where it complies with the appropriate essential requirements identified in Article 3 and the other relevant provisions of this Regulation.

2. Notwithstanding paragraph 1, and without prejudice to conditions attached to authorisations for the provision of the service concerned in conformity with Montenegrin law, Agency may restrict the putting into service of radio equipment only for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health.

3. Without prejudice to paragraph 4, Agency shall ensure that operators of public telecommunications networks do not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where that equipment complies with the applicable requirements of Article 3.

4. Where a Agency considers that apparatus declared to be compliant with the provisions of this Regulation causes serious damage to a network or harmful radio interference or harm to the network or its functioning, the operator may be authorised to refuse connection, to disconnect such apparatus or to withdraw it from service. The Agency shall notify each such authorisation to the Ministry, which shall convene a meeting of the Commission for the purpose of giving its

opinion on the matter. After the Commission has been consulted, the Ministry may initiate the procedures referred to in Article 5(2) and (3). The Ministry and the Agency may also take other appropriate measures.

5. In case of emergency, an operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected without delay and if the user can be offered, without delay and without costs for him, an alternative solution. The operator shall immediately inform the Agency who is responsible for the implementation of paragraph 4 and Article 9.

#### *Article 8*

### **Free movement of apparatus**

1. RTTE apparatus bearing the CE marking referred to in Annex VII, which indicates its conformity with all provisions of this Regulation, including the conformity assessment procedures set out in Chapter II may be placed on the market and put into service in territory of Montenegro. This shall be without prejudice to Articles 6(4), 7(2) and 9(5).

2. RTTE equipment which does not comply with this Regulation may be displayed on trade fairs, exhibitions, demonstrations, etc , provided that a visible sign clearly indicates that such apparatus may not be marketed or put into service until it has been made to comply.

3. Where the apparatus is subject to other regulations which concern other aspects and also provide for the affixing of the CE marking, the latter shall indicate that such apparatus also fulfils the provisions of those other regulations.

#### *Article 9*

### **Safeguards**

1. Where a inspectors and supervisors ascertains that apparatus within the scope of this Regulation does not comply with the requirements of this Regulation, it shall take all appropriate measures in its territory to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.

2. The Agency concerned shall immediately notify the Ministry of any such measures indicating the reasons for its decision and whether non-compliance is due to:

a) incorrect application of the harmonised standards referred to in Article 5(1);

b) shortcomings in the harmonised standards referred to in Article 5(1);

c) failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1).

3. If the measures referred to in paragraph 1 are attributed to incorrect application of the harmonised standards referred to in Article 5(1) or to a failure to satisfy the requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1), the Ministry shall consult the parties concerned as soon as possible. The Ministry

shall forthwith inform the Agency and other relevant subjects of its findings and of its opinion as to whether the measures are justified, within two months of Ministry notification of the said measures.

4. Where the decision referred to in paragraph 1 is attributed to shortcomings in the harmonised standards referred to in Article 5(1), the Ministry shall bring the matter before the Commission within two months. The Commission shall deliver an opinion in accordance with the procedure laid down in Article 14. After such consultation, the Ministry shall inform the Agency and other relevant subjects of its findings and of its opinion as to whether the action by the Ministry is justified. If it finds that the action is justified it shall forthwith initiate the procedure referred to in Article 5(2).

5. (a) Notwithstanding the provisions of Article 6, a Ministry may, acting in conformity with the Treaty, and in particular Articles 30 and 36 thereof, adopt any appropriate measures with a view to:

i. prohibiting or restricting the placing on its market, and/or

ii. requiring the withdrawal from its market,

of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.

b. Where a Ministry takes measures in accordance with subparagraph (a) it shall immediately inform the interested parties of the said measures, specifying the reasons for adopting them.

6. When a Ministry notifies the Agency and other interested parties of a measure referred to in paragraph 1 or 5 the Ministry shall consult the Commission on the matter.

Where, after such consultation, the Ministry considers that:

-the measure is justified, it shall immediately so inform the Agency and interested parties, which took the initiative ,

-the measure is unjustified, it shall immediately so inform the Agency and interested parties and request it to withdraw the measure.

7. The Ministry shall maintain a record of the cases notified by Agency, which shall be made available to them on request. Ministry may authorize Agency to take care about registry on its behalf.

