

**SUBSIDIARY LEGISLATION 427.35**  
**ELECTROMAGNETIC COMPATIBILITY**  
**REGULATIONS**

20th July, 2007

*LEGAL NOTICE 28 of 2007.*

- 1.** (1) The title of these regulations is the Electromagnetic Compatibility Regulations. Citation and commencement.
- (2) These regulations shall come into force on the 20th July 2007.
- (3) Notwithstanding the provisions of subregulation (2), the placing on the market or putting into service of equipment -
- (a) which is in compliance with the Electromagnetic Compatibility Regulations, 2002\* and,
  - (b) which is placed on the market before the 20th July, 2009,
- shall not be impeded.
- 2.** For the purposes of these regulations the following definitions shall apply. Scope.
- "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;
- "the Community" means the European Community;
- "the Director" has the same meaning as it has in the Product Safety Act; Cap. 427.
- "the Directorate" means the Consumer and Industrial Goods Directorate of the Malta Standards Authority as established by the Malta Standards Authority Establishments of Directorates Order; S.L. 419.03
- "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;
- "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;
- "electromagnetic environment" means all electromagnetic phenomena observable in a given location;
- "equipment" means any apparatus or fixed installation;

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\*Revoked by these regulations.

"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;

"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;

"immunity" means the ability of equipment to perform as intended without degradation in the presence of an electromagnetic disturbance;

"Member State" means a member state of the European Union;

"mobile installations" are defined as a combination of apparatus and, where applicable, other devices, intended to be moved and operated in a range of locations;

"safety purposes" means the purposes of safeguarding human life or property.

#### Part I

##### General Provisions

General scope.

**3.** These regulations transpose Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC, hereinafter referred to as "the Directive".

Applicability.

**4.** (1) These regulations shall apply to equipment as defined in these regulations.

(2) For the purposes of these regulations the following shall be deemed to be an apparatus within the meaning of regulation 2 hereof:

- "components" or "sub-assemblies" intended for incorporation into an apparatus by the end user, which are liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance;
- mobile installations.

(3) These regulations shall not apply to:

- (a) equipment covered by Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity, which has been implemented in Malta as the Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of their Conformity Regulations;
- (b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on

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common rules in the field of civil aviation and establishing a European Aviation Safety Agency;

- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution and Convention of the ITU1, 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.

(4) These regulations shall not apply to equipment the inherent nature of the physical characteristics of which is such that -

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

(5) Where, for the equipment referred to in subregulation (1), the essential requirements referred to in Schedule I are wholly or partly laid down more specifically by any other law that transposes Community directives, the present regulations shall not apply, or shall cease to apply, to that equipment insofar as such requirements which are dealt with by the other legislation as from the date of implementation of that law.

(6) These regulations shall not affect the application of Community or local laws regulating the safety of equipment.

**5.** (1) Equipment shall be placed on the market or put into service only if it complies with the requirements of these regulations when properly installed, maintained and used for its intended purpose.

Placing on the market and, or putting to use.

(2) The placing on the market or the putting into service of equipment which complies with these regulations shall not be impeded, for reasons relating to electromagnetic compatibility.

(3) The display or demonstration at trade fairs, exhibitions or similar events of equipment which does not comply with these regulations shall not be impeded, provided that a visible sign clearly indicates that such equipment shall not be placed on the market or put into service until it has been brought into conformity with these regulations. Demonstration shall only take place provided that adequate measures are taken to avoid electromagnetic disturbances.

**6.** (1) These regulations shall not prevent the application of the following special measures by any Authority or regulator in Malta concerning the putting into service or use of equipment:

Application of special measures.

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

- 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.
- (2) (a) The measures taken in subregulation (1) shall be notified immediately to the Directorate giving details of the measures, including whether the measures are to be applied for an indefinite or definite period, and the reasons justifying their implementation.
- (b) The Directorate shall deliver its opinion on the measures taken and shall notify these measures to the Commission and the other Member States.
- (3) Subregulation (2) shall be without prejudice to the provisions of the Notification Procedure Regulations.
- S.L. 419.06
- Essential requirements.
- 7.** (1) Equipment shall meet the essential requirements set out in Schedule I.
- (2) (a) The compliance of equipment with the relevant harmonized standards whose references have been published in the Official Journal of the European Union shall raise a presumption of conformity with the essential requirements referred to in Schedule I to which such standards relate.
- (b) Such presumption of conformity is limited to the scope of the harmonized standards applied and the relevant essential requirements covered by such harmonized standards.
- (3) Compliance with a "harmonised standard" is not compulsory.
- Part II**  
**Apparatus**
- Conformity assessment procedure for apparatus.
- 8.** Compliance of apparatus with the essential requirements referred to in Schedule I shall be demonstrated by means of the procedure described in Schedule II (internal production control). However, at the discretion of the manufacturer or of his authorised representative in the Community, the procedure described in Schedule III may also be followed.
- 'CE' marking.
- 9.** (1) Apparatus whose compliance with these regulations has been established by means of the procedure laid down in regulation 8 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 and it shall be affixed in accordance with Schedule V.
- (2) The affixing to the apparatus, or to its packaging, or to the instructions for its use, of marks which are likely to mislead third parties in relation to the meaning and, or graphic form of the CE marking is 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) Without prejudice to regulation 11, if it is established that the CE marking has been unduly affixed, the manufacturer or his authorised representative in the Community shall bring the apparatus into conformity with the provisions concerning the CE marking under conditions imposed by the Director.

