

L.N. 368 of 2002

PRODUCT SAFETY ACT
(ACT NO. V OF 2001)

Electromagnetic Compatibility Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

1.1. The title of these regulations is the Electromagnetic Compatibility Regulations, 2002. Citation and commencement.

1.2. These regulations shall become operative on such date as notified by the Authority in the Gazette.

2.1. The provisions of these regulations are intended to harmonise the electromagnetic compatibility protection requirements (including emission and immunity) in order to guarantee the operation and compatibility of apparatus in their intended electromagnetic compatibility environment. Scope.

2.2. These regulations shall apply to apparatus liable to cause electromagnetic disturbance or the performance of which is liable to be affected by such disturbance.

2.2.1. It defines the protection requirements and inspection procedures relating thereto.

3.1. For the purposes of these regulations, the following definitions shall apply: Definitions.

3.1.1. "apparatus" means all electrical and electronic appliances together with equipment and installations containing electrical and/or electronic components.

3.1.2. "manufacture" means manufacture in the course of a business, and includes:

¹ OJ No. L139, 23-05-89, P.19.

² OJ No. L128, 23-05-91, P.1.

³ OJ No. L126, 12-05-92, P.1.

⁴ OJ No. L220, 30-08-93, P.1.

⁵ OJ No. L290, 24-11-93, P.1.

⁶ OJ No. L204, 21-07-98, P.37.

⁷ OJ No. L217, 05-08-98, P.18.

- (a) assembly;
- (b) finishing;
- (c) reconditioning;
- (d) modification which substantially alters the electromagnetic compatibility characteristics of the apparatus; but does not include repair or the assembly of relevant apparatus from a kit; and cognate expressions shall be construed accordingly.

3.1.3. “kit” means a collection of all or substantially all the necessary components, for supply as a single commercial unit, required for the construction of an item of electrical apparatus and intended for such use, whether or not accompanied by instructions.

3.1.4. “electromagnetic disturbance” means any electromagnetic phenomenon which may degrade the performance of a device, unit of equipment or system. An electromagnetic disturbance may be electromagnetic noise, an unwanted signal or a change in the propagation medium itself. The phenomenon and effects listed in Schedule IV hereto may be regarded as electromagnetic disturbance.

3.1.5. “immunity” means the ability of a device, unit of equipment or system to perform without degradation of quality in the presence of an electromagnetic disturbance.

3.1.6. “electromagnetic compatibility” means the ability of a device, unit of equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything in that environment.

3.1.7. “radio amateur apparatus” means wireless telegraphy apparatus designed or adapted for use in the amateur service, but excludes citizen’s band apparatus, and in this definition:

(a) “amateur service” has the meaning given by Article 1, definition 53, of the 1990 edition of the Radio Regulations annexed to the International Telecommunications Convention 1982 pursuant to Articles 43 and 83 of that Convention; and

(b) “citizen’s band apparatus” means wireless telegraphy apparatus designed or adapted exclusively for the provision of voice radiocommunications in the frequency bands 26.965 MHz to 27.405 MHz.

3.1.8. “competent body” means any body which meets the criteria listed in Schedule II to these regulations and is recognised as such.

3.1.9. "EC type-examination certificate" is a document in which a notified body referred to in Article 10 (6) of the Directive certifies that the type of equipment examined complies with the provisions of these regulations which concern it.

3.1.10. "the Directive" means Council Directive 89/336/EEC¹ on the approximation of the laws of the Member States relating to electromagnetic compatibility, as amended by Directives 91/263/EEC², concerning telecommunication terminal equipment, 92/31/EEC³ defining the transitional period, 93/68/EEC⁴ concerning "CE marking" and 93/97/EEC⁵ supplementary Directive 91/263/EEC in respect of satellite earth station equipment.

3.1.11. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC⁶ of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC⁷ of the European Parliament and of the Council.

3.1.12. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.13. "OJ" means the Official Journal of the European Communities.

3.1.14. "Community" means the European Community.

