

SUBSIDIARY LEGISLATION 427.35

ELECTROMAGNETIC COMPATIBILITY REGULATIONS

20th April, 2016*

LEGAL NOTICE 98 of 2016.

1. (1) The title of these regulations is the Electromagnetic Compatibility Regulations. Citation and applicability.

(2) These regulations transpose Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on electromagnetic compatibility, repealing Directive 2004/108/EC.

(3) Notwithstanding the provisions of sub-regulation (2), the placing on the market or putting into service of equipment:

- (a) which is in compliance with the Electromagnetic Compatibility Regulations, 2007; and
- (b) which was placed on the market before the 20th April, 2016,

shall not be impeded.

(4) These regulations lay down electromagnetic compatibility requirements for equipment as defined in regulation 2 and made available on the market.

2. (1) In these regulations, unless the context otherwise requires: Interpretation.

"accreditation" means an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity;

"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;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

"CE marking" means a marking by which the manufacturer indicates that the apparatus is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

"conformity assessment" means the process demonstrating

* See regulation 1(5) of these Regulations as originally promulgated.

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whether the essential requirements of these regulations relating to an apparatus have been fulfilled;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

"Director General" means the Director General (Technical Regulations) as defined in article 2 of the Malta Competition and Consumer Affairs Act;

"distributor" means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market;

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

"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;

"European standard" means a standard adopted by a European standardisation organisation;

"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 European standard adopted on the basis of a request made by the Commission for the application of Union harmonization legislation;

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

"importer" means any natural or legal person established within the Union who places apparatus from a third country on the Union market;

"making available on the market" means any supply of apparatus for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any natural or legal person who manufactures apparatus or has apparatus designed or manufactured, and markets that apparatus under his name or trade mark;

"MCCAA" means the Malta Competition and Consumer Affairs Authority, as established by the Malta Competition and Consumer Affairs Act; Cap. 510.

"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;

"MSD" means the Market Surveillance Directorate within the TRD;

"national accreditation body" means the sole body in a Member State that performs accreditation with authority derived from the State;

"placing on the market" means the first making available of apparatus on the Union market;

"recall" means any measure aimed at achieving the return of apparatus that has already been made available to the end-user;

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

"technical specification" means a document that prescribes technical requirements to be fulfilled by the equipment;

"TRD" means the Technical Regulations Division of the MCCAA, established by the Malta Competition and Consumer Affairs Act; Cap. 510.

"Union harmonization legislation" means any Union legislation harmonising the conditions for the marketing of products;

"withdrawal" means any measure aimed at preventing apparatus in the supply chain from being made available on the market.

(2) For the purposes of these regulations, the following shall be considered as apparatus:

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

3. (1) These regulations shall apply to equipment as defined in regulation 2. Scope.

(2) These regulations shall not apply to:

- (a) equipment covered by Directive 1999/5/EC and made available on the market before 13th June, 2016;
- (b) aeronautical products, parts and appliances as referred to in Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on

- common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC;
- (c) radio equipment used by radio amateurs within the meaning of the Radio Regulations adopted in the framework of the Constitution of the International Telecommunication Union and the Convention of the International Telecommunication Union, unless the equipment is made available on the market;
 - (d) equipment the inherent nature of the physical characteristics of which is such that:
 - (i) 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
 - (ii) it operates without unacceptable degradation in the presence of the electromagnetic disturbance normally consequent upon its intended use;
 - (e) custom built evaluation kits destined for professionals to be used solely at research and development facilities for such purposes.

For the purposes of sub-regulation (2)(c), kits of components to be assembled by radio amateurs and equipment made available on the market and modified by and for the use of radio amateurs are not regarded as equipment made available on the market.

(3) Where, for the equipment referred to in sub-regulation (1), the essential requirements set out in Schedule I are wholly or partly laid down more specifically by other Union legislation, these regulations shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of that Union legislation.

(4) These regulations shall not affect the application of Union or national legislation regulating the safety of equipment.

Making available on the market/ putting into service and freedom of movement.

4. (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.

(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 and, 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.

5. (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.

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

(2) The measures taken in sub-regulation (1) shall be notified immediately to the TRD, 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.

(3) The TRD shall deliver its opinion on the measures taken and shall notify these measures to the Commission and the other Member States.

