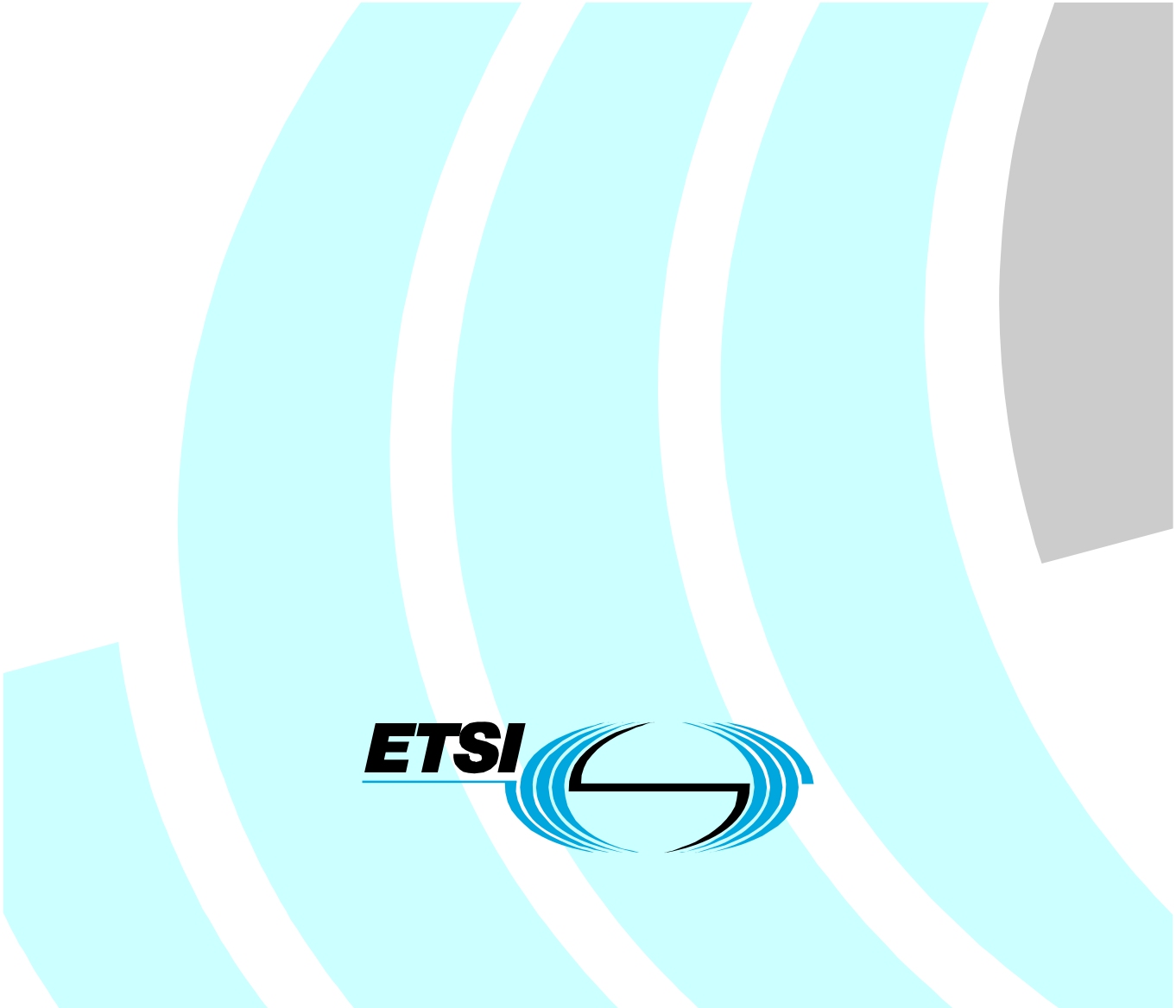
ETSI EN 302 510-2 V1.1.1 (2007-07)

Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive



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Foreword

This Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [4] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulations.

