L.N. 329 of 2001

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

THE RADIO EQUIPMENT AND TELECOMMUNICATIONS TERMINAL EQUIPMENT AND THE MUTUAL RECOGNITION OF THEIR CONFORMITY REGULATIONS, 2001

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:–

Citation and commencement

1.1. The title of these regulations is the Radio Equipment and Telecommunications Terminal Equipment and the Mutual Recognition of their Conformity Regulations, 2001.

1.2. These regulations shall become operative on the 1st January, 2002.

1.2.1. Provided that during the period commencing from the 1st January, 2002 and ending the 30th June, 2002 any responsible person may, notwithstanding any other provision of these regulations, place on the market:

1.2.1.1. apparatus imported or manufactured in conformity with these regulations; or

1.2.1.2. radio equipment in relation to which approval was similarly given by the Wireless Telegraphy Department prior to the 1st January, 2002; or

1.2.1.3. telecommunications apparatus in relation to which a type approval was issued prior to the 1st January, 2002 in accordance with Telecommunications Apparatus (Standards) Regulations, 1998 and the Fees for Type Approval of Telecommunications Equipment Regulations, 1998;

1.2.2. Provided that after the 1st July, 2002, no person shall place on the market any apparatus which is not in conformity with these regulations and the provisions of paragraphs 1.2.12 and 1.2.1.3. shall, as of the 1st July, 2002, no longer be applicable.

1.2.3. Provided that the requirements to provide information to the European Commission referred to in regulations 6.1.1, 6.3, 9.4 and 11.4 shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

Scope.

2.1. These regulations establish a regulatory framework for the placing on the market, free movement and putting into service in the Maltese territory of radio equipment and telecommunications terminal equipment.

2.2. Where apparatus as defined in regulation 3 of these regulations incorporates, as an integral part, or as an accessory:

(a) a medical device within the meaning of Article 1 of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[1], or

(b) an active implantable medical device within the meaning of Article 1 of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[2],

the apparatus shall be governed by these regulations, without prejudice to the application of the other Maltese regulations implementing Directives 93/42/EEC and 90/385/EEC on medical devices and active implantable medical devices, respectively.

2.3. Where apparatus constitutes a component or a separate technical unit of a vehicle within the meaning of Council Directive 72/245/EEC[3] relating to the radio interference (electromagnetic compatibility) of vehicles or a component or a separate technical unit of a vehicle within the meaning of Article 1 of Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles, the apparatus shall be governed by these regulations without prejudice to the application of Directive 72/245/EEC or of Directive 92/61/EEC respectively.

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[1]Implemented through L.N. 67 of 2001: Medical Devices Regulations, 2001.
[2]Implemented through L.N. 66 of 2001: Active Implantable Medical Devices Regulations, 2001.
[3]OJ L 225, 10.8.1992, p. 72. Directive as amended by the 1994 Act of Accession.

2.4. These regulations shall not apply to equipment listed in Annex I of the Directive which is set out in Schedule I hereto;

2.5. These regulations shall not apply to apparatus exclusively used for activities concerning public security, defence, State security (including the economic well-being of the State in the case of activities pertaining to State security matters) and the activities of the State in the area of criminal law.

3.1. For the purposes of these regulations, all the definitions of the Act shall apply, and in addition: Definitions.

3.1.1. "the Directive" means Council Directive 99/5/EC[4] of the European Parliament and of the Council on Radio Equipment and Telecommunications Terminal Equipment and the mutual recognition of their conformity;

3.1.2. "apparatus" means any equipment that is either radio equipment or telecommunications terminal equipment or both;

3.1.2.1. "telecommunications terminal equipment" means a product enabling communication or a relevant component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of public telecommunications networks (that is to say, telecommunications networks used wholly or partly for the provision of publicly available telecommunications services);

3.1.2.2. "radio equipment" means a product, or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial/space radio communication;

3.1.3. "radio waves" means electromagnetic waves of frequencies from 9 kHz to 3000 GHz, propagated in space without artificial guide;

3.1.4. "interface" means:

(i) a network termination point, which is a physical connection point at which a user is provided with access to public telecommunications network, and/or

[4]OJ No. L 091, 07-04-99, p. 10

(ii) an air interface specifying the radio path between radio equipment and their technical specifications;

3.1.5. "equipment class" means a class identifying particular types of apparatus which under these regulations are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;

3.1.6. "technical construction file" means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;

3.1.7. "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/EC[5] 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/EC[6] of the European Parliament and of the Council.

