

MINISTRY OF TRANSPORT AND COMMUNICATIONS

Pursuant to Article 20 paragraph 4 of the Law on Products Safety (Official Gazette of the Republic of Macedonia No. 33/06 and 63/07) the Minister for Transport and Communications, hereby adopts a

RULEBOOK ON RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT (*)

I. GENERAL PROVISIONS

Article 1

Subject

This Rulebook shall prescribe the essential requirements to be met by the radio equipment and telecommunications terminal equipment, for production, placing on the market and putting into service, the conformity assessment procedures, marking of the radio equipment and telecommunications terminal equipment and the conditions to be met by the conformity assessment bodies.

Article 2

Application

(1) The provisions of this Rulebook shall apply to apparatus referred to in Article 3, items 1 and 2 of this Rulebook.

(2) The provisions of this Rulebook shall not apply to equipment listed in Appendix 1, which is an integral part of this Rulebook.

(3) The provisions of this Rulebook shall not apply to apparatus intended for use in activities concerning public security, State security and defence. If these apparatus use radiofrequencies, they shall be in accordance with the Plan of radio frequency bands allocation in the Republic of Macedonia.

Article 3

Definitions

Certain terms used in this Rulebook shall have the following meanings:

1. **"apparatus"** means any equipment that is either radio equipment or telecommunications terminal equipment or both;
2. **"telecommunications terminal equipment"** means a product 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, communications networks used wholly or partly for the provision of publicly available communications services;
3. **"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

* Compliance with the Directive of the European Parliament and the Council of the European Union on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity is achieved by the provisions of this Rulebook CELEX No. 31999L0005

radiofrequency spectrum allocated to terrestrial or space radio-communication;

4. **"radio waves"** means electromagnetic waves of frequencies from 9 kHz to 3000 GHz,

5. **"interface"** means:

- a physical point at which a user is provided with access to public communication network (a network termination point);

- defined radio path between one or more transmitters or receivers or a combination of transmitters and receivers, including the necessary equipment and their technical specifications;

6. **"equipment class"** means a class identifying particular types of apparatus which according to this Rulebook are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;

7. **"technical documentation"** means a documentation containing data describing the apparatus and providing information and explanations on the application of, and compliance with the the essential requirements;

8. **"harmonised standard"** means a standard published by the European Organization for Standardisation, and which refers to the directives and obliges to its adoption at national level and publication in the Publication service for standards and other standardisation documents and

9. **"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 national regulations or regulations of the European Union.

II. ESSENTIAL REQUIREMENTS

Article 4

(1) The apparatus when placing on the market and putting into service should meet the essential requirements in terms of:

- the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements in accordance with other regulation that regulates the area of electrical equipment intended for use within defined voltage limits, but with no voltage limits applying and

- the protection with respect to electromagnetic compatibility, in accordance with the Rulebook on electromagnetic compatibility of electrotechnical equipment.

(2) The radio equipment shall be so constructed that it effectively uses the radiofrequency spectrum so as to avoid harmful interference and thus to meet the requirements:

- concerning the possibility of the apparatus to operate simultaneously with other apparatus and can be connected to other interfaces;
- it does not harm the network or its functioning nor misuse network resources;
- it incorporates safeguards to ensure that the personal data and privacy of the user/subscriber are protected;
- it provides protection against fraud and abuse and
- it provides access to emergency services and people with a disability.

Article 5

Publication of interface specifications

(1) The operators of public communications networks in the Republic of Macedonia publicly shall publish the type of interface of its public communications networks.

(2) The technical specifications of the interfaces, before services provided through those interfaces are made publicly available, shall be in sufficient detail to permit the design of communications terminal equipment capable of utilising all services through the corresponding interface. 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 6

Harmonised standards

When the equipment is constructed in compliance with Macedonian standards drawn up and adopted by the Institute for Standardisation of the Republic of Macedonia (hereinafter referred to as: the Institute for Standardisation) and published in the Publication service for standards and other standardisation documents of the Institute for Standardization, it shall be deemed that this equipment meets the essential requirements established by this Rulebook, as are covered by the said harmonised standards. The conformity of apparatus shall correspond only to the part of utilisation of harmonised standards and the relevant essential requirements, that are prescribed by these harmonised standards..