3.1.15. "CE marking" means marking as set out in Annex I of the Directive, which is set out in Schedule I to these regulations.

3.1.16. "placing on the market" of relevant apparatus other than a kit means importation, wholesale, retail sale and distribution free of charge by the person who assembled it or the person who imported it, cognate expressions shall be construed accordingly. However, relevant apparatus shall not be regarded as having been placed on the market only if it has been operated by or on behalf of the manufacturer at a trade fair or exhibition or by a supplier for demonstration purposes.

3.1.17. "manufacturer" means the person, who is primarily responsible for designing and manufacturing the apparatus so that this complies with the requirements of these regulations.

3.1.18. “authorized representative” means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.19. “importer” means any person who places the apparatus from a foreign country on to the Community or Maltese market so that he supplies such apparatus on the first occasion that it is supplied in the Community or Malta.

3.1.20. “person who supplies apparatus” means wholesalers, distributors, retailers etc.

3.1.21. “responsible person” in relation to relevant apparatus means:

- (a) the manufacturer thereof;
- (b) the manufacturer’s authorized representative; or
- (c) where the manufacturer is not established in the Community or Malta and he has not appointed an authorized representative, the person who places the relevant apparatus on the Community or Maltese market.

3.1.22. “spare part” means a component or combination of components intended for use in replacing parts of electrical apparatus.

3.1.23. “consumer” includes an industrial or commercial consumer.

3.1.24. “end user” means the consumer and, where the manufacturer makes apparatus for his own use, such manufacturer who first uses electrical apparatus for the purpose for which it is designed, but excludes a manufacturer who uses the apparatus by incorporating it into other apparatus.

3.1.25. “second-hand apparatus” means apparatus which has previously been used by an end user.

Applicability.

4.1. The provisions of these regulations shall apply to all imported apparatus as well as to that manufactured for the local market.

4.1.1. Regulation 4.1 above shall not be construed to prohibit any person from possessing for supply at any time before it is supplied, offered for supply or exposed for supply in Malta for the first time, or before it is agreed for the first time to supply it in Malta, any apparatus referred to in regulation 2.2 of these regulations which has been imported

into Malta and which does not comply with the requirements of these regulations.

4.2. Subject to regulation 4.3 below, the provisions of these regulations shall not apply to apparatus intended exclusively for export.

4.3. Subject to regulations 9.1 to 9.4.2 of these regulations, regulations 4.2. above shall not apply if the CE marking or any inscription liable to be confused therewith is affixed to the apparatus.

4.4. In so far as protection requirements specified in these regulations are harmonised, in the case of certain apparatus, by specific regulations, these regulations shall not apply or shall cease to apply with regard to such apparatus or protection requirements upon the entry into force of those specific regulations.

4.4.1. Apparatus totally excluded from the provisions of these regulations:

- motor vehicles
- active implantable medical devices
- *in vitro* diagnostic medical devices
- medical equipment.

4.4.2. Apparatus excluded for the immunity part of the provisions of these regulations:

- non-automatic weighing instruments.

4.4.3. Apparatus excluded for the emission part of the provisions of these regulations:

- agricultural and forestry tractors.

4.5. Radio equipment used by radio amateurs within the meaning of Article 1, definition 53, of the radio regulations in the International Telecommunications Convention, shall be excluded from the scope of these regulations, unless the apparatus is available commercially.

4.6. Subject to regulation 4.6.1 below, these regulations do not apply to spare parts.

4.6.1. Nothing in these regulations shall be taken to affect the application of these provisions to apparatus into which a spare part has been incorporated.

4.7. The provisions of these regulations do not apply to the supply of apparatus by the manufacturer thereof to his authorized representative.

4.8. Subject to regulation 4.8.1 below, the provisions of these regulations do not apply to second-hand apparatus.

4.8.1. Nothing in regulation 4.8 above shall be taken to disapply the provisions of these regulations to:

(a) the supply of second-hand apparatus which has, since it was last used, been subjected to further manufacture within the meanings of sub-paragraphs (c) and (d) of the definition of manufacture in regulation 3.1.2. of these regulations;

(b) the supply or taking into service of such apparatus following such further manufacture.