3.1.8. "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 technically equivalent to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.9. "harmful interference" means interference which endangers the functioning of a radio navigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with the applicable Community or national regulations;

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

3.1.11. "Community" means the European Community.

3.1.12. "CE marking" means the CE conformity marking consisting of the symbol "CE" as set out in Schedule VI to these regulations.

3.1.13. "Manufacturer" means the person:

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[5]OJ No. L 204, 21-07-98, p. 37
[6]OJ No. L 217, 05-08-98, p. 18

3.1.13.1. who is primarily responsible for the design and construction of the apparatus so that it complies with the requirements of these regulations;

3.1.13.2. who is responsible for "re-building" or modifying an existing apparatus, and who in so doing is creating an "as-new" product;

3.1.13.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported apparatus.

3.1.14. "Local authorised representative" means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.15. "Importer" means any person who imports goods produced outside, and imported into Malta, and includes goods produced in Malta, exported therefrom, and afterwards imported thereinto;

3.1.16. "Person who supplies apparatus" means wholesalers, distributors, retailers etc.

3.1.17. "supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly:

Provided that "supply" does not include exhibition at trade fairs and exhibitions of apparatus in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the apparatus in question to the effect:-

(a) that it does not satisfy those provisions; and

(b) that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.18. "Responsible person" in relation to apparatus means:

(a) the manufacturer thereof;

(b) the manufacturer's local authorised representative; or

(c) where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the apparatus on the local market.

3.1.19. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

Applicability.

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

4.1.1. No person may construct, import, place on the market or put into service any apparatus which does not comply with the provisions of these regulations.

Essential Requirements.

5.1. All apparatus, when properly installed and maintained and used for its intended purpose, shall satisfy the essential requirements set out hereunder:

5.1.1. the protection of the health and the safety of the user and any other person, including the objectives with respect to safety requirements contained in Directive 73/23/EEC[7], but with no voltage limit applying;

5.1.2. the protection requirements with respect to electromagnetic compatibility contained in Directive 89/336/EEC[8].

5.2. In addition, radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communication and orbital resources so as to avoid harmful interference.

5.3. When a measure has been adopted by the Commission pursuant to Articles 3.3, 6.2 and 15 of the Directive and published in the Official Journal of the European Communities determining that apparatus shall be so constructed that:

(a) it interworks via networks with other apparatus and that it can be connected to interfaces of the appropriate type throughout the Community; and/or that

(b) it does not harm the network or its functioning nor misuse network resources, thereby causing an unacceptable degradation of service; and/or that

(c) it incorporates safeguards to ensure that the personal data and privacy of the user and of the subscriber are protected; and/or that

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[7]Implemented through L.N. 23 of 1999: Low Voltage Electrical Equipment Order, 1999.
[8]Implemented through L.N. 24 of 1999: Electromagnetic Compatibility Order, 1999.

(d) it supports certain features ensuring avoidance of fraud; and/or that

(e) it supports certain features ensuring access to emergency services; and/or that

(f) it supports certain features in order to facilitate its use by users with a disability.

Notification and publication of interface specifications.

6.1. The Malta Communications Authority[9] shall notify the interfaces which it has regulated to the Consumer and Industrial Goods Directorate[10] of the Malta Standards Authority.

6.1.1. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission, which will thus establish the equivalence between notified interfaces and assign an equipment class identifier, details of which shall be published in the Official Journal of the European Communities.

6.2. The Malta Communications Authority shall notify to the Consumer and Industrial Goods Directorate of the Malta Standards Authority the types of interface offered in Malta by operators of public telecommunications networks.

6.2.1. The Malta Communications Authority shall ensure that such operators publish accurate and adequate technical specifications of such interfaces before services provided through those interfaces are made publicly available, and regularly publish any updated specifications.