The present document is intended to become a Harmonized Standard, the reference of which will be published in the Official Journal of the European Communities referencing the Council Directive on the approximation of the laws of the Member States relating to electromagnetic compatibility ("the EMC Directive") (2004/108/EC [5] as amended) and Directive 1999/5/EC [1] of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity ("the R&TTE Directive").

The present document is part 2 of a multi-part deliverable covering inductively coupled Ultra Low Power Active Medical Implant Membrane (ULP-AMI-M) devices in the frequency range 30 MHz to 37,5 MHz, as identified below:

Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

Technical specifications relevant to Directive 1999/5/EC [1] are given in annex A.

National transposition dates	
Date of adoption of this EN:	15 June 2007
Date of latest announcement of this EN (doa):	30 September 2007
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2008
Date of withdrawal of any conflicting National Standard (dow):	31 March 2009

1 Scope

The present document applies to Ultra Low Power-Active Medical Implants (ULP-AMI), Membrane Implants, and accessories as described in Directive 90/385/EEC [6], operating in a Medical Implant Communications System (MICS) in the frequency band 30 MHz to 37,5 MHz. An AIMD is regulated under the AIMD Directive 90/385/EEC [6]: radio parts contained therein (referred to herein as ULP-AMI and ULP-AMI-P for peripheral devices) are regulated under the R&TTE Directive 1999/5/EC [1].The present document is intended to cover the provisions of Directive 1999/5/EC [1] (R&TTE Directive) article 3.2, which states that "….. radio equipment shall be so constructed that it effectively uses the spectrum allocated to terrestrial/space radio communications and orbital resources so as to avoid harmful interference".

In addition to the present document, other ENs that specify technical requirements in respect of essential requirements under other parts of article 3 of the R&TTE Directive [1] will apply to equipment within the scope of the present document.

NOTE: A list of such ENs is included on the web site http://www.newapproach.org.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at http://docbox.etsi.org/Reference.

NOTE: While any hyperlinks included in this clause were valid at the time of publication ETSI cannot guarantee their long term validity.

[1] Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (R&TTE Directive).

[2] ETSI EN 302 510-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 1: Technical characteristics and test methods".

[3] ETSI TR 100 028 (V1.3.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics Part 1".

[4] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.

[5] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (EMC Directive).

[6] 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 (AMD Directive).

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive [1] and EN 302 510-1 [2] apply.

3.2 Symbols

For the purposes of the present document, the symbols given in EN 302 510-1 [2] apply.

3.3 Abbreviations

For the purposes of the present document, the abbreviations given in EN 302 510-1 [2] apply.

4 Technical requirements specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Conformance requirements

4.2.1 Mechanical and electrical design

4.2.1.1 General

The equipment shall be designed, constructed and manufactured in accordance with sound engineering practice and with the aim of minimizing harmful disturbance to other equipment and services and should not be disturbed by harmful interference from other electronic devices. Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the ULP-AMI band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, the connector shall be a unique type to prevent use of an antenna other than a dedicated antenna supplied by the manufacturer.

4.2.1.3 Controls

Those controls that, if maladjusted, might increase the disturbing potentialities of the equipment shall not be easily accessible to the user.

4.2.1.4 Transmitter shut-off facility

If the transmitter is equipped with an automatic transmitter shut-off facility or battery-saving feature and it interferes with testing of the device, it shall be capable of being made inoperative for the purpose of testing.

4.2.2 Maximum effective radiated power of the fundamental

4.2.2.1 Definition

The maximum effective radiated power shall be as defined in EN 302 510-1 [2], clause 7.2.2.

4.2.2.2 Limits

The effective radiated power limits shall be as defined in EN 302 510-1 [2], clause 7.2.4.

4.2.2.3 Conformance

Conformance tests as defined in clause 5.3.1 shall be carried out.

4.2.3 Out of band emissions

4.2.3.1 Definition

The effective radiated power shall be as defined in EN 302 510-1 [2], clause 7.3.1.

4.2.3.2 Limits

The effective radiated power limits shall be as defined in EN 302 510-1 [2], clause 7.3.3.