Article 7

Placing on the market and putting into service

(1) The apparatus shall be placed on the market only if it complies with the essential requirements established in this Rulebook, when it is properly installed and maintained and used for its intended purpose and used in a manner specified in the instructions for use of the apparatus.

(2) 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 in which countries or geographical areas within certain country the equipment is intended to be used and shall alert the user by the marking on the apparatus referred to in Appendix 2 item 5, that is an integral part of this Rulebook, to potential restrictions or requirements for

authorisation of use of the radio equipment in certain countries. 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.

(3) In the case of radio equipment putting into use and using frequency bands whose use is not harmonised throughout the European Union, the manufacturer or his authorised representative or the person responsible for placing the equipment on the market and putting into service shall notify the Agency for Electronic Communications of the intention to put such equipment into use, whereas it should indicate the applicant data and contact person of the applicant, as well as the following features: type, characteristics of radio equipment and description, manufacturer, purpose, selected conformity assessment procedure, the identification number of the authorised conformity body (if necessary), countries in which shall be used, applied standards, radiofrequency bands in which the radio equipment operates, operating frequency, width of the channel, maximum transmitter power, modulation type, antenna type and mode of operation (simplex / duplex).

Article 8

Putting into service and right to connect

(1) The apparatus shall be put into service for its intended purpose where it complies with the essential requirements referred to in Article 4 of this Rulebook.

(2) Notwithstanding paragraph 1 of this Article, the putting into service of radio equipment may be restricted 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) The operators of public telecommunications networks and services should not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds, where that equipment meets the essential requirements established in Article 4 of this Rulebook.

(4) Where the apparatus declared to be compliant with the provisions of this Rulebook, causes serious damage to the network or harmful radio interference or harm to the network or its functioning, the operator of the public communication network may refuse the connection of such apparatus, to disconnect or to withdraw it from service, and it shall notify the Agency for Electronic Communications thereof.

(5) In case of emergency, the operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected and if the user can be offered, without delay and without costs for him, an alternative solution, and it shall forthwith notify the Agency for Electronic Communications thereof.

Article 9

Free movement of apparatus

(1) Pursuant to Appendix 2 of this Rulebook, the placing on the market and putting into service shall be performed with apparatus bearing the CE marking, which

indicates its conformity with the provisions of this Rulebook.

(2) At professional fairs, exhibitions and demonstrations, apparatus which does not comply with the essential requirements established in this Rulebook may be also displayed, provided that a visible sign clearly indicates that such apparatus may not be marketed or put into service.

(3) Where the apparatus is subject to other regulations which provide for the affixing of the CE marking, they should be indicated. Where any of these regulations allow the manufacturer during a transitional period to choose which regulations to apply, in addition to the CE marking, it shall be indicated the regulation which provisions are fulfilled.

III. CONFORMITY ASSESSMENT

Article 10

Conformity assessment procedures

(1) The conformity assessment procedures shall be carried out for verifying the conformity of the apparatus with the essential requirements established in Article 4 of this Rulebook.

(2) Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial or space radio communication and receiving parts of radio equipment shall be subject to the conformity assessment procedures referred to in this Rulebook at the choice of the manufacturer.

(3) Where the manufacturer has applied the harmonised standards referred to in Article 6 of this Rulebook, the radio equipment not within the scope of paragraph (2) of this Article shall be subject to the procedures established in this Rulebook, at the choice of the manufacturer.

(4) Where the manufacturer has not applied or has only applied in part the harmonised standards referred to in Article 6 of this Rulebook, the radio equipment not within the scope of paragraph (2) of this Article shall be subject to the procedures established in this Rulebook, at the choice of the manufacturer.

(5) The records and correspondence relating to the conformity assessment procedures referred to in paragraphs (2), (3) and (4) of this Article, shall be in Macedonian language.