6.2.2. The specifications shall be in sufficient detail to permit the design of telecommunications terminal equipment capable of utilising all services provided through the corresponding interface.

6.2.3. The specifications shall include, inter alia, all the information necessary to allow manufacturers to carry out, at their choice, the relevant tests for the essential requirements applicable to the telecommunications terminal equipment.

6.2.4. The Malta Communications Authority shall ensure that those specifications are made readily available by the operators.

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[9]Malta Communications Authority Act, Cap. 418 (Act XVIII of 2000).

[10]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.

6.3. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately notify to the Commission all the information related to regulation 6.2 of these regulations.

Harmonised standards.

7.1. Where apparatus meets the relevant harmonised standards or parts thereof whose reference numbers have been published in the Official Journal of the European Communities, the Director shall presume compliance with those of the essential requirements referred to in regulation 5 of these regulations as are covered by the said harmonised standards or parts thereof.

7.2. Standards under Directive 73/23/EEC or 89/336/EEC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the essential requirements referred to in regulation 5.1.1 and 5.1.2 of these regulations.

7.3. Common technical regulations under Directive 98/13/EC whose references have been published in the Official Journal of the European Communities may be used as the basis for a presumption of conformity with the other relevant essential requirements referred to in regulation 5 of these regulations.

Placing on the market.

8.1. The responsible person shall ensure that apparatus is placed on the market only if it complies with the appropriate essential requirements identified in regulation 5 of these regulations and the other relevant provisions of the Directive when it is properly installed and maintained and used for its intended purpose.

8.1.1. It shall not be subject to further national provisions in respect of placing on the market.

8.2. The responsible person shall provide information for the user on the intended use of the apparatus, together with the declaration of conformity to the essential requirements.

8.2.1. Where it concerns radio equipment, such information shall be sufficient to identify on the packaging and the instructions for use of the apparatus its intended use in the Maltese territory and shall alert the user by the marking on the apparatus referred to in Annex VII paragraph 5 of the Directive (which is set out in Schedule VI hereto), to potential restrictions or requirements for authorisation of use of the radio equipment in Malta.

8.2.2. Where it concerns telecommunications terminal equipment, such information shall be sufficient to identify interfaces of

the public telecommunications networks to which the equipment is intended to be connected. For all apparatus such information shall be prominently displayed.

8.3. In the case of radio equipment using frequency bands whose use is not harmonized throughout the Community, the manufacturer or his authorised representative or the person responsible for placing the equipment on the market shall notify the Wireless Telegraphy Department of the intention to place such equipment in Malta.

8.3.1. This notification shall be given no less than four weeks in advance of the start of placing on the market and shall provide information about the radio characteristics of the equipment (in particular frequency bands, channel spacing, type of modulation and RF-power) and the identification number of the notified body referred to in Annex IV or V (which are set out in Schedule IV and V hereto).

8.4. The information required in regulations 8.2, 8.2.1 and 8.2.2 of these regulations, including the declaration of conformity and other correspondence specified in regulations 8.3 and 8.3.1 of these regulations shall be in either the Maltese or English language.

Putting into service and right to connect.

9.1. The Director shall allow the putting into service of apparatus for its intended purpose where it complies with the appropriate essential requirements identified in regulation 5 of these regulations and the other relevant provisions of the Directive.

9.2. Not withstanding regulation 9.1 of these regulations, and without prejudice to conditions attached to authorisations for the provision of the service concerned in conformity with Community law, the Director may restrict the putting into service of radio equipment only for reasons related to the effective and appropriate use of the radio spectrum, avoidance of harmful interference or matters relating to public health.

9.3. Without prejudice to regulation 9.4 of these regulations, the Director shall ensure that operators of public telecommunications networks do not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where that equipment complies with the applicable requirements of regulation 5 of these regulations.

9.4. Where the Director considers that apparatus declared to be compliant with the provisions of these regulations causes serious damage to a network or harmful radio interference or harm to the network or its functioning, the operator may be authorized to refuse connection, to

disconnect such apparatus or to withdraw it from service. The Director shall notify each such authorisation to the Consumer and Industrial Goods Directorate of the Malta Standards Authority.