4.2.3.3 Conformance

Conformance tests as defined in clause 5.3.2 shall be carried out.

4.2.4 Unwanted emissions in the spurious domain

4.2.4.1 Definition

The unwanted emissions in the spurious domain shall be as defined in EN 302 510-1 [2], clause 7.4.1.

4.2.4.2 Limits

The unwanted emissions in the spurious domain limits shall be as defined in EN 302 510-1 [2], clause 7.4.3.

4.2.4.3 Conformance

Conformance tests as defined in clause 5.3.3 shall be carried out.

4.2.5 Duty cycle

4.2.5.1 Definition

The duty cycle shall be as defined in EN 302 510-1 [2], clause 7.5.1.

4.2.5.2 Limit

The maximum duty cycle shall not exceed the limits in EN 302 510-1 [2], clause 7.5.3.

4.2.6 Receiver blocking or desensitization

4.2.6.1 Definition

The blocking or desensitization, shall be as defined in EN 302 510-1 [2], clause 8.1.1.

4.2.6.2 Limit

The limit shall not be less than the limits in EN 302 510-1 [2], clause 8.1.3, table 4.

This requirement applies to equipment class 1 and equipment class 2 receivers, as defined in EN 302 510-1 [2], clause 4.1.1.

4.2.6.3 Conformance

Conformance tests as defined in clause 5.3.4 shall be carried out.

4.2.7 Spurious radiation of receivers

4.2.7.1 Definition

The spurious radiation of receivers shall be as defined in EN 302 510-1 [2], clause 8.2.1.

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 302 510-1 [2], clause 8.2.3.

4.2.7.3 Conformance

Conformance tests as defined in clause 5.3.5 shall be carried out.

5 Testing for compliance with technical requirements

5.1 Environmental conditions for testing

Tests defined in the present document shall be carried out at representative points within the boundary limits of the declared operational environmental profile.

Where technical performance varies subject to environmental conditions, tests shall be carried out under a sufficient variety of environmental conditions (within the boundary limits of the declared operational environmental profile) to give confidence of compliance for the affected technical requirements.

5.2 Interpretation of the measurement results

The interpretation of the results recorded in a test report for the measurements described in the present document shall be as follows:

- the measured value related to the corresponding limit will be used to decide whether an equipment meets the requirements of the present document;
- the value of the measurement uncertainty for the measurement of each parameter shall be included in the test report;
- the recorded value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures in table 1.

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with TR 100 028 [3] and shall correspond to an expansion factor (coverage factor) k = 1,96 or k = 2 (which provide confidence levels of respectively 95 % and 95,45 % in the case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

Table 1 is based on such expansion factors.

Table 1: Maximum measurement uncertainty

RF frequency	±1 x10^{-7}
RF power, conducted	±1 dB
RF power, radiated	±6 dB
Temperature	±1°C
Humidity	±5 %

5.3 Essential radio test suites

5.3.1 Effective radiated power of the fundamental emission

The test for effective radiated power of the fundamental emission specified in EN 302 510-1 [2], clause 7.2.3 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.2.2 in order to assess compliance with the requirement.

5.3.2 Out of band emissions

The test for effective radiated power of the fundamental emission specified in EN 302 510-1 [2], clause 7.3.2 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.3.2 in order to assess compliance with the requirement.

5.3.3 Unwanted emissions in the spurious domain

The test for effective radiated power of unwanted emissions in the spurious domain specified in EN 302 510-1 [2], clause 7.4.2 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.4.2 in order to assess compliance with the requirement.

5.3.4 Blocking or desensitization

The test for blocking or desensitization of receivers specified in EN 302 510-1 [2], clause 8.1.2 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.6.2 in order to assess compliance with the requirement.

5.3.5 Spurious radiation of receivers

The test for spurious radiation of receivers specified in EN 302 510-1 [2], clause 8.2.2 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.7.2 in order to assess compliance with the requirement.

5.3.6 Normal and extreme test-conditions

The test conditions shall be as declared by the manufacturer. The requirements and test procedures shall be as specified in EN 302 510-1 [2], clauses 5.3 and 5.4.