(4) Sub-regulations (2) and (3) shall be without prejudice to the provisions of the Notification Procedure Regulations.

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6. The equipment shall meet the essential requirements set out in Schedule I.

Essential requirements.

7. (1) When placing their apparatus on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential requirements set out in Schedule I.

Obligations.

(2) Manufacturers shall draw up the technical documentation referred to in Schedule II or Schedule III and carry out the relevant conformity assessment procedure referred to in regulation 14 or have it carried out.

(3) Where compliance of apparatus with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

(4) Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the apparatus has been placed on the market.

(5) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in apparatus design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of apparatus is declared shall be adequately taken into account.

(6) Manufacturers shall ensure that apparatus which they have placed on the market bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the apparatus does not allow it, that the required information is

provided on the packaging or in a document accompanying the apparatus.

(7) Manufacturers shall indicate, on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and the MSD.

(8) Manufacturers shall ensure that the apparatus is accompanied by instructions and the information referred to in regulation 18, in Maltese or English. Such instructions and information, as well as any labelling, shall be clear, understandable and intelligible.

(9) Manufacturers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the apparatus presents a risk, manufacturers shall immediately inform the MSD, giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) Manufacturers shall, further to a reasoned request from the MSD, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the apparatus with these regulations, in Maltese or English. They shall cooperate with the MSD, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

Authorised
representatives.

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative.

(2) The obligations laid down in regulation 7(1) and the obligation to draw up technical documentation referred to in regulation 7(2) shall not form part of the authorised representative's mandate.

(3) An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of the MSD for 10 years after the apparatus has been placed on the market;
- (b) further to a reasoned request from the MSD, provide it with all the information and documentation necessary to demonstrate the conformity of the apparatus; and
- (c) cooperate with the MSD, at their request, on any action taken to eliminate the risks posed by the apparatus covered by the authorised representative's

mandate.

9. (1) Importers shall place only compliant apparatus on the market. Obligations of importers.

(2) Before placing apparatus on the market importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 14 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the apparatus bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in regulations 7(6) and 7(7).

(3) Where an importer considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Schedule I, he shall not place the apparatus on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the importer shall inform the manufacturer and the MSD to that effect.

(4) Importers shall indicate on the apparatus their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The contact details shall be in a language easily understood by end-users and the MSD.

(5) Importers shall ensure that the apparatus is accompanied by instructions and the information referred to in regulation 18 in Maltese or English.

(6) Importers shall ensure that, while an apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Schedule I.

(7) Importers who consider or have reason to believe that an apparatus which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate.

(8) Furthermore, where the apparatus presents a risk, importers shall immediately inform the MSD to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) Importers shall, for 10 years after the apparatus has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the MSD and ensure that the technical documentation can be made available to it, upon request.

(10) Importers shall, further to a reasoned request from the MSD, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of apparatus in Maltese or English. They shall cooperate with the MSD, at its request, on any action taken to eliminate the risks posed by apparatus which they have placed on the market.

Obligations of distributors.

10. (1) When making apparatus available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making apparatus available on the market distributors shall verify that the apparatus bears the CE marking, that it is accompanied by the required documents and by instructions and the information referred to in regulation 18 in Maltese or English and that the manufacturer and the importer have complied with the requirements set out in regulations 7(6), 7(7) and 9(4) respectively.

(3) Where a distributor considers or has reason to believe that apparatus is not in conformity with the essential requirements set out in Schedule I, he shall not make the apparatus available on the market until it has been brought into conformity. Furthermore, where the apparatus presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the MSD.

(4) Distributors shall ensure that, while apparatus is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential requirements set out in Schedule I.

(5) Distributors who consider or have reason to believe that apparatus which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that apparatus into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the apparatus presents a risk, distributors shall immediately inform the MSD to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) Distributors shall, further to a reasoned request from the MSD, provide it with all the information and documentation in paper or electronic form, necessary to demonstrate the conformity of the apparatus. They shall cooperate with the MSD, at its request, on any action taken to eliminate the risks posed by apparatus which they have made available on the market.

Obligations of manufacturers applying to importers and distributors.

11. An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 7, where he places apparatus on the market under his name or trade mark or modifies apparatus already placed on the market in such a way that compliance with these regulations may be affected.

Identification of economic operators.

