

Hellenic Republic

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Presidential Decree No 44

Radio equipment and telecommunications terminal equipment and mutual recognition of their conformity. Adaptation of Greek law to Directive 99/5/EC of the European Parliament and of the Council of 9 March 1999.

**WE, THE PRESIDENT
OF THE HELLENIC REPUBLIC,**

Having regard to:

1. the provisions:
 - a) of Article 3 and Article 4 of Law 1338/1983 on the application of Community law (I 34), as amended, respectively, by Article 65 of Law 1892/1990 on modernisation and development and containing other provisions (I 101), by Article 6(4) of Law 1440/1984 on the participation of Greece in the capital, reserves and provisions of the European Investment Bank, in the capital of the European Coal and Steel Community and in the Euratom supply agency (I 70), by Article 7 of Law 1775/1988 on venture capital companies and containing other provisions (I 101), by Article 31 of Law 2076/1992 on the assumption and exercise of credit institution activity and containing other provisions (I 130), by Article 19 of Law 2367/1995 on new financial institutions and containing other provisions (I 261) and by Article 22 of Law 2789/2000 on the adaptation of Greek law to Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems, and containing provisions (I 21),
 - b) of Law 1843/1989 ratifying final acts of the World Administrative Radiocommunications Conference (Geneva, 1979) (I 96),
 - c) of Law 2867/2000 on the organisation and operation of telecommunications and containing other provisions (I 273),
 - d) of the Article 29A which was added to Law 1558/1985 on governance and organs of government (I 237) by Article 27 of Law 2081/1992 (I 154) and replaced by Article 1(2)(a) of Law 2469/1997 (I 38),
 - e) of Presidential Decree 293/99 on the organisation of the Ministry of Transport and Communications (I 263),
 - f) of Presidential Decree 424/95 on telecommunications terminal equipment in conformity with Directive 91/263/EEC as amended by Directive 93/68/EEC (I 243);

- g) of Presidential Decree 122/98 on satellite earth station equipment in compliance with Directive 93/97/EC supplementing Directive 91/263/EEC (I 103),
2. Commission Decision 2000/299/EC of 6 April 2000 establishing the initial classification of radio equipment and telecommunications terminal equipment and associated identifiers,
3. Commission Decision 2000/637/EC of 22 September 2000 on the application of Article 3(3)(e) of Directive 99/5/EC to radio equipment covered by the regional arrangement concerning the radiotelephone service on inland waterways,
4. Decision No 68096/19463/31.10.2001 of the Prime Minister and of the Minister for Transport and Communications delegating responsibilities of the Minister for Transport and Communications to the State Secretary for Transport and Communications (II 1484),
5. the fact that the implementation of this Decree will not place a charge on the state budget;
6. Opinion 1/2002 of the Council of State subsequent to a proposal of the Minister for Economic Affairs and Finance and the State Secretary for Transport and Communications,

hereby decree as follows:

Chapter I

General Aspects

Article 1 (Article 1 of Directive 99/5/EC)

Scope and aim

1. This Decree adapts Greek law to Directive 99/5/EC of the European Parliament and of the Council on radio equipment and telecommunications terminal equipment and mutual recognition of their conformity (OJ L 191). This Decree establishes a regulatory framework for the placing on the market, free movement and putting into service of radio equipment and telecommunications terminal equipment.
2. Apparatus as defined in Article 2(a) shall also fall within the scope of this Decree where:
 - a) it incorporates, as an integral part or as an accessory, a medical device within the meaning of Joint Ministerial Decision DY7/oik.2480/94 of the Minister for Economic Affairs, the Minister for Health, the Minister for Welfare and Social Security and the Minister for Industry, Energy and Technology harmonising Greek law with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (II 679, II 755 and II 757) or an active implantable device within the meaning of Joint Ministerial Decision DY7/2351/94 of the Minister for Economic Affairs, the Minister for Health, the Minister for Welfare and Social Security and the Minister for Industry and Energy harmonising Greek law with Council Directive 90/385/EEC of 20 June 1990 concerning active implantable medical

devices (II 639 and II 703), without prejudice to the application of Joint Ministerial Decision DY7/2480/94 and of Joint Ministerial Decision DY7/2351/94 respectively;