5.3.7 Test power source

The test power source shall meet the requirements of EN 302 510-1 [2], clause 5.2.

5.3.8 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 302 510-1 [2], clauses 4.2.1 and 4.2.2.

Annex A (normative): HS Requirements and conformance Test specifications Table (HS-RTT)

The HS Requirements and conformance Test specifications Table (HS-RTT) in table A.1 serves a number of purposes, as follows:

- it provides a statement of all the essential requirements in words and by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in a specific referenced document;
- it provides a statement of all the test procedures corresponding to those essential requirements by cross reference to (a) specific clause(s) in the present document or to (a) specific clause(s) in (a) specific referenced document(s);
- it qualifies each requirement to be either:
  - Unconditional: meaning that the requirement applies in all circumstances; or
  - Conditional: meaning that the requirement is dependant on the manufacturer having chosen to support optional functionality defined within the schedule.
- in the case of Conditional requirements, it associates the requirement with the particular optional service or functionality;
- it qualifies each test procedure to be either:
  - Essential: meaning that it is included with the Essential Radio Test Suite and therefore the requirement shall be demonstrated to be met in accordance with the referenced procedures;
  - Other: meaning that the test procedure is illustrative but other means of demonstrating compliance with the requirement are permitted.

Table A.1: HS Requirements and conformance Test specifications Table (HS-RTT)

Harmonized Standard EN 302 510-2 The following essential requirements and test specifications are relevant to the presumption of conformity under Article 3.2 of the R&TTE Directive						
Essential Requirement			**Requirement Conditionality**		**Test Specification**	
No	**Description**	**Reference: Clause No**	**U/C**	**Condition**	**E/O**	**Reference: Clause No**
1	Mechanical and electrical design	4.2.1	U		X	
2	Effective radiated power of the fundamental emission	4.2.2	U		E	**5.3.1**
3	Out of band emissions	4.2.3	U		E	**5.3.2**
4	Unwanted emissions in the spurious domain (of transmitters)	4.2.4	U		E	**5.3.3**
5	Duty Cycle	4.2.5	U		X	
6	Receiver blocking or desensitization	4.2.6	U		E	**5.3.4**
7	Spurious radiation of receivers	4.2.7	U		E	**5.3.5**

Key to columns:

Essential Requirement:

No A unique identifier for one row of the table which may be used to identify a requirement or its test specification.

Description A textual reference to the requirement.

Clause Number Identification of clause(s) defining the requirement in the present document unless another document is referenced explicitly.

Requirement Conditionality:

U/C Indicates whether the requirement is to be *unconditionally* applicable (U) or is *conditional* upon the manufacturers claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement shall or shall not be applicable for a technical requirement which is classified "conditional".

Test Specification:

E/O Indicates whether the test specification forms part of the Essential Radio Test Suite (E) or whether it is one of the Other Test Suite (O).

NOTE: All tests whether "E" or "O" are relevant to the requirements. Rows designated "E" collectively make up the Essential Radio Test Suite; those designated "O" make up the Other Test Suite; for those designated "X" there is no test specified corresponding to the requirement. The completion of all tests classified "E" as specified with satisfactory outcomes is a necessary condition for a presumption of conformity. Compliance with requirements associated with tests classified "O" or "X" is a necessary condition for presumption of conformity, although conformance with the requirement may be claimed by an equivalent test or by manufacturer's assertion supported by appropriate entries in the technical construction file.

Clause Number Identification of clause(s) defining the test specification in the present document unless another document is referenced explicitly. Where no test is specified (that is, where the previous field is "X") this field remains blank.