12. (1) Economic operators shall, on request, identify the following to the TRD:

- (a) any economic operator who has supplied them with apparatus;
- (b) any economic operator to whom they have supplied apparatus.

(2) Economic operators shall be able to present the information referred to in sub-regulation (1) for 10 years after they have been supplied with the apparatus and for 10 years after they have

supplied the apparatus.

13. Equipment which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential requirements set out in Schedule I covered by those standards or parts thereof.

Presumption of conformity of equipment.

14. (1) Compliance of apparatus with the essential requirements set out in Schedule I shall be demonstrated by means of either of the following conformity assessment procedures:

Conformity assessment procedures for apparatus.

- (a) internal production control set out in Schedule II;
- (b) EU type examination that is followed by Conformity to type based on internal production control set out in Schedule III.

(2) The manufacturer may choose to restrict the application of the procedure referred to in sub-regulation (1)(b) to some aspects of the essential requirements, provided that for the other aspects of the essential requirements the procedure referred to in sub-regulation (1)(a) is applied.

15. (1) The EU declaration of conformity shall state that the fulfillment of the essential requirements set out in Schedule I has been demonstrated.

EU declaration of conformity.

(2) The EU declaration of conformity shall have the model structure set out in Schedule IV, shall contain the elements specified in the relevant modules set out in Schedules II and III and shall be continuously updated. It shall be translated into Maltese or English.

(3) Where apparatus is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the apparatus with the requirements laid down in these regulations.

16. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

General principles of the CE marking.

17. (1) The CE marking shall be affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging and to the accompanying documents.

Rules and conditions for affixing the CE marking.

(2) The CE marking shall be affixed before the apparatus is placed on the market.

(3) Improper use of the CE marking shall subject the relevant economic operator/s to the measures described in regulation 37.

Information concerning the use of apparatus.

18. (1) Apparatus shall be accompanied by 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 essential requirements set out in point 1 of Schedule I.

(2) Apparatus for which compliance with the essential requirements set out in point 1 of Schedule I is not ensured in residential areas shall be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging.

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

Fixed installations.

19. (1) Apparatus which has been made available on the market and which may be incorporated into a fixed installation shall be subject to all relevant provisions for apparatus set out in these regulations:

Provided that, the requirements of regulations 6 to 12 and regulations 14 to 18 shall not be compulsory in the case of apparatus which is intended for incorporation into a particular fixed installation and is otherwise not made available on the market.

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 also include the information referred to in regulations 7(6), 7(7) and 9(4).

The good engineering practices referred to in point 2 of Schedule I shall be documented and the documentation shall be held by the person or persons responsible at the disposal of the MSD for inspection for as long as the fixed installation is in operation.

(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 MSD may request evidence of compliance of the fixed installation, and, when appropriate, initiate an evaluation.

Where non-compliance is established, the MSD shall impose appropriate measures to bring the fixed installation into compliance with the essential requirements set out in Schedule I.

(3) Member States 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.

Notification.

20. Bodies authorised to carry out third-party conformity assessment tasks under these regulations shall be notified to the European Commission and the other Member States by the TRD.

Notifying authorities.

21. The TRD shall be the designated notifying authority responsible for setting up and carrying out the necessary

procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with regulation 26.

22. The assessment and monitoring referred to in regulation 21 shall be carried out by the National Accreditation Board as the national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

National
Accreditation
Board.

23. Conformity assessment bodies shall be notified to the European Commission and the other Member States by the TRD using the electronic notification tool developed and managed by the European Commission.

Information
obligation on
notifying
authorities.

24. (1) For the purposes of notification, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (11).

Requirements
relating to notified
bodies.

(2) A conformity assessment body shall be established as stipulated in the Method for Designating Conformity Assessment Bodies Regulations.

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(3) A conformity assessment body shall be a third-party body independent of the organisation or the apparatus it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of apparatus which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

(4) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the apparatus which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed apparatus that are necessary for the operations of the conformity assessment body or the use of such apparatus for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those apparatus, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

(5) Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures

and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

(6) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Schedule III and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of apparatus in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

(7) The personnel responsible for carrying out conformity assessment tasks shall have the following:

- (a) per sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential requirements set out in Schedule I, of the applicable harmonised standards and of the relevant provisions of European Union harmonisation legislation and of national legislation;
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

(8) The impartiality of the conformity assessment bodies, their

top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

(9) Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law.