Conformity.

5.1. All appropriate measures shall be taken to ensure that the apparatus referred to in regulation 2.2 of these regulations may be placed on the market or taken into service only if it bears the CE marking provided for in regulations 9.1 to 9.4.2 of these regulations indicating its conformity to all the provisions of these regulations, including the conformity assessment procedures laid down in regulations 8.1 to 8.2.3 of these regulations, when it is properly installed and maintained and when it is used for the purposes for which it is intended.

5.1.1. The information to enable use in accordance with the intended purpose of the relevant apparatus must be contained in the manufacturer's instructions accompanying the apparatus.

5.2. The apparatus referred to in regulation 2.2 of these regulations shall be so constructed that:

(a) the electromagnetic disturbance it generates does not exceed a level allowing radio and telecommunications equipment and other apparatus to operate as intended;

(b) the apparatus has an adequate level of intrinsic immunity of electromagnetic disturbance to enable it to operate as intended.

5.2.1. The principal protection requirements are set out in Annex III of the Directive, which is set out in Schedule III to these regulations.

5.2.2. Without prejudice to the generality of the foregoing provisions of these regulations, the performance of relevant apparatus shall be taken to be degraded if any of the following types of interference with its function occur:

(a) permanent, temporary or intermittent:

- (i) total loss of function;
- (ii) significant impairment of function; or

(b) where the apparatus is information storage or retrieval equipment, destruction or corruption of information stored thereby.

5.2.3. For the purpose of these regulations, a nuclear electromagnetic pulse (NEMP) shall not be regarded as electromagnetic disturbance.

5.3. Subject to the provisions of regulation 8.2 of these regulations, apparatus shall be presumed to meet the protection requirements referred to in regulation 5.2 of these regulations.

5.4. The placing on the market and the taking into service of apparatus covered by these regulations shall not be impeded for reasons relating to electromagnetic compatibility, provided that such apparatus satisfies the requirements thereof.

5.5. The requirements of these regulations shall not prevent the application of the following special measures:

- (a) measures with regard to the taking into service and use of the apparatus taken for a specific site in order to overcome an existing or predicted electromagnetic compatibility problem;
- (b) measures with regard to the installation of the apparatus taken in order to protect the public telecommunications networks or receiving or transmitting stations used for safety purposes.

6.1. Compliance with the protection requirements referred to in regulation 5.2 of these regulations shall be presumed in the case of apparatus which is in conformity: Certificates of Conformity.

(a) with the relevant national standards transposing the harmonised standards, the reference numbers of which have been published in the *Official Journal of the European Communities*;

(b) or with the relevant national standards in so far as, in the areas covered by such standards, no harmonised standards exist.

6.2. Where the manufacturer has not applied, or has applied only in part, the standards referred to in regulation 6.1 of these regulations,

or where no such standards exist, apparatus shall be regarded as satisfying the protection requirements provided that such apparatus has been certified by the means of attestation provided for in regulation 8.2 of these regulations.

6.3. The conformity of apparatus designed for the transmission of radiocommunications, as defined in the International Telecommunication Union Convention, with the provisions of these regulations shall be certified in accordance with the procedure laid down in regulation 8.1 once the manufacturer or his authorized representative has obtained an EC type-examination certificate concerning this apparatus issued by one of the notified bodies.

6.3.1. The provisions in regulation 6.3 of these regulations shall not apply to equipment falling within the scope of Directive 1999/05/EC⁸.

6.3.2. The provisions in regulation 6.3 of these regulations shall not apply to the above apparatus where it is designed and intended exclusively for radio amateurs within the meaning of regulation 2.3 of these regulations.

Withdrawal and
prohibition from
market.

7.1. Where it is ascertained that apparatus accompanied by one of the means of attestation provided for in regulations 8.1 to 8.2.3 of these regulations does not comply with the protection requirements referred to in regulation 5.2 of these regulations, all appropriate measures shall be taken to withdraw the apparatus from the market, prohibit its placing on the market or restrict its free movement.