9.4.1. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulation 9.4

9.5. In case of emergency, an operator may disconnect apparatus if the protection of the network requires the equipment to be disconnected without delay and if the user can be offered, without delay and without costs for him, an alternative solution. The operator shall immediately inform the Director and the Malta Communications Authority.

Free movement of apparatus.

10.1. Without prejudice to regulations 8.3, 9.2 and 11.2 of these regulations, the placing on the market and putting into service in the Maltese territory of apparatus bearing the CE marking referred to in Annex VII of the Directive (which is set out in Schedule VI hereto), which indicates its conformity with all provisions of these regulations and the Directive, including the conformity assessment procedures set out in regulation 12 of these regulations, shall not be prohibited, restricted or impeded.

10.2. Where the apparatus is subject to other directives which concern other aspects and also provide for the affixing of the CE marking, the latter shall indicate that such apparatus also fulfils the provisions of those other directives. However, should one or more of those directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate that the apparatus fulfils the provisions only of those directives applied by the manufacturer. In this case, the particulars of those directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by those directives and accompanying such products.

Safeguards.

11.1. Where the Director ascertains that apparatus within the scope of these regulations does not comply with the requirements of these regulations, it shall take all appropriate measures to withdraw the apparatus from the market or from service, prohibit its placing on the market or putting into service or restrict its free movement.

11.1.1. The Director shall immediately notify the Consumer and Industrial Goods Directorate of the Malta Standards Authority of any such measures indicating the reasons for its decision and whether non-compliance is due to:

(a) incorrect application of the harmonised standards referred to in regulation 7.1 of these regulations;

(b) shortcomings in the harmonised standards referred to in regulation 7.1 of these regulations;

(c) failure to satisfy the requirements referred to in regulation 5 of these regulations where the apparatus does not meet the harmonised standards referred to in regulation 7.1 of these regulations.

11.2. Notwithstanding the provisions of regulation 8 of these regulations and Article 6 of the Directive, the Director may, acting in conformity with the Treaty, and in particular Articles 30 and 36 thereof, adopt any appropriate measures with a view to:

(i) prohibiting or restricting the placing on the Maltese market, and/or

(ii) requiring the withdrawal from the Maltese market, of radio equipment, including types of radio equipment, which has caused or which he reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands.

11.3. Where the Director takes measures in accordance with regulation 11.2 of these regulations he shall immediately inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority of the said measures, specifying the reasons for adopting them.

11.4. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 11.1, 11.1.1, 11.2 and 11.3 of these regulations.

Conformity assessment procedures.

12.1. The conformity assessment procedures identified in regulation 12 of these regulations shall be used to demonstrate the compliance of the apparatus with all the relevant essential requirements identified in regulation 5 of these regulations.

12.2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in regulations 5.1.1 and 5.1.2 may be demonstrated using the procedures specified in L.N. 23 of 1999: Low Voltage Electrical Equipment Order, 1999, implementing Directive 73/23/EEC and L.N. 24 of 1999: Electromagnetic Compatibility Order, 1999, implementing Directive

89/336/EEC respectively, where the apparatus is within the scope of those Directives, as an alternative to the procedures laid out below.

12.3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial/space radio communication and receiving parts of radio equipment shall be subject to the procedures described in any one of Annexes II, IV or V to the Directive (which are set out in Schedules II, IV and V hereto) at the choice of the manufacturer.

12.4. Where a manufacturer has applied the harmonised standards referred to in regulation 7.1 of these regulations, radio equipment not within the scope of regulations 12.3 of these regulations shall be subject to the procedures described in any one of Annexes III, IV or V to the Directive (which are set out in Schedules III, IV and V hereto) at the choice of the manufacturer.

12.5. Where a manufacturer has not applied or has only applied in part the harmonized standards referred to in regulation 7.1 of these regulations, radio equipment not within the scope of regulation 12.3 of these regulations shall be subject to the procedures described in either of Annexes IV or V to the Directive (which are set out in Schedules IV and V hereto) at the choice of the manufacturer.

12.6. Records and correspondence relating to the conformity assessment procedure referred to in regulations 12.2 to 12.5 of these regulations shall be in an official language of the Member State where the procedure will be carried out, or in a language accepted by the notified body involved.