(10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Schedule III or any provision of national law giving effect to it, except in relation to the TRD. Proprietary rights shall be protected.

(11) Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant European Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

25. Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union it shall be presumed to comply with the requirements set out in regulation 24 in so far as the applicable harmonised standards cover those requirements.

Presumption of conformity of notified bodies.

26. (1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in regulation 24 and shall inform the notifying authority accordingly.

Subsidiaries of and subcontracting by notified bodies.

(2) Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

(3) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(4) Notified bodies shall keep at the disposal of the TRD the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Schedule III.

27. (1) A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

Application for notification.

(2) The application for notification shall be accompanied by a

description of the conformity assessment activities, the conformity assessment module or modules and the apparatus for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in regulation 24.

(3) Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in regulation 24.

Notification procedure.

28. (1) Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in regulation 24.

(2) They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the European Commission.

(3) The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and apparatus concerned and the relevant attestation of competence.

(4) Where a notification is not based on an accreditation certificate as referred to in regulation 27(2), the notifying authority shall provide the European Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in regulation 24.

(5) The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of these regulations.

Changes to notifications.

29. (1) Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the European Commission and the other Member States accordingly.

(2) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the TRD shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

30. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedule III.

Operational obligations of notified bodies.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators.

Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the apparatus technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the apparatus with these regulations.

(3) Where a notified body finds that the essential requirements set out in Schedule I or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate.

(4) Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that an apparatus no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

(5) Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

31. Member States shall ensure that an appeal procedure against decisions of the notified bodies is available.

Appeal against decisions of notified bodies.

32. (1) Notified bodies shall inform the TRD of the following:

Information obligation on notified bodies.

- (a) any refusal, restriction, suspension or withdrawal of a certificate;
- (b) any circumstances affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) Notified bodies shall provide the other bodies notified under these regulations carrying out similar conformity assessment activities covering the same apparatus with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Coordination of notified bodies

33. Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European Commission.

Union market surveillance and control of apparatus entering the Union market.

34. Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to apparatus.

Procedure for dealing with apparatus presenting a risk at national level.

35. (1) Where the MSD has sufficient reason to believe that an apparatus covered by these regulations presents a risk to aspects of public interest protection covered by these regulations, it shall carry out an evaluation in relation to the apparatus concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the MSD for that purpose.

(2) Where, in the course of the evaluation referred to in sub-regulation (1), the MSD finds that the apparatus does not comply with the requirements laid down in these regulations, it shall without delay require the relevant economic operator to take all appropriate corrective actions to bring the apparatus into compliance with those requirements, to withdraw the apparatus from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

(3) The MSD shall inform the relevant notified body accordingly.

(4) Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in sub-regulation (2).

(5) Where the MSD considers that non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation, and of the actions which it has required the economic operator to take.

(6) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the apparatus concerned that it has made available on the market throughout the European Union.

(7) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (2), the MSD shall take all appropriate provisional measures to prohibit or restrict the apparatus's being made available on the national market, to withdraw the apparatus from that market or to recall it.

(8) The MSD shall inform the Commission and the other Member States, without delay, of those measures.

(9) The information referred to in sub-regulation (8) shall include all available details, in particular the data necessary for the identification of the non-compliant apparatus, the origin of the apparatus, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the MSD shall indicate whether the non-compliance is

due to either of the following:

- (a) failure of the apparatus to meet the requirements relating to aspects of public interest protection covered by these regulations; or
- (b) shortcomings in the harmonised standards referred to in regulation 13 conferring a presumption of conformity.

(10) Member States other than the Member State initiating the procedure under these regulations shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the apparatus concerned, and, in the event of disagreement with the adopted national measure, of their objections.

(11) Where, within three months of receipt of the information referred to in sub-regulation (8), no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

(12) The TRD in such instances shall ensure that appropriate restrictive measures, such as withdrawal of the apparatus from the market, are taken in respect of the apparatus concerned without delay.

36. (1) Without prejudice to regulation 35, where the MSD makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

Formal non-compliance.

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of regulation 17 of these regulations;
- (b) the CE marking has not been affixed;
- (c) the EU declaration of conformity has not been drawn up;
- (d) the EU declaration of conformity has not been drawn up correctly;
- (e) technical documentation is either not available or not complete;
- (f) the information referred to in regulation 7(7) or regulation 9(4) is absent, false or incomplete;
- (g) any other administrative requirement provided for in regulations 7 and 9 is not fulfilled.