Annex B (informative): The EN title in the official languages

Language	EN title
Bulgarian	Електромагнитна съвместимост и въпроси на радиоспектъра (ERM). Радиосъоръжения в честотния обхват от 30 MHz до 37,5 MHz за свръхмаломощни активни медицински мембрани за имплантиране и принадлежности. Част 2: Хармонизиран европейски стандарт (EN), покриващ съществените изисквания на член 3.2 от Директивата за радиосъоръжения и крайни далекосъобщителни устройства (R&TTED)
Czech	Elektromagnetická kompatibilita a rádiové spektrum (ERM) - Rádiová zařízení v kmitočtovém rozsahu 30 MHz až 37,5 MHz pro aktivní lékařské membránové implantáty a doplňky velmi nízkého výkonu - Část 2: Harmonizovaná EN pokrývající základní požadavky článku 3.2 Směrnice R&TTE
Danish	Elektromagnetisk kompatibilitet og Radiospektrum Anliggender (ERM); Radio udstyr med ultra lav sendeeffekt, der benytter frekvensområdet 30 til 37,5 MHz, beregnet til aktive medicinske membran implantater og tilbehør - Del 2: Harmoniseret EN som dækker de væsentlige krav i R&TTE direktivets artikel 3.2
Dutch	Elektromagnetische compatibiliteit en radiospectrumaangelegenheden (ERM);Radioapparatuur in het frequentiegebied van 30 MHz tot 37,5 MHz met ultra-laag vermogen, voor actieve medische membraan inplantaten en toebehoren;Deel 2: Geharmoniseerde EN welke invulling geeft aan de essentiële eisen van artikel 3.2 van de R&TTE richtlijn
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive
Estonian	Elektromagnetilise ühilduvuse ja raadiospektri küsimused (ERM); Raadiosagedusalas 30 MHz kuni 30,5 MHz töötavad väga väikese võimsusega aktiivsed meditsiinilised membraanimplantaadid ja nende lisatarvikud; Osa 2: Harmoneeritud EN R&TTE direktiivi artikli 3.2 põhinõuete alusel
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); 30 - 37,5 MHz:n taajuusalueella toimivat radiolaitteet erittäin pienitehoisille aktiivisille lääketieteellisille kalvoistutteille ja niiden lisälaitteille; Osa 2: Yhdenmukaistettu standardi (EN), joka kattaa R&TTE-direktiivin artiklan 3.2 mukaiset olennaiset vaatimukset
French	Télécommunications - CEM et spectre radioélectrique (ERM) - Équipements radio dans la bande de fréquence de 30 MHz à 37,5 MHz pour membrane d' implants médicaux actifs de puissance ultra basse et accessoires - Partie 2: EN harmonisée couvrant les exigences essentielles de l'article 3.2 de la Directive R&TTE
German	Elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten (ERM) - Funkanlagen mit geringer Reichweite (SRD) - Funkgeräte im Frequenzbereich von 30 MHz bis 37,5 MHz für aktive medizinische Membranimplantate mit sehr kleiner Leistung und Zubehör - Teil 2: Harmonisierte EN, die wesentliche Anforderungen nach Artikel 3.2 der R&TTE
Greek	Ηλεκτρομαγνητική Συμβατότητα και Θέματα Ραδιοφάσματος (ERM) - Ραδιοεξοπλισμός στην περιοχή συχνοτήτων 30 MHz ως 37,5 MHz για ενεργητικά ιατρικά μεμβρανοειδή εμφυτεύματα υπερχαμηλής ισχύος - Μέρος 2: Εναρμονισμένο EN για την κάλυψη των ουσιωδών απαιτήσεων του άρθρου 3.2 της Οδηγίας R&TTE
Hungarian	Elektromágneses összeférhetőségi és rádióspektrumügyek (ERM). A 30 MHz-től 37,5 MHz-ig terjedő frekvenciasávban működő ultrakis teljesítményű aktív orvosi membrán-implantátumok és tartozékaik rádióberendezései. 2. rész: Az R&TTE
Icelandic	
Italian	Compatibilità elettromagnetica ed argomenti di spettro della radio (ERM); Apparecchiatura radiofonica nella gamma di frequenza 30 megahertz - 37.5 megahertz per Ultra Low Power Active Medical Membrane Implants and Accessories; Parte 2: EN armonizzata che soddisfa le esigenze essenziali dell'articolo 3.2 di R&TTE Directive
Latvian	Elektromagnētiskā saderība un radiofrekvenču spektra jautājumi (ERM). Radioiekārta frekvenču intervālā no 30 MHz līdz 37,5 MHz ļoti zemas jaudas aktīvo medicīnisko membrānu implantiem un piederumiem; 2. daļa:Harmonizēts Eiropas standarts (EN), kas atbilst R&TTE
Lithuanian	Elektromagnetinio suderinamumo ir radijo dažnių spektro dalykai. Ypač mažos galios aktyviųjų medicininių membraninių implantatų ir pagalbinių reikmenų radijo ryšio įranga, veikianti nuo 30 MHz iki 37,5 MHz dažnių diapazone. 2 dalis. Darnusis Europos standartas, apimantis esminius 1999/5/EC direktyvos 3.2 straipsnio reikalavimus
Maltese	Kompatibilità elettromanjetika u materji relatati ma' spettru radjofoniku (ERM); Tagħmir radjofoniku fil-medda ta' frekwenzi 37,5 MHz għal Implantazzjonijiet Membrani Mediċi Attivi b'Enerġija Ultra-Baxxa u Aċċessorji tagħhom Parti 2: EN armonizzat li jkopri rekwiżiti essenzjali taħt l-artiklu 3.2 tad-Direttiva R&TTE
Norwegian	

