

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

## **RULEBOOK ON ELECTROMAGNETIC COMPATIBILITY OF ELECTRO-TECHNICAL EQUIPMENT**

### **I. GENERAL PROVISIONS**

#### **Article 1**

##### **Purpose**

This Rulebook shall prescribe the essential requirements which should be met by the electro-technical equipment with regard to the electromagnetic compatibility and conformity marking, prior to placement on the market or putting into service of this equipment and the necessary prerequisites to be met by the conformity assessment bodies.

#### **Article 2**

##### **Definitions**

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

- (a) “electro-technical equipment” (hereinafter referred to as: “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.
- (i) “components” or “sub-assemblies” means assembly parts 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; and
- (j) “mobile installations” means a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations.

#### **Article 3**

##### **Application**

The provisions of this Rulebook shall not apply to:

- (a) radio equipment and telecommunications terminal equipment in accordance with Directive 1999/5/EC;
- (b) radio equipment used and assembled by radio amateurs and which is not placed on the market;
- (c) equipment and aeronautical products, parts and appliances intended for installation in aircrafts;
- (d) **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.**

**2. This Directive 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.

3. Where, for the equipment referred to in paragraph 1 of this Article, the essential requirements referred to in Article 5 of this Rulebook are wholly or partly laid down more specifically by other the European Union directives, this Rulebook shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those directives.

#### Article 4

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

1) The equipment shall be placed on the market and/or put into service only if it complies with the requirements of this Rulebook provided that it is properly installed, maintained and used for its intended purpose.

2) Placing on the market or putting into service of equipment pursuant to the provisions of this Rulebook may be prevented when there are safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

3) The equipment which does not comply with the provisions of this Rulebook may be displayed and/or demonstration at trade fairs, exhibitions or similar events, provided that adequate measures are taken to avoid electromagnetic disturbances.

#### Article 4-a

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

1) Placing on the market or putting into service of equipment pursuant to the provisions of this Rulebook may be prevented when there are safety reasons to protect public telecommunications networks or receiving or transmitting stations when used for safety purposes in well-defined spectrum situations.

2. The requirements of this Rulebook shall not prevent the application in any Member State 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.

Without prejudice to Directive 98/34/EC, Member States shall notify those special measures to the Commission and to the other Member States.

The special measures which have been accepted shall be published by the Commission in the Official Journal of the European Union.

3. Member States 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 Rulebook, 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 Rulebook. Demonstration may only take place provided that adequate measures are taken to avoid electromagnetic disturbances.

2) The equipment which does not comply with the provisions of this Rulebook may be displayed and/or demonstration at trade fairs, exhibitions or similar events, provided that adequate measures are taken to avoid electromagnetic disturbances.

#### Article 5

##### **Essential requirements**

1) The equipment should meet the following essential requirements:

(a) The equipment should be so designed and manufactured as to ensure that the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;

(b) The equipment should have 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. A fixed installation should 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 pursuant to paragraph 1 of this Article. Those good engineering practices should be documented and the documentation should be held by the person(s) responsible at the disposal of the relevant authorities responsible for market monitoring for as long as the fixed installation is in operation.

#### Article 5-a

## Harmonised standards

1. "Harmonised standard" means a technical specification adopted by a recognised European standardisation body under a mandate from the Commission in conformity with the procedures laid down in Directive 98/34/EC for the purpose of establishing a European requirement. 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 Journal of the European Union shall raise a presumption, on the part of the Member States, of conformity with the essential requirements referred to in Article 5 of this Rulebook 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 Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential requirements referred to in Annex I, it shall bring the matter before the Standing Committee set up by Directive 98/34/EC (hereinafter "the Committee"), stating its reasons. The Committee shall deliver an opinion without delay.
4. Upon receipt of the Committee's opinion, the Commission shall take one of the following decisions with regard to the references to the harmonised standard concerned:
  - (a) not to publish;
  - (b) to publish with restrictions;
  - (c) to maintain the reference in the Official Journal of the European Union;
  - (d) to withdraw the reference from the Official Journal of the European Union.The Commission shall inform the Member States of its decision without delay.

## II APPARATUS

### Article 6

#### Conformity assessment procedure for apparatus

Compliance of apparatus with the essential requirements referred to in Article 5 of this Rulebook shall be demonstrated by means of the procedure described in Article 6-a of this Rulebook (internal production control). However, at the discretion of the manufacturer or of his authorised representative in the European Union, the procedure described in Article 6-b of this Rulebook may also be followed.

### Article 6-a

#### Conformity assessment procedure for apparatus

- 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 Article 5, paragraph 1 of this Rulebook. The correct application of all the relevant harmonised standards whose references have been published in the *Official Journal of the European Union* 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 Article 5, paragraph 1 of this Rulebook, in all the possible configurations identified by the manufacturer as representative of its intended use.
- 3) In accordance with the provisions set out in Article 7 of this Rulebook, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of this Rulebook.
- 4) The manufacturer or his authorised representative in the European Union 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 the European Union.
- 6) The manufacturer or his authorised representative in the Community 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 Community, 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 European Union 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 Rulebook e that apply to them. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Article 7 of this Rulebook.