**10.** (1) Each apparatus shall be identified in terms of type, batch, serial number or any other information allowing for the identification of the apparatus. Other marks.

(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 shall 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 Schedule I, point 1.

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

(5) The information required to enable apparatus to be used in accordance with the intended purpose of the apparatus shall be contained in the instructions accompanying the apparatus.

**11.** (1) Where it is ascertained that apparatus bearing the CE marking does not comply with the requirements of these regulations, 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 shall be taken. Withdrawal from the market.

(2) The Director shall immediately inform the head of the Directorate of any such measure, indicating the reason for its decision and in particular, whether non-conformity is due to -

- (a) failure to satisfy the essential requirements referred to in Schedule I, where the apparatus does not comply with harmonised standards referred to in regulation 7;
- (b) incorrect application of the standards referred to in regulation 7;
- (c) shortcomings in the standards themselves referred to in regulation 7.

(3) Any decision taken pursuant to these regulations 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 laws of Malta and of the time limits to

which such remedies are subject.

(4) In the event of a decision as referred to in subregulation (3) 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.

Notified bodies.

**12.** (1) Bodies which have been designated to carry out the tasks referred to in Schedule III shall be notified to the Commission.

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(2) Such bodies are subject to the Method for Designating Conformity Assessment Bodies Regulations, and to the criteria set out in Schedule VI.

(3) Such notification shall state whether the bodies are designated to carry out the tasks referred to in Schedule III for all apparatus covered by these regulations, or the essential requirements referred to in Schedule I or whether the scope of designation is limited to certain specific aspects or categories of apparatus.

(4) Bodies which comply with the assessment criteria established by the relevant harmonised standards shall be presumed to comply with the criteria set out in Schedule VI covered by such harmonised standards. The references of these harmonized standards shall be found published in the Official Journal of the European Union.

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(5) Where a non-compliant apparatus has been subject to the conformity assessment procedure referred to in Schedule III and the body concerned has been designated by Malta, then the body shall be subject to extraordinary surveillance referred to in regulation 8 of the Method for Designating Conformity Assessment Bodies Regulations.

(6) The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall inform the Commission and the other Member States accordingly.

### Part III

#### Fixed Installations

Fixed installations.

**13.** (1) Apparatus which has been placed on the market and which may be incorporated into a fixed installation is subject to all relevant provisions for apparatus set out in these regulations.

(2) The provisions of regulations 7(1), 8, 9 and 10 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 regulation 10(1) and (2).

(3) Where there are indications of non-compliance of the fixed installation, and in particular, where there are complaints about disturbances being generated by the installation, evidence of compliance of the fixed installation shall be requested by the Director:

Provided that -

- (a) an assessment, when appropriate, shall be initiated, and
- (b) the parties involved are identified.

(4) Where non-compliance is established, appropriate measures to bring the fixed installation into compliance with the protection requirements set out in Schedule I, point 1, shall be imposed by the Director after consulting the parties involved.

The Directorate shall be informed of any such measures if the non-compliance was due to a shortcoming in good engineering practice, a shortcoming in a standard or the failure of apparatus to satisfy the essential requirements.

(5) The person who by virtue of ownership or operation has control of the relevant fixed installation shall be responsible to establish the compliance of a fixed installation with the relevant essential requirements.

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## Schedule I

(Regulation 7)

## 1. Protection requirements

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

- (a) the electromagnetic disturbance generated does not exceed the level above which radio and telecommunications equipment or other equipment cannot operate as intended;
- (b) it has a level of immunity to the electromagnetic disturbance to be expected in its intended use which allows it to operate without unacceptable degradation of its intended use.