- b) it constitutes a component or a separate technical unit of a vehicle within the meaning of Presidential Decree 1376/1981 on conformity of Greek law with the provisions of Council Directive 72/245/EEC of 20 June 1972 on the approximation of the laws of the Member States relating to the radio interference (electromagnetic compatibility) of vehicles (II 342), as amended by Joint Ministerial Decision 36090/2874/96 of the Minister for Economic Affairs and the Minister for Transport and Communications on conformity with the provisions of Commission Directive 95/54/EC of 31 October 1995 adapting to technical progress Council Directive 72/245/EEC relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles and amending Council Directive 70/156/EEC relating to the type approval of motor vehicles and their trailers (II 122), or within the meaning of Joint Ministerial Decision 21090/1874/93 of the Minister for Economic Affairs and the Minister for Transport and Communications on the type approval of two or three-wheel motor vehicles in conformity with the provisions of Council Directive 92/61/EEC of 30 June 1992 (II 428), without prejudice to the application of Presidential Decree 1376/81, as in force, and of Joint Ministerial Decision 21090/1874/93 respectively.
3. This Decree shall not apply to equipment listed in Annex I and to apparatus exclusively used for activities concerning public security, defence, state security and the activities of the state in the area of criminal law.

Article 2
(Article 2 of Directive 99/5/EC)

Definitions

For the purpose of this Decree the following definitions shall apply:

- a) ‘apparatus’ means any equipment that is either radio equipment or telecommunications terminal equipment or both;
- b) ‘telecommunications terminal equipment’ means a product enabling communication or a component thereof which is intended to be connected directly or indirectly by any means whatsoever to interfaces of telecommunications networks used wholly or partly for the provision of publicly available telecommunications services;
- c) ‘radio equipment’ means a product, or a component thereof, capable of communication by means of the emission and/or reception of radio waves utilising the spectrum allocated to terrestrial / space radiocommunication;
- d) ‘radio waves’ means electromagnetic waves of frequencies from 9 kHz to 3 000 GHz propagated in space without artificial guide;
- e) ‘interface’ means:
- ea) a network termination point, which is a physical connection at which a user is provided with access to the public telecommunications network, and/or

- eb) an air interface specifying the radio path between radio equipment and their technical specifications;
- f) ‘equipment class’ means a class identifying particular types of apparatus which under this Decree are considered similar and those interfaces for which the apparatus is designed. Apparatus may belong to more than one equipment class;
- g) ‘technical construction file’ means a file describing the apparatus and providing information and explanations as to how the applicable essential requirements have been implemented;
- h) ‘harmonised standard’ means a technical specification adopted by a recognised standards body under a mandate from the Commission in conformity with the procedures laid down in Presidential Decree 39/2001 laying down a procedure for the provision of information in the field of technical standards and specifications and of regulations applying to information society services in conformity with Directive 98/34/EC and Directive 98/48/EC (I 28);
- i) ‘harmful interference’ means interference which endangers the functioning of a radionavigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with the applicable Community or national regulations.

Article 3
(Article 3 of Directive 99/5/EC)

Essential (key) requirements

1. The following essential (key) requirements are applicable to all apparatus:
 - a) the requirements for the protection of the health and the safety of the user and any other person, including the safety requirements contained in Joint Ministerial Decision 470/1985 of the Minister for Economic Affairs, the Minister for Finance and the Minister for Industry, Energy and Technology on electrical equipment designed for use within certain voltage limits in conformity with Council Directive 73/23/EEC (II 183), as amended by Joint Ministerial Decision B6467/608/88 of the Minister for Economic Affairs, the Minister for Finance and the Minister for Industry, Energy and Technology amending Joint Ministerial Decision 470/1985 of the Minister for Economic Affairs and the Minister for Finance on electrical equipment designed for use within certain voltage limits in conformity with Council Directive 73/23/EEC (Government Gazette 183/II/4.4.85) (II 214), but with no voltage limit applying;
 - b) the protection requirements with respect to electromagnetic compatibility contained in Joint Ministerial Decision 94649/8682/93 of the Minister for Economic Affairs, the Minister for Transport and Communications and the Minister for Industry, Energy and Technology on electromagnetic compatibility in conformity with the provisions of Council Directive 89/336/EEC as amended by Directive 92/31/EEC and Directive 93/68/EEC (II 688/94).