CE marking.

13.1. Apparatus complying with all relevant essential requirements shall bear the EC conformity marking referred to in Annex VII to the Directive, which is set out in Schedule VI hereto.

13.1.1. It shall be affixed under the responsibility of the manufacturer, his authorized representative or the person responsible for placing the apparatus on the market.

13.1.2. Where the procedures identified in Annex III, IV or V to the Directive (which are set out in Schedules III, IV and V hereto) are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 11 (1) of the Directive.

13.1.3. Radio equipment shall, in addition, be accompanied by the equipment class identifier, where such indentifier has been assigned.

13.1.4. Any other marking may be affixed to the equipment provided that the visibility and legibility of the EC marking is not thereby reduced.

13.2. No apparatus, whether or not it complies with the relevant essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the EC marking specified in Annex VII to the Directive, which is set out in Schedule VI hereto.

13.3. The Director shall take appropriate action against any person who has affixed a marking not in conformity with regulations 13.1 and 13.2 of these regulations.

13.3.1. If the person who affixed the marking is not identifiable, appropriate action may be taken against the holder of the apparatus at the time when non-compliance was discovered.

13.4. Apparatus shall be identified by the manufacturer by means of type, batch and/or serial numbers and by the name of the manufacturer or the person responsible for placing the apparatus on the market.

SCHEDULE I

Based on Annex I of the Directive

EQUIPMENT NOT COVERED BY THESE REGULATIONS AS REFERRED TO IN REGULATION 2.4 OF THESE REGULATIONS

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations unless the equipment is available commercially.

Kits of components to be assembled by radio amateurs and commercial equipment modified by and for the use of radio amateurs are not regarded as commercially available equipment.

2. Equipment falling within the scope of Council Directive 96/98/EC of 20 December 1996 on marine equipment[11].

3. Cabling and wiring.

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

5. Products, appliances and components within the meaning of Article 2 of Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonisation of technical requirements and administrative procedures in the field of civil aviation[12].

6. Air-traffic-management equipment and systems within the meaning of Article 1 of Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic-management equipment and systems[13].

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[11]OJ L 46, 17.2.1997, p. 25.
[12]OJ L 373, 31.12.1991, p.4. Regulation as amended by Commission Regulation (EC) No. 2176/96 (OJ L 291, 14.11.1996, p. 15).
[13]OJ L 187, 29.7.1993, p. 52. Directive as last amended by Commission Directive 97/15/EC (OJ L 95, 10.4.1997, p. 16).

SCHEDULE II

Based on Annex II of the Directive

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN REGULATION 12 OF THESE REGULATIONS

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorised representative, who carries out the obligations laid down in paragraph 2 of this Schedule, ensures and declares that the products concerned satisfy the requirements of these regulations and the Directive that apply to them. The manufacturer or his authorized representative must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in paragraph 4 of this Schedule and he or his authorised representative must keep it for a period ending at least 10 years after the last product has been manufactured at the disposal of the relevant national authorities of any Member State for inspection purposes.

3. Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

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

- a general description of the product,

- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,

- a list of the standards referred to in regulation 7 of these regulations, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements of these regulations where such standards referred to in regulation 7 of these regulations have not been applied or do not exist,

- results of design calculations made, examinations carried out, etc.,

- test reports.

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

6. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in paragraph 2 of this Schedule and with the requirements of these regulations that apply to them.

SCHEDULE III

Based on Annex III of the Directive

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN REGULATION 12.4 OF THESE REGULATIONS

(Internal production control plus specific apparatus tests)[14]

This Schedule consists of Schedule II to these regulations, plus the following supplementary requirements:

For each type of apparatus, all essential radio test suites must be carried out by the manufacturer or on his behalf. The identification of the test suites that are considered to be essential is the responsibility of a notified body chosen by the manufacturer except where the test suites are defined in the harmonised standards. The notified body must take due account of previous decisions made by notified bodies acting together.

The manufacturer or his authorised representative or the person responsible for placing the apparatus on the market must declare that these tests have been carried out and that the apparatus complies with the essential requirements and must affix the notified body's identification number during the manufacturing process.