Article 11

(1) The manufacturer or his authorised representative, who carries out the obligations established in paragraph (2) of this Article, ensures and declares that the products concerned satisfy the requirements of this Rulebook and must affix the CE marking to each product and draw up a declaration of conformity.

(2) The manufacturer or his authorised representative must draw up the technical documentation referred to in paragraph (4) of this Article and it must keep it for a period ending at least 10 years after the last product has been manufactured.

(3) Where neither the manufacturer nor his authorised representative is established in

the Republic of Macedonia, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market in the Republic of Macedonia.

(4) The technical documentation must enable the conformity of the product with the essential requirements to be assessed. It must cover the purpose, manufacture and operation of the product, and shall include:

- description of the product;
- conceptual design, manufacturing drawings, schemes of components, sub-assemblies, the circuit, etc.;
- descriptions and explanations necessary for the understanding of said schemes and the operation of the product;
- a list of the harmonised standards referred to in Article 6 of this Rulebook, applied in full or in part, and descriptions and explanations of the solutions adopted to meet them;
- essential requirements referred to in Article 4 of this Rulebook, where such harmonised standards referred to in Article 6 of this Rulebook have not been applied or do not exist;
- results of design calculations made, examinations carried out, etc., and
- test reports.

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

(6) The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation and with the requirements of this Rulebook.

Article 12

Internal production control and specific apparatus tests

(1) For each type of radio equipment, all essential radio tests must be carried out by the manufacturer or on his behalf. The identification of these tests that are considered to be essential is the responsibility of an authorised legal or natural person (hereinafter referred to as: authorised body) chosen by the manufacturer except where the tests are defined in the harmonised standards. The authorised body must take due account of previous decisions made by authorised bodies acting together.

(2) The manufacturer or his authorised representative 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 indicate the authorised body's identification number during the manufacturing process.

Article 13 Technical documentation

- (1) The technical documentation should contain the documentation referred to in Article 11 paragraph (5) of this Rulebook and the declaration of conformity considering the specific radio tests.
- (2) The manufacturer or his authorised representative or the person responsible for placing the apparatus on the market, must present the technical documentation to the competent authority for market surveillance.
- (3) The competent authority for market surveillance must review the technical documentation and if it is considered that it has not been properly demonstrated that the essential requirements of this Rulebook have been met, may request the manufacturer, his representative or the person responsible for placing on the market to provide additional information.
- (4) The competent authority for market surveillance shall submit the request within four weeks of receipt of the technical documentation. Upon receipt of the technical documentation, and after the end of the four-week period, if additional data are not requested, the apparatus may be placed on the market.
- (5) The manufacturer or his authorised representative or the person responsible for placing the apparatus on the market must keep the technical documentation for a period ending at least 10 years after the last apparatus has been manufactured at the disposal of the relevant national authorities for inspection.

Article 14 Full quality assurance

- (1) Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of paragraph (2) of this Article ensures that the products satisfy the requirements provided for in this Rulebook, and it must affix the marks referred to in Article 19 of this Rulebook 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 laid down in Article 15 of this Rulebook, and must be subject to surveillance as laid down in Article 16 of this Rulebook.

Article 15 Quality system

- (1) The manufacturer, in terms of quality assurance, must lodge an application for assessment of his quality system with the authorised body.
- (2) The application must include:
 - all relevant information for the products envisaged and
 - the quality system's documentation.
- (3) The quality system must ensure compliance of the products with the requirements

of this Rulebook. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality system documentation must ensure a common understanding of the quality measures and procedures such as quality programmes, plans, manuals and records. The documentation must contain 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 6 of this Rulebook will not be applied in full, the means that will be used to ensure that the essential requirements 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,
- the means by which it is ensured that the test and examination equipment respects 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. and
- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

(4) The authorised body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 1 of this Article. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard. The authorised body must assess in particular whether the quality control system ensures conformity of the products with the requirements of this Rulebook in the light of the relevant documentation supplied in accordance with paragraphs (2) and (3) of this Article including, where relevant, test results supplied by the manufacturer.

(5) The authorised body for quality system assessment shall establish an auditing team that must have at least one member experienced in assessment of the product technology concerned.