### Article 6-b

1. This procedure consists of applying Article 6-a of this Rulebook, completed as follows:
2. The manufacturer or his authorised representative in the European Union shall present the technical documentation

to the notified body referred to in Article 10-c of this Rulebook and request the notified body for an assessment thereof. The manufacturer or his authorised representative in the Community 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 Rulebook 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 European Union 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.

## Article 7

### **Technical documentation and declaration of conformity**

1. The technical documentation should enable the conformity of the apparatus with the essential requirements referred to in the Article 5 of this Rulebook to be assessed, in particular:

- a general description of the apparatus;
- evidence of compliance with the harmonised standards. 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, including a description of the electromagnetic compatibility assessment pursuant to Article 6, paragraph 1 item a) of this Rulebook, results of design calculations made, examinations carried out, test reports, etc.;
- a statement from the notified body when the procedure referred to in Article 6-b of this Rulebook has been followed.

2) The declaration of conformity should in particular contain the following:

- a reference to the provisions of this Rulebook,
- an identification of the apparatus to which it refers, pursuant to Article 10, paragraph 1 of this Rulebook,
- the name and address of the manufacturer or his authorised representative,
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of this Rulebook,
- the date of that declaration,
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative.

## Article 8

### **Criteria for the conformity assessment bodies**

1) The notified bodies should meet 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 Rulebook;
- (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.

2. Fulfilment of the conditions referred to in paragraph 1 of this Article shall be verified at intervals by the Institute for Accreditation of the Republic of Macedonia in accordance with the Law on Accreditation.

## Article 9

### **“CE” marking**

1. Apparatus whose compliance with this Rulebook has been established by means of the procedure laid down in Article 6 this Rulebook 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 Community. The "CE" marking shall be affixed in accordance with Article 5 of this Rulebook.

2) 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 shall be prohibited.

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) Provided a competent authority for market monitoring establishes that the “CE” marking has been unduly affixed, the manufacturer or his authorised representative should bring the apparatus into conformity with the provisions of this Rulebook concerning the “CE” marking on the total quantity of improperly marked products.

5) Where an apparatus bearing the "CE" marking does not comply with the requirements of this Rulebook, appropriate measures shall be taken 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.

#### Article 10

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

- 1) Each apparatus should 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 Community, the name and address of his authorised representative or of the person in the Community responsible for placing the apparatus on the Community market.
- 3) The manufacturer should provide information 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 Article 5, item 1 of this Rulebook.
- 4) Apparatus for which compliance with the protection requirements is not ensured in residential areas should be accompanied by a clear indication of this restriction of use. The indication shall also be provided on its packaging.
- 5) The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus should be contained in the instructions accompanying the apparatus.

##### **Article 10-a**

1. Where a Member State ascertains that apparatus bearing the "CE" marking does not comply with the requirements of this Rulebook, 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 Member State concerned shall immediately inform the Commission and the other Member States 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 Article 5 of this Rulebook, where the apparatus does not comply with the harmonised standards referred to in Article 5-a of this Rulebook;
  - (b) incorrect application of the harmonised standards referred to in Article 5-a of this Rulebook;
  - (c) shortcomings in the harmonised standards referred to in Article 5-a of this Rulebook.
3. The Commission shall consult the parties concerned as soon as possible, following which it shall inform the Member States whether or not it finds the measure to be justified.
4. Where the measure referred to in paragraph 1 of this Article is attributed to a shortcoming in harmonised standards, the Commission, after consulting the parties, shall, if the Member State concerned intends to uphold the measure, bring the matter before the Committee and initiate the procedure laid down in Article 5-a (3) and (4) of this Rulebook.
5. Where the non-compliant apparatus has been subject to the conformity assessment procedure referred to in Article 6-b of this Rulebook, the Member State concerned shall take appropriate action in respect of the author of the statement referred to in Article 6-b, paragraph 3 of this Rulebook, and shall inform the Commission and the other Member States accordingly.

##### **Article 10-b**

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

1. Any decision taken pursuant to this Directive 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 Member State 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 of this Article, 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 10-c**

Notified bodies

1. Member States shall notify the Commission of the bodies which they have designated to carry out the tasks referred to in Article 6-b of this Rulebook. When determining the bodies to be designated, Member States shall apply the criteria laid down in Article 5 of this Rulebook. Such notification shall state whether the bodies are designated to carry out the tasks referred to in Article 6-b of this Rulebook for all apparatus covered by this of Rulebook, and/or the essential requirements referred to in Article 5 of this Rulebook 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 Article 8 of this Rulebook covered by such harmonised standards. The Commission shall publish in the Official Journal of the European Union the references of those standards.
3. The Commission shall publish in the Official Journal of the European Union a list of notified bodies. The Commission shall ensure that the list is kept up to date.
4. If a Member State finds that a notified body no longer meets the criteria listed in Article 8 of this Rulebook, it shall inform the Commission and the other Member States accordingly. The Commission shall withdraw the reference to that body from the list referred to in paragraph 3 of this Article.