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[14] Annex based on Module A with additional requirements appropriate to the sector.

SCHEDULE IV

Based on Annex IV of the Directive

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN REGULATION 12.5 OF THESE REGULATIONS

(Technical construction file)

This Schedule consists of Schedule III to these regulations plus the following supplementary requirements:

The technical documentation described in paragraph 4 of Schedule II to these regulations and the declaration of conformity to specific radio test suites described in Schedule III to these regulations must form a technical construction file.

The manufacturer, his authorised representative or the person responsible for placing the apparatus on the market, must present the file to one or more notified bodies, each of the notified bodies must be informed of others who have received the file.

The notified body must review the file and if it is considered that it has not been properly demonstrated that the requirements of these regulations have been met, the notified body may issue an opinion to the manufacturer, his representative or the person responsible for placing the apparatus on the market and must inform the other notified bodies who have received the file accordingly. Such an opinion must be given within four weeks of receipt of the file by the notified body. On receipt of this opinion, or after the end of the four-week period, the apparatus may be placed on the market, without prejudice to regulations 8.3 and 11.2 of these regulations.

The manufacturer or his authorised representative or the person responsible for placing the apparatus on the market must keep the file for a period ending at least 10 years after the last apparatus has been manufactured at the disposal of the relevant national authorities of any Member States for inspection.

SCHEDULE V

Based on Annex V of the Directive

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN REGULATION 12 OF THESE REGULATIONS

(Full quality assurance)

1. Full quality assurance is the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 of this Schedule ensures and declares that the products concerned satisfy the requirements of these regulations that apply to them. The manufacturer must affix the marks referred to in regulation 13.1 of these regulations to each product and draw up a written declaration of conformity.

2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in paragraph 3 of this Schedule and must be subject to surveillance as specified in paragraph 4 of this Schedule.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

The application must include:

- all relevant information for the products envisaged,

- the quality system's documentation.

3.2. The quality system must ensure compliance of the products with the requirements of these regulations that apply to them. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality,

- the technical specifications, including the harmonised standards and technical regulations as well as relevant test specifications that will be applied and, where the standards referred to in regulation 7.1 will not be applied in full,

the means that will be used to ensure that the essential requirements of these regulations that apply to the products will be met,

- the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out, as well as the results of the tests carried out before manufacture where appropriate,

- the means by which it is ensured that the test and examination facilities respect the appropriate requirements for the performance of the necessary test,

- the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

- the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2 of this Schedule. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard.

The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of the Directive in the light of the relevant documentation supplied in respect of paragraphs 3.1 and 3.2 of this Schedule including, where relevant, test results supplied by the manufacturer.

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorised representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 of this Schedule or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. EC surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

- the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must carry out audits at reasonable intervals to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years after the last product has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of paragraph 3.1 of this Schedule,

- the updating referred to in the second paragraph of paragraph 3.4 of this Schedule,

- the decisions and reports from the notified body which are referred to in the final paragraph of paragraph 3.4 of this Schedule and in paragraphs 4.3 and 4.4 of this Schedule.

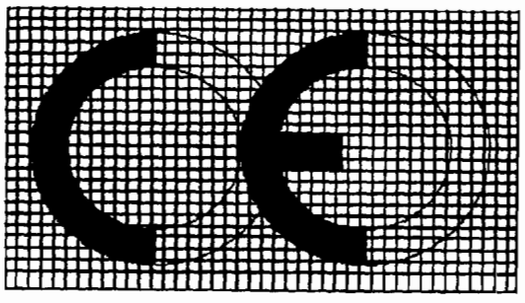
6. Each notified body must make available to the other notified bodies the relevant information concerning quality system approvals including references to the product(s) concerned, issued and withdrawn.

SCHEDULE VI

Based on Annex VII of the Directive

MARKING OF EQUIPMENT REFERRED TO IN REGULATION 13 OF THESE REGULATIONS

1. The CE conformity marking must 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.

2. The CE marking must have a height of at least 5 mm except where this is not possible on account of the nature of the apparatus.

3. The CE marking must be affixed to the product or to its data plate. Additionally it must be affixed to the packaging, if any, and to the accompanying documents.