(6) The auditing team shall pay visit to the manufacturer's premises due to quality system assessment, and after that adopts a decision. The decision shall be notified to the manufacturer. The notification must contain the conclusions of the examination

and the reasoned assessment decision.

(7) 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 authorised body that has approved the quality system informed of any intended updating of the quality system. The authorised body must evaluate the modifications proposed and decide whether the amended quality system will satisfy the requirements referred to in paragraph (3) of this Article and 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.

Article 16

Minimum criteria to be taken into account by the authorised body

(1) The authorised conformity assessment body (hereinafter referred to as: the authorised body), its director and the staff responsible for carrying out the tasks for which the authorised body has been designated by the competent authority, must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, an 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 development, 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 authorised body.

(2) The authorised body and its staff must carry out the tasks for which the authorised 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 authorised 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:

- appropriate professional education,
- knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections and
- the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.

(5) The staff referred to in paragraph (3) of this Article must be impartial during the performance of the inspections. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.

(6) The authorised body must take out liability insurance provided that such liability

is not envisaged by the regulations in the insurance area.

(7) The staff of the authorised body is bound to observe professional secrecy with regard to all information gained in carrying out its inspections in accordance with this Rulebook.

Article 17

Staff of the authorised body

(1) The authorised body shall have necessary staff at disposal with technical knowledge and appropriate experience in terms of issuing conformity assessment for each category of apparatus for which it is authorised, and it shall possess necessary facilities in order to properly carry out the technical and administrative tasks related to verification, and shall have access to equipment required for special inspections.

(2) The body referred to in paragraph (1) of this Article must have regular employees, and at least three professionals involved in the conformity assessment process, including:

- two graduate electrical engineers, with at least three years experience in matters related to conformity assessment and examination of apparatus in the respective area and
- one employee with secondary vocational education, with at least three years experience in matters related to conformity assessment and examination of apparatus in the respective area.

IV. "CE" MARKING AND INSCRIPTIONS

Article 18

"CE" marking

(1) Apparatus complying with the essential requirements in accordance with this Rulebook shall bear the "CE" conformity marking referred to in Appendix 2 of this Rulebook. The "CE" marking shall be affixed by the manufacturer or his authorised representative. In case of applying the procedures laid down in Article 10 of this Rulebook, the marking shall be accompanied by the identification number of the authorised body referred to in Article 12 paragraph (2) of this Rulebook. 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 "CE" marking is not thereby reduced.

(2) Any other marking that can mislead third parties as to the meaning or graphic form of the "CE" marking should not be affixed to the apparatus, their packaging or instructions for use.

(3) If the authority for market surveillance establishes that the "CE" marking is not in accordance with the provisions of this Rulebook, then the manufacturer or his authorised representative, should make the apparatus in conformity with the Law on Products Safety, and if the apparatus is not in conformity with that Law, the body responsible for market surveillance shall take appropriate measures to restrict or ban its placing on the market or guarantee that it has been withdrawn from the market in accordance with Article 36 of the Law on Product Safety.

(4) The manufacturer of the apparatus should indicate the type, serial numbers, and the name of the manufacturer or person responsible for placing on the market.

Article 19
Safeguards

If the apparatus bearing the "CE" marking does not comply with the requirements of this Rulebook, the authority responsible for market surveillance shall take appropriate measures 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. It may also request evidence of conformity, and if necessary, may initiate a conformity assessment procedure.

V. FINAL AND TRANSITIONAL PROVISIONS

Article 20

The provisions referred to in Article 18 of this Rulebook concerning the "CE marking will apply from the date of accession of the Republic of Macedonia to the European Union or after the entry into force of an appropriate conformity assessment protocol and with the appointment of a body authorised by the Republic of Macedonia to the European Union.

Article 21

(1) Until the accession of the Republic of Macedonia to the European Union, the manufacturer or his authorised representative established in the Republic of Macedonia may place on the market and put into service products, in accordance with this Rulebook, by affixing a conformity marking satisfying the essential requirements laid down by the provisions of this Rulebook.