## 2. Specific requirements for fixed installations

Installation and intended use of components:

A fixed installation shall be installed applying good engineering practices and respecting the information on the intended use of its components, with a view to meeting the protection requirements set out in Point 1 above. Those good engineering practices shall be documented and the documentation shall be held by the person(s) responsible at the disposal of the bodies mentioned in regulation 13 for inspection purposes for as long as the fixed installation is in operation.

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Schedule II

(Regulation 8)

## Conformity assessment procedure

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 Schedule I, point 1, hereto. 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 Schedule I, point 1 hereto, in all the possible configurations identified by the manufacturer as representative of its intended use.

3. In accordance with the provisions set out in Schedule IV, the manufacturer shall draw up technical documentation providing evidence of the conformity of the apparatus with the essential requirements of these regulations.

4. The manufacturer or his authorised representative in the Community shall hold the technical documentation at the disposal of the competent authorities for at least ten years after the date on which such apparatus was last manufactured.

5. The compliance of apparatus with all relevant essential requirements shall be attested by an EC declaration of conformity issued by the manufacturer or his authorised representative in the Community.

6. The manufacturer or his authorised representative in the 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 Community 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 these regulations that apply to them.

9. The technical documentation and the EC declaration of conformity shall be drawn up in accordance with the provisions set out in Schedule IV.

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### Schedule III

(Regulation 8)

#### Alternative conformity assessment procedure

1. This procedure consists of applying Schedule II, completed as follows:

2. The manufacturer or his authorised representative in the Community shall present the technical documentation to a notified body referred to in Article 12 of the Directive 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 these regulations 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 Community confirming the compliance of the apparatus. That statement shall be limited to those aspects of the essential requirements which have been assessed by the notified body.

4. The manufacturer shall add the statement of the notified body to the technical documentation.

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### Schedule IV

#### Technical documentation and EC declaration of conformity

1. Technical documentation

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

- a general description of the apparatus;
- evidence of compliance with the harmonised standards, if any, applied in full or in part;

- where the manufacturer has not applied harmonised standards, or has applied them only in part, a description and explanation of the steps taken to meet the essential requirements of these regulations, including a description of the electromagnetic compatibility assessment set out in Schedule II, point 1, results of design calculations made, examinations carried out, test reports, etc.;
  - a statement from the notified body, when the procedure referred to in Schedule III has been followed.
2. EC declaration of conformity

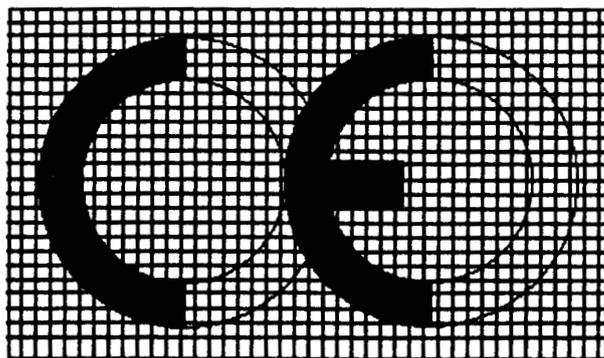
The EC declaration of conformity must contain, at least, the following:

- a reference to these regulations,
- an identification of the apparatus to which it refers, as set out in regulation 10(1),
- the name and address of the manufacturer and, where applicable, the name and address of his authorised representative in the Community,
- a dated reference to the specifications under which conformity is declared to ensure the conformity of the apparatus with the provisions of these regulations,
- the date of that declaration,
- the identity and signature of the person empowered to bind the manufacturer or his authorised representative.

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Schedule V  
(Regulation 9)  
CE marking

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



The CE marking must have a height of at least 5 mm. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. The CE marking must be affixed to the apparatus or to its data plate. Where this is not possible or not warranted on account of the nature of the apparatus, it must be affixed to the packaging, if any, and to the accompanying

documents. Where the apparatus is the subject of other regulations covering other aspects and which also provide for the CE marking, the latter shall indicate that the apparatus also conforms with those other regulations. However, where one or more of those regulations allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the regulations applied by the manufacturer. In that case, particulars of the regulations applied or Directives which they transpose (as published in the Official Journal of the European Union), must be given in the documents, notices or instructions required by the regulations and accompanying such apparatus.

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#### Schedule VI

#### (Regulation 12)

##### Criteria for the assessment of the bodies to be notified

1. The bodies notified by the Member States shall fulfill 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 these regulations;
- (d) independence of staff and technical personnel in relation to all interested parties, groups or persons directly or indirectly concerned with the equipment in question;
- (e) maintenance of professional secrecy by personnel;
- (f) possession of civil liability insurance unless such liability is covered by the Member State under national law.

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