## CHAPTER II

### CONFORMITY ASSESSMENT

#### *Article 10*

##### **Conformity assessment procedures**

1. The conformity assessment procedures identified in this Article shall be used to demonstrate the compliance of the apparatus with all the relevant essential requirements identified in Article 3.
2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Article 3(1)(a) and (b) may be demonstrated using the procedures specified in regulation relating to electrical equipment designed for use within certain voltage limits and regulation relating to electromagnetic compatibility respectively, where the apparatus is within the scope of those regulations, as an alternative to the procedures laid out below.
3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in any one of Annexes II, IV or V at the choice of the manufacturer.
4. Where a manufacturer has applied the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 shall be subject to the procedures described in any one of Annexes III, IV or V at the choice of the manufacturer.
5. Where a manufacturer has not applied or has only applied in part the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 of this Article shall be subject to the procedures described in either of Annexes IV or V at the choice of the manufacturer.
6. Records and correspondence relating to the conformity assessment procedures referred to in paragraphs 2 to 5 shall be in an official language of the Montenegro and English. Documentation on Montenegrin language should consist of enough information for conformity assessment procedure.

#### *Article 11*

##### **Notified bodies and surveillance authorities**

1. Ministry shall notify of the bodies which they have designated to carry out the relevant tasks referred to in Article 10. Ministry shall apply the criteria laid down in Annex VI in determining the bodies to be designated.
2. Ministry shall notify relevant international organisations of the authorities established within their territory which are to carry out the surveillance tasks related to the operation of this Regulation.



3. The Ministry shall publish a list of the notified bodies, together with their identification numbers and the tasks for which they have been notified, in the Official Gazette of the Montenegro. Closer procedure designating of bodies are regulated Decree on manner and procedures of assessment of conformity of products with prescribed requirements (*Official Gazette of Montenegro*, No. 71/08).

### **CHAPTER III**

#### **CE CONFORMITY MARKING AND INSCRIPTIONS**

##### *Article 12*

##### **CE marking**

1. Apparatus complying with all relevant essential requirements shall bear the EC conformity marking referred to in Annex VII. It shall be affixed under the responsibility of the manufacturer, his authorized representative within the Montenegro or the person responsible for placing the apparatus on the market.

Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 11(1). Radio equipment shall in addition be accompanied by the equipment class identifier where such identifier has been assigned. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced.

2. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the EC marking specified in Annex VII.

3. The Ministry shall take appropriate action against any person who has affixed a marking not in conformity with paragraphs 1 and 2. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance was discovered.

4. Apparatus shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market.

5. Closer procedure on CE conformity marking and inscription are regulated by Decree on manner and procedures of assessment of conformity of products with prescribed requirements (*Official Gazette of Montenegro*, No. 71/08).

## CHAPTER IV

### THE COMMISSION

#### *Article 13*

#### **Constitution of the Commission**

The Ministry shall be assisted by a Commission, the Telecommunication Conformity Assessment and Market Surveillance Commission (TCAM), composed of representatives of the Ministry and chaired by a representative of the Ministry. The task of Commission is conformity assessment of technical documentation, which is associated with equipment and which has been done on the basis of foreign technical regulations and which has been submitted by manufacturers and their authorised representatives, with this Regulation. Conditions for this assessment are closer regulated 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 Commission is obligated to submit to the Ministry proposal on issuing approval for import and placing on the market, and Ministry will issue this approval.

Expert and administrative support to the Commission will be provided by Agency, on the way to accept and preparation expert materials for decision making process of Commission. Agency will bring Pricelist of their services which is intended for covering fees preparation of expert basis for Commission work, which will be approved by Ministry.

Closer guidelines for Commission work will be brought by Ministry.

#### *Article 14*

#### **Advisory Commission procedure**

1. The Commission shall be consulted on the matters covered by Articles 5, 6(2), 7(4), 9(4) and Annex VII(5). The Commission will prepare proposal of technical specification which is associated with Regulation on the basis 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).
2. The Ministry shall consult the Commission periodically on the surveillance tasks related to the application of this Regulation, and, where appropriate, issue guidelines on this matter.
3. The representative of the Ministry shall submit to the Commission a draft of the measures to be taken. The Commission shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

The opinion shall be recorded in the minutes; in addition, each member shall have the right to ask to have its position recorded in the minutes.

The Ministry shall take the utmost account of the opinion delivered by the Commission. It shall inform the Commission of the manner in which its opinion has been taken into account and decide within one month after having received the opinion of the Commission.

4. The Ministry shall periodically consult the representatives of the telecommunications networks providers, the consumers and the manufacturers. It shall keep the Commission regularly informed of the outcome of such consultations.

#### *Article 15*

### **Regulatory Commission procedure**

1. Notwithstanding the provisions of Article 14, the following procedure shall apply in respect of the matters covered by Articles 3(3) and 4(1).