2. 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.

Article 4
(Article 4 of Directive 99/5/EC)

Notification and publication of interface specifications

1. The interfaces which may be placed on the market and put into service without restriction, insofar as the said interfaces have not been notified under the provisions of Presidential Decree 39/2001, shall be determined via decisions of the National Telecommunications and Postal Commission (hereinafter 'EETT') in accordance with Article 3(14)(xxviii) of Law 2867/2000 (I 273).

2. The EETT shall notify to the Commission the types of interface offered by the telecommunications bodies.

3. The telecommunications bodies shall publish accurate and adequate technical specifications of all the interfaces before services provided through those interfaces are made publicly available, and publish any updated specifications at least once a year. 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. The specifications shall include all the information necessary to allow manufacturers to carry out tests for the essential requirements applicable to the telecommunications terminal equipment. The EETT shall issue a decision in accordance with Article 3(14)(xxviii) of Law 2867/2000 specifying the conditions and the procedure necessary for ensuring that the specifications are made readily available and published by the telecommunications bodies.

Article 5
(Article 5 of Directive 99/5/EC)

Harmonised standards

1. Apparatus shall be presumed to comply with the essential requirements where it meets the harmonised standards or parts thereof whose reference numbers have been published in the Official Journal of the European Communities.

2. The presumption referred to in paragraph 1 shall not preclude subjection to the conformity assessment procedures provided for in this Decree.

3. Where the EETT considers with good reason that conformity with a harmonised standard does not ensure compliance with the essential requirements referred to in Article 3, it shall bring the matter before the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM).

Chapter II
Putting into service and free movement of apparatus

Article 6

(Article 6(1) of Directive 99/5/EC)

Conditions for placing apparatus on the market

Apparatus may be placed on the market only if it complies with the essential requirements identified in Article 3 and the other relevant provisions of this Decree when it is properly installed and maintained and used for its intended purpose.

Article 7

(Article 6(3) and (4) of Directive 99/5/EC)

Obligation to provide information

1. The manufacturer or the person responsible for placing the apparatus on the market shall provide the user with the declaration of conformity to essential requirements and with necessary information on the intended use of the apparatus. The information shall be clearly displayed on the apparatus.
2. In the case of radio equipment, the manufacturer or the person responsible for placing the equipment on the market, in addition to meeting the obligations stated in paragraph 1, shall provide sufficient information on the packaging and in the instructions for use of the apparatus concerning the possibility of use of the apparatus in the territory of Greece or in another Member State, or in a geographical area thereof, and shall alert the user by the special marking referred to in Annex VII, paragraph 5, to potential restrictions or requirements for authorisation of use of the radio equipment in certain Member States.
3. In the case of radio equipment using frequency bands whose use is not harmonised throughout the Community, the manufacturer or his authorised representative established within the Community or the person responsible for placing the equipment on the market shall notify the EETT of the intention to place such equipment on the market no less than four weeks in advance of the start of the placing on the market. The notification shall provide: a) information about the radio characteristics of the equipment, in particular about the frequency bands, channel spacing, type of modulation and RF-power; b) the identification number of the notified body referred to in Annex IV or V. The EETT shall check the information and, in accordance with Article 3(14)(xxviii) of Law 2867/2000, impose conditions or restrictions on the putting into service of the apparatus in compliance with the specific requirements indicated in Article 10 of this Decree. The EETT may issue a decision in accordance with Article 3(14)(xxviii) of Law 2867/2000 laying down specific conditions governing the notification and determining the procedure to be followed.
4. In addition to the obligations referred to in paragraph 1, the manufacturer of telecommunications terminal equipment or the person responsible for placing the equipment on the market shall provide information 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.