7.2. Where apparatus which does not comply is accompanied by one of the means of attestation referred to in regulations 8.1 to 8.2.3 of these regulations, all appropriate action shall be taken against the author of the attestation.

7.3. The Consumer and Industrial Goods Directorate⁹ of the Malta Standards Authority shall be immediately informed of any such measures taken under regulations 7.1 and 7.2 above, indicating the reasons for such decision and whether non-compliance is due to:

- (a) incorrect application of the harmonised standards referred to in regulation 6.1 of these regulations;
- (b) shortcomings in the harmonised standards referred to in regulation 6.1 of these regulations;

⁸ OJ No. L091, 07-04-99, P. 10-28.

⁹ L.N. 213 of 2000 -- Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

(c) failure to satisfy the requirements referred to in regulation 5.2 and 5.2.1 of these regulations where the apparatus does not meet the harmonised standards referred to in regulation 6.1 of these regulations.

7.4. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 7.1 and 7.2 of these regulations.

8.1. In the case of apparatus for which the manufacturer has applied the standards referred to in regulation 6.1 of these regulations, the conformity of apparatus with these regulations shall be certified by an EC declaration of conformity issued by the manufacturer or his authorized representative. EC Declaration of Conformity.

8.1.1. This declaration shall be held at the disposal of the Director of Consumer Affairs for ten years following the placing of the apparatus on the market.

8.1.2. The manufacturer or his authorized representative shall also affix the CE marking provided for in regulations 9.1 to 9.4.2 of these regulations to the apparatus or else to the packaging, instructions for use or guarantee certificate.

8.1.3. Where the manufacturer is not established in the Community or Malta, the above obligation to keep the EC declaration of conformity available shall be the responsibility of the person who places the apparatus on the Community or Maltese market.

8.1.4. The provisions governing the declaration of conformity and the CE marking are set out in Annex I of the Directive, which is set out in Schedule I to these regulations.

8.2. In the case of apparatus for which the manufacturer has not applied, or has applied only in part, the standards referred to in regulation 6.1 of these regulations or failing such standards, the manufacturer or his authorized representative shall hold, at the disposal of the Director of Consumer affairs, as soon as the apparatus is placed on the market, a technical construction file. This file shall describe the apparatus, set out the procedures used to ensure conformity of the apparatus with the protection requirements referred to in regulation 5.2 of these regulations and include a technical report or certificate, one or other obtained from a competent body.

8.2.1. The file shall be held at the disposal of the Director of Consumer Affairs for ten years following the placing of the apparatus on the market.

8.2.2. Where the manufacturer is not established in the Community or Malta, this obligation to keep a technical file available shall be the responsibility of the person who places the apparatus on the Community or Maltese market.

8.2.3. The conformity of apparatus with that described in the technical file shall be certified in accordance with the procedure laid down in regulation 8.1 of these regulations.

CE Conformity
Marking.

9.1. The CE conformity marking shall consist of the initials "CE" in the form shown in the specimen in Annex I of the Directive, which is set out in Schedule I to these regulations.

9.2. The CE marking shall be affixed distinctly, visibly, legibly and indelibly to apparatus or else to the packaging, instructions for use or guarantee certificate.

9.3. The affixing to apparatus, its packaging, instructions for use or guarantee certificate of markings which are likely to deceive third parties as to the meaning and form of the CE marking, shall be prohibited. Any other marking may be affixed to the apparatus, its packaging, instructions for use or guarantee certificate, provided that the visibility and legibility of the CE marking is not thereby reduced.

9.4. Without prejudice to regulations 7.1 to 7.4 of these regulations:

9.4.1. where it is established that the CE marking has been unduly affixed, the responsible person shall be obliged to make the product conform as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Director of Consumer Affairs.

9.4.2. where non-compliance continues, all appropriate measures shall be taken to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in regulations 7.1 to 7.4 of these regulations.

Revokes L.N. 24 of
1999.