(2) Where the non-compliance referred to in sub-regulation (1) persists, the MSD shall take all appropriate measures to restrict or prohibit the apparatus being made available on the market or ensure that it is recalled or withdrawn from the market.

37. Economic operators failing to comply with the requirements of these regulations are subject to the provisions of article 26 of the Product Safety Act.

Penalties.

Cap. 427.

SCHEDULE I

ESSENTIAL REQUIREMENTS

1. General 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 essential requirements set out in point 1.

SCHEDULE II

MODULE A: INTERNAL PRODUCTION CONTROL

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4 and 5 of this Schedule, and ensures and declares on his sole responsibility that the apparatus concerned satisfy the requirements of these regulations that apply to it.

2. **Electromagnetic compatibility assessment**

The manufacturer shall perform an electromagnetic compatibility assessment of the apparatus, on the basis of the relevant phenomena, with a view to meeting the essential requirements set out in point 1 of Schedule I.

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 essential requirements set out in point 1 of Schedule I in all the possible configurations identified by the manufacturer as representative of its intended use.

3. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the apparatus conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall, wherever applicable, contain at least the following elements:

- (a) a general description of the apparatus;
- (b) conceptual design and manufacturing drawings and schemes of

- components, sub-assemblies, circuits, etc.;
- (c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
- (d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
- (e) results of design calculations made, examinations carried out, etc.;
- (f) test reports.

4. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured apparatus with the technical documentation referred to in point 3 of this schedule and with the essential requirements set out in point 1 of Schedule I.

5. **CE marking and EU declaration of conformity**

5.1 The manufacturer shall affix the CE marking to each individual apparatus that satisfies the applicable requirements of these regulations.

5.2 The manufacturer shall draw up a written EU declaration of conformity for an apparatus model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. **Authorised representative**

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE III

PART A

MODULE B: EU-TYPE EXAMINATION

EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an apparatus and verifies and attests that the technical design of the apparatus meets the essential requirements set out in point 1 of Schedule I.

EU-type examination shall be carried out by assessment of the adequacy of the technical design of the apparatus through examination of the technical documentation referred to in point 3, without examination of a specimen (design type). It may be restricted to some aspects of the essential requirements as specified

by the manufacturer or his authorised representative.

The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall specify the aspects of the essential requirements for which examination is requested and shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation. The technical documentation shall make it possible to assess the apparatus conformity with the applicable requirements of these regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the apparatus. The technical documentation shall contain, wherever applicable, at least the following elements:
 - (i) a general description of the apparatus;
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the apparatus;
 - (iv) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union, and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential requirements of these regulations, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied;
 - (v) results of design calculations made, examinations carried out, etc.;
 - (vi) test reports.

4. The notified body shall examine the technical documentation to assess the adequacy of the technical design of the apparatus in relation to the aspects of the essential requirements for which examination is requested.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of these regulations that apply to the apparatus concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant

information to allow the conformity of manufactured apparatus with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of these regulations, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these regulations, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the apparatus with the essential requirements of these regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and, or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and, or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and, or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and, or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and, or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the apparatus has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

PART B

MODULE C: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the apparatus concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of these regulations that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured apparatus with the approved type described in the EU-type examination certificate and with the requirements of these regulations that apply to them.

3. CE marking and EU declaration of conformity

3.1 The manufacturer shall affix the CE marking to each individual apparatus that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these regulations.

3.2 The manufacturer shall draw up a written EU declaration of conformity for each apparatus model and keep it at the disposal of the national authorities for 10 years after the apparatus has been placed on the market. The EU declaration of conformity shall identify the apparatus model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE IV**EU declaration of conformity (No Xxxx) (*)**

1. Apparatus model/Product (product, type, batch or serial number):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer.
4. Object of the declaration (identification of apparatus allowing traceability; it may include a colour image of sufficient clarity where necessary for the identification of the apparatus):
5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) performed ... (description of intervention) and issued the certificate:
8. Additional information:
Signed for and on behalf of:
(place and date of issue):
(name, function) (signature):

* It is optional for the manufacturer to assign a number to the declaration of conformity.