Article 8

(Article 7 of Directive 99/5/EC)

Putting into service and right to connect

1. Apparatus may be put into service for its intended purpose where it complies with the appropriate essential requirements identified in Article 3 and the other provisions of this Decree.
2. Notwithstanding paragraph 1, and without prejudice to conditions attached to authorisations for the provision of the service concerned in conformity with Community law, the EETT 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 interference or matters relating to public health.
3. Without prejudice to paragraph 4, telecommunications bodies may not refuse to connect telecommunications terminal equipment to appropriate interfaces on technical grounds where that equipment complies with the essential requirements of Article 3.
4. Where apparatus which is compliant with the essential requirements laid down in this Decree causes serious damage to the network or radio interference which is harmful to its functioning, the EETT may authorise the telecommunications body to refuse connection, to disconnect such apparatus or to withdraw it from service. The EETT shall notify each such authorisation to the Commission. The EETT may also take other technically appropriate measures via the issue of a decision in accordance with Article 3(14)(xxviii) of Law 2867/2000.
5. In case of emergency, a telecommunications body 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 telecommunications body shall immediately inform the EETT, which may implement the provisions of the preceding paragraph and of Article 10.

Article 9
(Article 8 of Directive 99/5/EC)

Free movement

1. No prohibition, restriction or impediment may be imposed on the placing on the market and putting into service of apparatus bearing the CE marking referred to in Annex VII, which indicates its conformity with the provisions of this Decree, including the conformity assessment procedure set out in Article 12 and Article 13. This shall be without prejudice to Article 7(3), Article 8(2) and Article 10(2).
2. Apparatus which does not comply with the essential requirements of this Decree may be displayed at trade fairs or demonstrations only if it is provided with a visible sign indicating that such apparatus may not be marketed or put into service until it has been made to comply with the requirements of this Decree.
3. Where the apparatus is subject to directives other than Directive 99/5/EC, which is incorporated by this Decree, which regulate other aspects and also provide for the affixing of the CE marking, the latter shall expressly indicate that the CE marking also fulfils the provisions of those other directives. If the manufacturer is allowed, during the transitional period, to choose which arrangements to apply, the CE marking shall indicate only those directives which the manufacturer has applied. The numbers of those directives, as published in the Official Journal of the European Communities, must be given in the accompanying documents, notices or instructions.

Article 10
(Article 9 of Directive 99/5/EC)

Protection and safeguards

1. Where, in carrying out a check, the EETT ascertains that apparatus does not comply with the requirements of this Decree it shall issue a reasoned decision withdrawing the apparatus from the market, prohibiting its putting into service or restricting its free movement. The EETT shall immediately notify the Commission of the measures taken and indicate the reasons for its decision and whether non-compliance is due to (a) incorrect application of the harmonised standards referred to in Article 5(1), (b) shortcomings in the said harmonised standards or (c) failure to satisfy the essential requirements referred to in Article 3 where the apparatus does not meet the harmonised standards referred to in Article 5(1).
2. Notwithstanding the provisions of Article 7, the EETT may, acting in conformity with the Treaty on European Union, and in particular Article 28 and Article 30 thereof, issue a reasoned decision prohibiting or restricting the placing on the market, or requiring the withdrawal from the market, of radio equipment, including types of radio equipment, which has caused or which it reasonably considers will cause harmful interference, including interference with existing or planned services on nationally allocated frequency bands. The EETT shall immediately inform the Commission of the reasons for the measures taken.
3. In order to exercise its responsibilities more effectively, the EETT may request the assistance of other administrative services, in particular for carrying out the checks which are necessary before protection or safeguarding measures are taken or before the penalties laid down in Article 16 are imposed.
4. The EETT may appoint external public or private bodies to carry out technical checks on radio equipment and telecommunications terminal equipment.

Chapter III
Conformity assessment

Article 11
(Article 12 of Directive 99/5/EC)

CE marking

1. Apparatus complying with all essential requirements identified in this Decree shall bear the CE conformity marking referred to in Annex VII. The marking shall be affixed under the responsibility of the manufacturer, his authorised representative within the Community or the person responsible for placing the apparatus on the market.
2. Where the procedures identified in Annex III, IV or V are used, the marking shall be accompanied by the identification number of the notified body referred to in Article 13. Radio equipment shall in addition be accompanied by the equipment class identifier where such identifier has been assigned. Other markings may be affixed to the apparatus provided that the visibility and legibility of the CE marking is not thereby reduced.

3. No apparatus, whether or not it complies with the essential requirements, may bear any other marking which is likely to deceive third parties as to the meaning and form of the CE marking specified in Annex VII.

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.