4. The CE marking must be affixed visibly, legibly and indelibly.

5. Equipment Class Identifiers and the Alert Sign

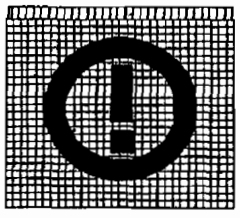
In relation to the equipment class identifiers noted in regulation 6 of these regulations and Article 4.1 of the Directive, apparatus falling under these regulations will be classified into 2 classes as follows:

Class 1:

Radio equipment and telecommunications terminal equipment which can be placed on the market and be put into service without restrictions will constitute a class. This class will be referred to as "Class 1". An Equipment Class Identifier is not defined for this class of equipment.

Class 2:

Radio equipment and telecommunications terminal equipment for which restrictions are applied on the putting into service as foreseen in regulation 9.2 of these regulations or for which restrictions are applied on the placing on the market as foreseen by regulation 11.2 of these regulations will constitute a class. This class will be referred to as "Class 2". The following Equipment Class Identifier or " alert sign" is defined for equipment within this class:



Where appropriate it must include an element intended to provide information to the user that the apparatus makes use of radio frequency bands where their use is not harmonised throughout the Community.

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

Attachment 1: List of subclasses

Terminal equipment attached to fixed networks and non-transmitting radio equipment:

Class 1.1 ISDN[15] (ISDN Basic Rate, ISDN Primary Rate, ISDN U, Broadband ISDN ATM)

Class 1.2 PSTN[16] (Analogue single line, Analogue multi-line (with/without DDI), equipment attached to Centrex interfaces or Virtual Private Networks)

Class 1.3 Leased lines[17] (2w and 4w analogue (baseband), 2w and 4w analogue (voiceband), Digital, SDH, optical)

Class 1.4 Wired data equipment[18] (X.21, X.25, ethernet, token ring, token bus, TCP/IP, frame relay)

Class 1.5 Wired interactive broadcast equipment (unswitched vision/sound, switched vision/sound)

Class 1.6 Telex (single line equipment, multiple line equipment)

Class 1.7 Receive-only radio[19] equipment

Class 1.8 Other terminal equipment attached to fixed networks

Radio equipment, which transmits only under the control of a network:

Class 1.9 GSM handsets[20], including GSM 900, GSM 1800, GSM 1900 (and when it appears GSM 450)

Class 1.10 TFTS[21] terminal equipment

Class 1.11 Land Mobile earth stations[22] in the 1,5/1,6 GHz bands

Class 1.12 Land Mobile earth stations[23] operating in the Ku-band

Class 1.13 TETRA[24] end-user equipment (non-DMO)

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15 Equipment within the scope of TBR3 and TBR4
16 Equipment within the scope of TBR21 and TBR37
17 Equipment within the scope of TBR12, TBR13, TBR15, TBR17, TBR24 and TBR25
18 Equipment within the scope of TBR1/2
19 Including equipment within the scope of TBR7
20 Equipment within the scope of TBR19 and TBR31
21 Equipment within the scope of TBR23
22 Equipment within the scope of TBR26
23 Equipment within the scope of TBR27
24 Equipment within the scope of TBR35

Class 1.14 Satellite Personal Communication earth stations[25] operating in the 1,6/2,4 GHz bands

Class 1.15 Satellite Personal Communication earth stations[26] operating in the 1,9/2,1 GHz bands

Class 1.16 Low data rate Land Mobile earth stations[27] in the 1,5/1,6 GHz bands

Class 1.17 Other Radio equipment, which transmits only under the control of a network[28]

Radio transmitters, technically harmonised in the Community for which Member States do not constrain their putting into service

Class 1.18 DECT[29] equipment

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[25] Equipment within the scope of TBR41
[26] Equipment within the scope of TBR42
[27] Equipment within the scope of TBR44
[28] This class would typically include analogue mobile systems like NMT, TACS and ETACS, but also equipment, which can only be connected to mobile networks, which are not authorised in the Community as they would operate in bands allocated to other services (e.g. PDC, PHS, IS95).
[29] Equipment within the scope of TBR6

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