2. The representative of the Ministry shall submit to the Commission a draft of the measures to be taken. The Commission shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter.

3. The Ministry shall adopt the measures envisaged if they are in accordance with the opinion of the Commission.

## **CHAPTER V**

### **FINAL AND TRANSITIONAL PROVISIONS**

#### *Article 16*

### **Third countries**

1. Ministry may inform the Government of Montenegro of any general difficulties encountered, de jure or de facto, by Montenegrin undertakings with respect to placing on the market in third countries, which have been brought to their attention.

2. Whenever the Ministry is informed of such difficulties, it may, if necessary, submit proposals to the Government for an appropriate mandate for negotiation of comparable rights for Montenegro undertakings in these third countries.

3. Measures taken pursuant to paragraph 2 shall be without prejudice to the obligations of the Montenegro and of the Ministry under relevant international agreement.

#### *Article 17*

### **Review and reporting**

The Ministry shall review the operation of this Regulation and report thereon to the Government which will be prepared by Agency, on the first occasion not later than 31

December 2010, 18 months after the entry into force of this Regulation and every third year thereafter. The report shall cover progress on drawing up the relevant standards, as well as any problems that have arisen in the course of implementation. The report shall also outline the activities of the Commission, assess progress in achieving an open competitive market for apparatus at Montenegro level and examine how the regulatory framework for the placing on the market and putting into service of apparatus should be developed to:

- a) ensure that a coherent system is achieved at Montenegro level for all apparatus;
- b) allow for convergence of the telecommunications, audiovisual and information technology sectors;
- c) enable harmonisation of regulatory measures at international level.

It shall in particular examine whether essential requirements are still necessary for all categories of apparatus covered and whether the procedures contained in Annex IV, third paragraph, are proportionate to the aim of ensuring that the essential requirements are met for apparatus covered by that Annex. Where necessary, further measures may be proposed in the report for full implementation of the aim of the Regulation.

#### *Article 18*

#### **Transitional provisions**

1. Standards under regulation relating to electrical equipment designed for use within certain voltage limits or regulation relating to electromagnetic compatibility respectively whose references have been published in the Official Gazette of the Montenegro may be used as the basis for a presumption of conformity with the essential requirements referred to in Article 3(1)(a) and Article 3(1)(b).
2. Ministry shall not impede the placing on the market and putting into service of apparatus which is in accordance with the provisions regulation which has been valid before or at present or rules in force in Montenegro and was placed on the market for the first time before this Regulation entered into force or at the latest 31.12.2009. after this Regulation entered into force.
3. Apart from the essential requirements referred to in Article 3(1), the Agency may request to continue, for a period of up to 12 months following the date referred to in the first sentence of Article 19(1), to require telecommunications terminal equipment not to be capable of causing unacceptable deterioration of a voice telephony service accessible within the framework of the universal service as defined in Regulation.

The Agency shall inform the Ministry of the reasons for requesting a continuation of such a requirement, the date by which the service concerned will no longer need the requirement, and the measures envisaged in order to meet this deadline. The Ministry shall consider the request taking into account the particular situation in the Montenegro, and shall inform the Agency whether it deems that the particular situation in that Ministry justifies a continuation and, if so, until which date such continuation is justified.

*Article 19*

**Transposition**

1. Agency shall not later than 30 September 2009 adopt and publish the regulations and administrative provisions necessary to comply with this Regulation. They shall forthwith inform the Ministry thereof. They shall apply these provisions as from 01 October 2009.

When Agency adopt these measures, they shall contain a reference to this Regulation or shall be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by Agency.

2. Agency shall inform the Ministry of the main provisions of their regulations which it adopt in the field covered by this Regulation.

*Article 20*

**Repeal**

It is hereby repealed all regulations which has been concerned on the import, placing on the market and putting into service RTTE equipment , the day on enter into force this Regulation.

*Article 21*

**Entry into force**

This Regulation shall enter into force on the day of its publication in the Official Gazette of the Montenegro.

## **ANNEX I**

### **EQUIPMENT NOT COVERED BY THIS REGULATION AS REFERRED TO IN ARTICLE 1(4)**

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations 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.

2. Equipment falling within the scope of regulation on marine equipment.

3. Cabling and wiring.

4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services.

5. Products, appliances and components within the meaning of regulation on the harmonisation of technical requirements and administrative procedures in the field of civil aviation .

6. Air-traffic-management equipment and systems within the meaning regulation on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems.