Article 12

(Article 10 of Directive 99/5/EC)

Conformity assessment procedures

1. The conformity assessment procedures identified in the following paragraphs of this Article shall be used to demonstrate the compliance of the apparatus with the essential requirements identified in Article 3.

2. At the choice of the manufacturer, compliance of the apparatus with the essential requirements identified in Article 3(1)(a) and (b) may be demonstrated using the procedures specified in Joint Ministerial Decision 470/1985 of the Minister for Economic Affairs, the Minister for Finance and the Minister for Industry, Energy and Technology, as amended by Joint Ministerial Decision B6467/608/88 (II 214), and in Joint Ministerial Decision 94649/8682/93, respectively, where the apparatus is within the scope of those decisions, as an alternative to the procedures laid out below.

3. Telecommunications terminal equipment which does not make use of the spectrum allocated to terrestrial / space radio communication and receiving modules of radio equipment shall be subject to the procedures referred to in Annex II, IV or V at the choice of the manufacturer.

4. Where a manufacturer has applied the harmonised standards referred to in Article 5(1), radio equipment within the scope of paragraph 3 shall be subject to the procedures described in any one of Annexes III, IV or V at the choice of the manufacturer.

5. Where a manufacturer has not applied or has only applied in part the harmonised standards referred to in Article 5(1), radio equipment not within the scope of paragraph 3 of this Article shall be subject to the procedures described in either of Annexes IV or V at the choice of the manufacturer.

6. Records and correspondence relating to the conformity assessment procedures shall be in the Greek language or, when the procedure will be carried out outside Greece, in a language accepted by the notified body involved.

Article 13

(Article 11 of Directive 99/5/EC)

Notified bodies and surveillance authorities

1. The EETT shall issue a decision, in accordance with Article 3(14)(xxviii) of Law 2867/2000, designating the bodies to carry out the tasks referred to in the Article 12.

2. The EETT shall issue a decision, in accordance with Article 3(14)(xxviii) of Law 2867/2000, laying down the criteria, the procedures and all other details relating to assessment of the bodies which may be designated as notified bodies in accordance with the requirements identified in Annex VI.

3. The EETT shall notify the Commission of the bodies designated in accordance with paragraph 1 and shall provide the necessary information for updating of the list of notified bodies to be published in the Official Journal of the European Communities.

4. The EETT shall be the surveillance authority for the application of the provisions of this Decree. The EETT may request the assistance of other administrative services, in particular for carrying out the checks which are necessary before protection or safeguarding measures are taken or before the penalties laid down in Article 16 are imposed. The EETT shall provide the necessary information for updating of the list of surveillance authorities to be published in the Official Journal of the European Communities.

Article 14

(Article 13 and Article 14 of Directive 99/5/EC)

The Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM)

1. The EETT shall represent Greece in the work of the Telecommunication Conformity Assessment and Market Committee. It shall keep a dossier covering that aspect and shall publish information and the opinions issued by the committee.

2. The EETT shall consult the Telecommunication Conformity Assessment and Market Committee on the matters covered by Article 5(3), Article 8(4), Article 10(2) and Annex VII(5).

Chapter IV

Final and transitional provisions

Article 15

(Article 16 of Directive 99/5/EC)

Third countries

The EETT may inform the Commission of difficulties encountered, de jure or de facto, by Greek undertakings or by undertakings having a registered office or an official representative in Greece with respect to the placing of radio equipment and telecommunications terminal equipment on the market in third countries.

Article 16

Penalties

In cases of violation of the provisions of this Decree, the EETT may, via a specifically reasoned decision in accordance with Article 3(15) of Law 2867/2000, after hearing

the parties concerned, issue a caution or impose the following fines in addition to the penalties referred to in Article 10 of this Decree:

- a) a fine of from EUR 3 000 to EUR 30 000 on the manufacturer or his authorised representative or the person responsible for placing the apparatus on the market for a failure to comply with the obligations referred to in Article 7(1), (2) and (4);
- b) a fine of from EUR 3 000 to EUR 60 000 on the manufacturer or his authorised representative or the person responsible for placing the apparatus on the market for a failure to comply with the obligations referred to in Article 7(3);
- c) a fine of from EUR 3 000 to EUR 30 000 on the manufacturer or his authorised representative or the person responsible for placing the apparatus on the market for a failure to comply with the obligations referred to in Article 9(2) and (3);
- d) a fine of from EUR 3 000 to EUR 60 000 for a violation of the obligations referred to in Article 11(1), (2) and (3). The fine shall be imposed on the person responsible for affixing the marking or, if that person cannot be identified, on the person in possession of the apparatus when the failure to comply with the obligation is discovered.