(2) In the case referred to paragraph (1) of this Article, the manufacturer or his authorised representative established in the Republic of Macedonia, at their choice, should provide products certificate by the authorised body registered in the Republic of Macedonia, in accordance with the conformity assessment procedures laid down by the provisions of this Rulebook.

(3) The manufacturer or his authorised representative established in the Republic of Macedonia, must keep the issued certificate referred to in paragraph (2) of this Article for a period ending at least 10 years after the last product has been manufactured. The certified documentation of the manufacturer for each product must be accompanied by a copy of the certificate.

Article 22

(1) Until the accession of the Republic of Macedonia to the European Union or until the entry into force of an appropriate conformity assessment protocol with the European Union or until the entry into force of an appropriate bilateral agreement on mutual recognition of documents, each radio equipment and telecommunications terminal equipment which is imported and placed on the market in the Republic of Macedonia, should have a certificate issued by an authorised body registered in the Republic of Macedonia.

(2) The certificate referred to in paragraph (1) of this Article shall be issued upon a declaration of conformity by the manufacturer, product certificate in accordance with the conformity assessment procedure under which the assessment issued by the authorised body has been carried out, results from the relevant tests conducted and analysis of the degree of compliance with the essential requirements laid down by the provisions of this Rulebook.

(3) The certificate referred to in paragraph (1) of this Article shall be issued for each apparatus and must accompany the documentation for each individual apparatus.

(4) If it is determined that the product does not meet the requirements laid down by the provisions of this Rulebook, a certificate shall not be issued, and the authorised body shall inform the Product Safety Commission referred to in Article 27 paragraph (3) of the Law on Products Safety of its decision.

Article 23

(1) After the accession of the Republic of Macedonia to the European Union, or after the entry into force of an appropriate conformity assessment protocol with the European Union in the light of this Rulebook the following terms will be used:

- "An authorised representative in the European Union or the Republic of Macedonia" instead of "an authorised representative established in the Republic of Macedonia";
- "EC declaration of conformity" instead of "declaration of conformity";
- "CE marking" instead of "conformity marking";
- "notified body" instead of "authorised body".

Article 24 (entry into force)

This Rulebook shall enter into force on the eight day following that of its publication in the Official Gazette of the Republic of Macedonia.

No. 01-16978/1

24 December 2010

Skopje

Minister,

Mile Janakieski

APPENDIX 1

Equipment not covered by this Rulebook

1. Radio equipment used by radio amateurs within the meaning of Article 1, definition 53 of the Rulebook on Radio Communications of the International Telecommunications Union (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.

2. Equipment covered by the technical rules of the authorised ship classification association.

3. Cabling and wiring.

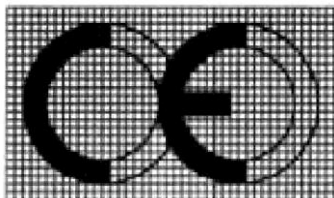
4. Receive only radio equipment intended to be used solely for the reception of sound and TV broadcasting services.

5. Products, apparatus and components in the light of harmonisation of the technical regulations and administrative procedures in the area of civil aviation in accordance with the applicable regulations in the Republic of Macedonia.

6. Air-traffic-management equipment and systems in the light of definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems in accordance with the applicable regulations in the Republic of Macedonia.

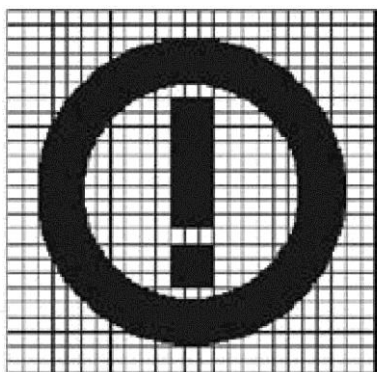
Marking of the equipment

1. The CE conformity marking shall take 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 second class equipment identifier, which notifies the user that the apparatus makes use of radiofrequency bands where their use is not harmonised throughout the entire territory of Europe, must take the following form:



It must have the same height as the "CE" marking.