10.1. The Electromagnetic Compatibility Order, 1999 is hereby being revoked.

Schedule I

Based on Annex I of the Directive

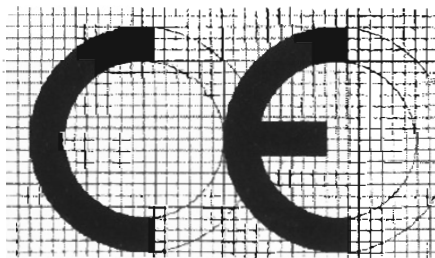
1. EC declaration of conformity

The EC declaration of conformity must contain the following:

- description of the apparatus to which it refers,
- reference to the specifications under which conformity is declared, and, where appropriate, to the national measures implemented to ensure the conformity of the apparatus with the provisions of these regulations,
- identification of the signatory empowered to bind the manufacturer or his authorized representative,
- where appropriate, reference to the EC type-examination certificate issued by a notified body.

2. CE conformity marking

- The CE conformity marking shall consist of the initials "CE" taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

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

- Where apparatus is the subject of other Directives, as published in the Official Journal of the European Communities, covering other aspects and which also provide for the CE conformity marking, the latter shall indicate that the apparatus are also presumed to conform to those other Directives.

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- However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

Schedule II

Based on Annex II of the Directive

CRITERIA FOR THE ASSESSMENT OF THE BODIES TO BE NOTIFIED

The bodies designated by the Member States must fulfil the following minimum conditions:

1. availability of personnel and of the necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the verification function provided for in these regulations, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with the product in question;
4. maintenance of professional secrecy by personnel;
5. possession of civil liability insurance unless such liability is covered by the State under national law.

Fulfilment of the conditions under points 1 and 2 shall be verified at intervals by the competent authorities of the Member States.

Schedule III

Based on Annex III of the Directive

ILLUSTRATIVE LIST OF THE PRINCIPAL PROTECTION REQUIREMENTS

The maximum electromagnetic disturbance generated by the apparatus shall be such as not to hinder the use of in particular the following apparatus:

- (a) domestic radio and television receivers
- (b) industrial manufacturing equipment
- (c) mobile radio equipment
- (d) mobile radio and commercial radiotelephone equipment
- (e) medical and scientific apparatus
- (f) information technology equipment
- (g) domestic appliances and household electronic equipment
- (h) aeronautical and marine radio apparatus
- (i) educational electronic equipment
- (j) telecommunications networks and apparatus
- (k) radio and television broadcast transmitters
- (l) lights and fluorescent lamps.

Apparatus, and especially the apparatus referred to in (a) to (l), should be constructed in such a way that it has an adequate level of electromagnetic immunity in the usual electromagnetic compatibility environment where the apparatus is intended to work so as to allow its unhindered operation taking into account the levels of disturbance generated by apparatus complying with the standards laid down in Article 7 of the Directive and regulations 6.1 and 6.2 of these regulations.

The information required to enable use in accordance with the intended purpose of the apparatus must be contained in the instructions accompanying the apparatus.

Schedule IV**PHENOMENA AND EFFECTS WHICH MAY BE REGARDED
AS ELECTROMAGNETIC DISTURBANCE**

Without prejudice to the generality of regulation 3.1.4 of these regulations, the following phenomena and effects may be regarded as electromagnetic disturbance:

1. Conducted low-frequency phenomena:

- harmonics, interharmonics;
- signalling voltages;
- voltage fluctuations;
- voltage dips and interruptions;
- voltage unbalance;
- power-frequency variations;
- induced low-frequency voltages;
- DC in AC networks; and
- DC ground circuits;

2. Radiated low-frequency phenomena:

- magnetic fields; and
- electric fields;

3. Conducted high-frequency phenomena:

- induced continuous wave (CW) voltages or currents;
- unidirectional transients; and
- oscillatory transients;

4. Radiated high frequency phenomena:

- magnetic fields;
- electric fields;
- electromagnetic fields;
- continuous waves; and
- transients; and

5. Electrostatic discharge phenomena (ESD).