### III FIXED INSTALLATIONS

#### Article 11

1) Apparatus which has been placed on the market and which may be incorporated into a fixed installation should be subject to the provisions of this Rulebook. However, the provisions of Articles 5, 6, 9 and 10 of this Rulebook 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 10 (1) and (2) of this Rulebook.

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, the competent authorities for market monitoring may request evidence of compliance of the fixed installation, and, when appropriate, initiate an assessment. Where non-compliance is established, the competent authority should impose appropriate measures to bring the fixed installation into compliance with the essential requirements referred to in Article 5 of this Rulebook.

3. **Notified bodies** 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.

### IV TRANSITIONAL AND FINAL PROVISIONS

#### Article 12

"The provisions of the Articles 9 and 10 of this Rulebook that refer to CE marking shall be applied from the day of accession of the Republic of Macedonia in the European Union or after the entry into force of corresponding Protocol for conformity assessment with the European Union for electro technical equipment produced in Republic of Macedonia".

#### Article 13

1) Prior to the EU accession of the Republic of Macedonia, the manufacturer or his authorised representative registered in the Republic of Macedonia may place on the market or put in use products in accordance with this Rulebook by affixing the conformity mark on the products which meet the essential requirements as laid down in the provisions of this Rulebook.

2) "In the case of item (1) of this Article after the selection, the producer or its authorized representative shall obtain from authorized body for conformity assessment in the European Union, or from Republic of Macedonia certificate or other document for conformity of the electro technical equipment, pursuant procedures for conformity assessment regulated in the provisions of this Rulebook.

3) The manufacturer or his authorised representative established in the Republic of Macedonia should keep the statement awarded pursuant to paragraph 2 of this Article, for at least ten years after the date on which such product was last manufactured. Verified documentation for each product of the producer should be accompanied by the copy of the statement.

#### Article 14

1) Until the accession of Republic of Macedonia in the European Union or entry into force of corresponding Protocol for conformity assessment with the European Union, or until the entry into force of suitable bilateral agreement for mutual recognition of documents, every electro technical equipment that is imported and placed on the market of Republic of Macedonia, needs to possess certificate or other document for conformity from authorized or notified body from the European Union or from authorized body registered in the Republic of Macedonia.

2) The statement referred to in paragraph 1 of this Article shall be issued based upon declaration of conformity from the producer, product statement in accordance with the procedure for conformity assessment used to perform the assessment, issued by the notified body, results from the performed tests and analysis of the of the level of harmonisation with the essential requirements laid down in the provisions of this Rulebook.

3) The statement referred to in paragraph 1 of this Article shall be issued for each type of products and it should be accompanied by documentation for each individual product.

4) A statement shall not be issued if determined that the product does not satisfy the requirements set out in the provisions of this Rulebook, and the notified body shall communicate its decision to the Product Safety Commission pursuant to Article 27, paragraph 3 of the Law on Product Safety.

#### Article 15

After the EU accession of the Republic of Macedonia or with entry into force of an appropriate Assessment of Conformity Protocol with the EU for the purposes of this Rulebook, the following terms shall be used:

- “authorised representative established in the European Union or in the Republic of Macedonia” instead of “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 16

The Rulebook on electromagnetic compatibility (Official Gazette of the Republic of Macedonia No. 129/06) shall cease to be valid on the date of entry into force of this Rulebook.

#### Article 17

This Rulebook shall enter into force on the eighth day from its publication in the Official Gazette of the Republic of Macedonia.

No. 25-179/2

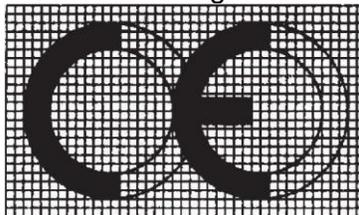
18 February 2009  
Skopje

Minister,  
**Fatmir Besimi**

### ANNEX 1

#### “CE” MARKING

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



The “CE” marking must have a vertical dimension 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 Rulebooks covering other aspects and which also provide for the “CE” marking, the latter shall indicate that the apparatus also conforms with those other Rulebooks.

However, where one or more of those Rulebooks allow the manufacturer, during a transitional period, to choose which arrangements to apply, the “CE” marking shall indicate conformity only with the Rulebooks applied by the manufacturer. In that case, particulars of the Rulebooks applied must be given in the documents, notices or instructions accompanying such apparatus.