Article 17
(Article 18 of Directive 99/5/EC)

Transitional provisions

1. Standards under Joint Ministerial Decision 470/1985 (II 183), as amended by Joint Ministerial Decision B6467/608/88 or by Joint Ministerial Decision 94649/8682/93, 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 Article 3(1)(a) and (b).
2. Common technical regulations under Directive 98/13/EC (OJ L 74) 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 essential requirements referred to in Article 3.
3. Apparatus which is in accordance with the provisions in Directive 98/13/EC may continue to be placed on the market and put into service after this Decree enters into force if it was placed on the market for the first time by 7 April 2001.
4. Apart from the essential requirements referred to in Article 3(1), the Minister for Transport and Communications may, via a decision issued with the authorisation of the Commission, continue, until 7 October 2002, to require telecommunications terminal equipment not to be capable of causing unacceptable deterioration of a voice telephony service accessible within the framework of the universal service as defined in Presidential Decree 181/99 on adaptation to Directive 98/10/EC on the application of open network provision (ONP) to voice telephony and on universal service for telecommunications in a competitive environment (I 70). The Minister for Transport and Communications shall inform the Commission of the reasons for requesting a continuation of such a requirement, the date by which the service concerned will no longer need the requirement, and the measures envisaged in order to meet this deadline.

Article 18
(Article 20 of Directive 99/5/EC)

Repeal

The provision of Article 2(7) of Law 2801/2000 (I 46) and all general and specific provisions of law and of regulatory administrative acts which run counter to the provisions of this Decree are hereby repealed.

Article 19

The following Annexes form an integral part of this Decree.

ANNEX I

EQUIPMENT NOT COVERED BY THIS DIRECTIVE
AS REFERRED TO IN ARTICLE 1(3)

1. Radio equipment used by radio amateurs within Article 1, definition 53, of the International Telecommunications Union (ITU) radio regulations, as ratified by Law 1843/1989 ratifying final acts of the World Administrative Radiocommunications Conference (Geneva, 1979), 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 Presidential Decree 347/98 (I 231) on marine equipment within the scope of Council Directive 96/98/EC of 20 December 1996.
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, as amended by Commission Regulation (EC) No 2176/96.
6. Air traffic management equipment and systems within the meaning of Presidential Decree 351/96 adapting Greek law to the provisions of Council Directive 93/65/EEC on the definition and use of compatible technical specifications for the procurement of air traffic management equipment and systems (I 230), as amended by Presidential Decree 7/1999 adapting Greek law to the provisions of Commission Directive 97/15/EC adopting Eurocontrol standards and amending Council Directive 93/65/EEC on the definition and use of compatible technical specifications for the procurement of air traffic management equipment and systems (I 4).

ANNEX II

CONFORMITY ASSESSMENT PROCEDURE
REFERRED TO IN ARTICLE 12(3)

Module A – Internal production control

1. The manufacturer or his authorised representative established within the Community, who carries out the operations laid down in paragraph 2, ensures and declares that the products concerned satisfy the requirements of this Decree that apply to them. The manufacturer or his authorised representative established within the Community 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 and he or his authorised representative established within the Community 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.
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 and include 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 the drawings and schemes and the operation of the product,
 - a list of the standards referred to in Article 5, applied in full or in part, and descriptions and explanations of the solutions adopted to meet the essential requirements where the standards referred to in Article 5 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 3 and with the requirements of this Decree that apply to them.

ANNEX III

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 12(4)

Internal production control plus specific apparatus tests

Annex based on Module A, with additional requirements
appropriate to the sector

This Annex consists of Annex II 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 established within the Community 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.

ANNEX IV

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 12(5)

Technical construction file

This Annex consists of Annex III plus the following supplementary requirements:

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

The manufacturer, his authorised representative established within the Community 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 other notified bodies which 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 this Decree have been met, the notified body may, within four weeks of its receipt of the file, 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 which have received the file accordingly. 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 Article 7(3) and Article 10(2).