## **ANNEX II**

### **CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(3)**

#### **Module A (internal production control)**

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Montenegro, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of this Regulation that apply to them. The manufacturer or his authorised representative established within the Montenegro must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in point 4 and he or his authorised representative established within the Montenegro must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities or Agency for inspection purposes.

3. Where neither the manufacturer nor his authorised representative is established within the Montenegro, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Montenegro market.

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

a general description of the product,

conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,

a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of the Regulation where such standards referred to in Article 5 have not been applied or do not exist,

results of design calculations made, examinations carried out, etc.,

test reports.

1. The manufacturer or his authorised representative must keep a copy of the declaration of conformity with the technical documentation.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Regulation that apply to them.

### ***ANNEX III***

#### **CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(4)**

(Internal production control plus specific apparatus tests) (1)

This Annex consists of Annex II, plus the following supplementary requirements:

For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the harmonised standards. The notified body must take due account of previous decisions made by notified bodies acting together.

The manufacturer or his authorised representative established within the Montenegro or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

*(1) Annex based on Module A with additional requirements appropriate to the sector.*

## ***ANNEX IV***

### CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10(5)

(Technical construction file)

This Annex consists of Annex III plus the following supplementary requirements:

The technical documentation described in point 4 of Annex II and the declaration of conformity to specific radio test suites described in Annex III must form a technical construction file.

The manufacturer, his authorised representative established within the Montenegro or the person responsible for placing the apparatus on the market, must present the file to one or more notified bodies, each of the notified bodies must be informed of others who have received the file.

The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of the Regulation have been met, the notified body may issue an opinion to the manufacturer, his representative or the person responsible for placing the apparatus on the market and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market, without prejudice to Articles 6(4) and 9(5).

The manufacturer or his authorised representative established within the Montenegro or the person responsible for placing the apparatus on the market must keep the file for a period ending at least 10 years after the last apparatus has been manufactured at the disposal of the relevant national authorities or Agency for inspection.

## ***ANNEX V***

### CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 10

Full quality assurance

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned satisfy the requirements of the Regulation that apply to them. The manufacturer must affix the marks referred to in Article 12(1) to each product and draw up a written declaration of conformity.
2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and must be subject to surveillance as specified in point 4.



### 3. Quality system

3.1 The manufacturer must lodge an application for assessment of his quality system with a notified body. The application must include:

all relevant information for the products envisaged,

the quality system's documentation.

3.2. The quality system must ensure compliance of the products with the requirements of the Regulation that apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in Article 5(1) will not be applied in full, the means that will be used to ensure that the essential requirements of the Regulation that apply to the products will be met,

the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,

the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,

the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard.

The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of the Regulation in the light of the relevant documentation supplied in respect of points 3.1 and 3.2 including, where relevant, test results supplied by the manufacturer.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

#### 4. EC surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

the quality system documentation,

the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the

proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:

the documentation referred to in the second indent of point 3.1,

the updating referred to in the second paragraph of point 3.4,

the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4 and in points 4.3 and 4.4.

6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

## ***ANNEX VI***

### **MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MINISTRY WHEN DESIGNATING NOTIFIED BODIES IN ACCORDANCE WITH ARTICLE 11(1)**

1. The notified body, its director and the staff responsible for carrying out the tasks for which the notified body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications terminal equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the tasks for which the notified body has been designated with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of any inspection, especially from persons or groups of persons with an interest in such results.

3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.

4. The staff responsible for inspections must have:

i. sound technical and professional training,

ii. satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,

iii. the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.

1. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.

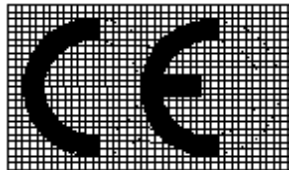
2. The notified body must take out liability insurance unless its liability is assumed by the Ministry in accordance with national law, or the Ministry itself is directly responsible.

3. The staff of the notified body is bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the Ministry in which its activities are carried out) under this Regulation or any provision of national law giving effect thereto.

## ***ANNEX VII***

### **MARKING OF EQUIPMENT REFERRED TO IN ARTICLE 12(1)**

1. The CE conformity marking must consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.

3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.

4. The CE marking must be affixed visibly, legibly and indelibly.

5. The equipment class identifier must take a form to be decided by the Ministry in accordance with the procedure laid down in Article 14.

Where appropriate it must include an element intended to provide information to the user that the apparatus makes use of radio frequency bands where their use is not harmonised throughout the Montenegro.

It must have the same height as the initials 'CE'.