The manufacturer, his authorised representative established within the Community 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 approved apparatus has been manufactured at the disposal of the relevant national authorities of any Member State for inspection.

ANNEX V

CONFORMITY ASSESSMENT PROCEDURE REFERRED TO IN ARTICLE 12

Full quality assurance

1. Full quality assurance is the procedure whereby the manufacturer which satisfies the obligations of the following paragraph ensures and declares that the products concerned satisfy the requirements of this Decree that apply to them. The manufacturer must affix the mark referred to in Article 11(1) 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 and must be subject to surveillance as specified in paragraph 4.

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 this Decree that apply to them. All the elements, requirements and provisions (in the form of written policies, procedures and instructions) adopted by the manufacturer must be documented in a systematic manner. The quality system documentation must ensure a common understanding of the quality control policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular:

- 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 Article 5(1) will not be applied in full, the means that will be used to ensure that the essential requirements of this Decree 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. It must presume compliance with these requirements in respect of quality systems that implement the relevant harmonised standard, in this case ELOT EN ISO 9001, supplemented, where necessary, to take account of the particular characteristics of the products to which it will be applied.

The notified body must assess in particular whether the quality control system ensures conformity of the products with the requirements of the Decree in the light of the documentation supplied in respect of paragraphs 3.1. and 3.2., 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. or whether a reassessment is required.

The notified body 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 the 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 the 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, assessment 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 competent services of the Ministry of Transport and Communications and of the EETT:

- the documentation referred to in the second point of the second indent of paragraph 3.1.,
- the updating referred to in the second indent of paragraph 3.4.,
- the decisions and reports from the notified body which are referred to in the final indent of paragraph 3.4. and in paragraphs 4.3. and 4.4.

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

ANNEX VI

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT WHEN DESIGNATING NOTIFIED BODIES IN ACCORDANCE WITH ARTICLE 13

1. The notified body, its director and the staff responsible for carrying out the tasks for which the designated body has been designated must not be a designer, manufacturer, supplier or installer of radio equipment or telecommunications terminal equipment, or a network operator or a service provider, nor the authorised representative of any of such parties. They must be independent and not become directly involved in the design, construction, marketing or maintenance of radio equipment or telecommunications terminal equipment, nor represent the parties

engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer and the notified body.

2. The notified body and its staff must carry out the tasks for which the notified body has been designated with professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of any inspection, especially from persons or groups of persons with an interest in such results.
3. The notified body must have at its disposal the necessary staff and facilities to enable it to perform properly the administrative and technical work associated with the tasks for which it has been designated.
4. The staff responsible for inspections must have:
 - sound technical and professional training,
 - satisfactory knowledge of the requirements of the tests or inspections that are carried out and adequate experience of such tests or inspections,
 - the ability to draw up the certificates, records and reports required to authenticate the performance of the inspections.
5. The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests or inspections carried out nor on the results of such inspections.
6. The notified body must take out liability insurance unless its liability is assumed by the state in accordance with the law in force, or the state itself is directly responsible.
7. The staff of the notified body is bound to observe professional secrecy with regard to all information gained in carrying out its task under this Decree or any provision of law giving effect thereto. The requirement for secrecy does not apply vis-à-vis the Ministry of Transport and Communications, the EETT and the judicial authorities.

ANNEX VII

MARKING OF EQUIPMENT REFERRED TO IN ARTICLE 11(1)

1. The CE conformity marking must consist of the initials 'CE' taking the following form:

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. The equipment class identifier must take a form to be decided by the Commission in accordance with the procedure laid down in Article 14 of Directive 99/5/EC. 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'.

Article 20

Entry into force

This Decree shall enter into force on 8 April 2000.

We charge the State Secretary for Transport and Communications with the publication and execution of this Decree.

Athens, 5 March 2002

THE PRESIDENT OF THE REPUBLIC

KONSTANDINOS STEFANOPOULOS

THE MINISTERS

ECONOMIC AFFAIRS
AND FINANCE
NIKOLAOS CHRISTODOULAKIS

STATE SECRETARY FOR
TRANSPORT AND COMMUNICATIONS
SPYRIDON VOUGIAS