Language	EN title
Polish	Kompatybilność elektromagnetyczna i zagadnienia widma radiowego (ERM) - Urządzenia radiowe pracujące w zakresie częstotliwości od 30 MHz do 37,5 MHz dla aktywnych membranowych implantów medycznych ultra niskiego poziomu mocy i ich urządzenia pomocnicze - Część 2: Zharmonizowana EN zapewniająca spełnienie zasadniczych wymagań zgodnie z artykułem 3.2 dyrektywy R&TTE
Portuguese	Assuntos de Espectro Radioeléctrico e Compatibilidade Electromagnética (ERM); Equipamentos de rádio na faixa de frequências de 30 MHz a 37,5 MHz para Implantes Médicos Activos de Membranas de Ultra Baixa Potência e Acessórios; Parte 2: EN Harmonizada cobrindo os requisitos essenciais no âmbito do artigo 3.º, n.º 2, da Directiva R&TTE
Romanian	Compatibilitate electromagnetică şi probleme de spectru radio (ERM); Echipamente radio în domeniul de frecvenţă de la 30 MHz până la 37,5 pentru implanturi active de membrane medicale cu putere ultra mică şi accesorii; Partea 2: EN armonizat acoperind cerinţele esenţiale ale Articolului 3.2 al Directivei R&TTE
Slovak	Elektromagnetick kompatibilita a z lezitosti r dioveho spektra (ERM). R diove zariadenia vo frekvencnom rozsahu od 30 MHz do 37,5 MHz pre akt¡vne zdravotn¡cke membr nove implant ty s ultran¡zkym vìkonom a pr¡slusenstvo. Cast 2: Harmonizovan EN vztahuj£ca sa na z kladne poziadavky podla cl nku 3.2 smernice R&TTE
Slovenian	Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenčnem območju od 30 MHz do 37,5 MHz za aktivne membranske medicinske vsadke ultra majhnih moči in pribor - 2. del: Harmonizirani EN, ki zajema bistvene zahteve člena 3.2 direktive R&TTE
Spanish	Cuestiones de compatibilidad electromágnetica y espectro de radiofrecuencia (ERM); Equipos radioeléctricos en la gama de frecuencias de 30 MHz a 37,5 MHz para Implantes Médicos Activos de Membrana de Potencia Ultra Baja y Accesorios; Parte 2: Norma Europea (EN) armonizada que cubre los requisitos esenciales según el artículo 3.2 de la Directiva RTTE
Swedish	Elektromagnetisk kompatibilitet och radiospektrumfrågor (ERM); Radioutrustning i frekvensområdet 30 MHz till 37,5 MHz för aktiva medicinska membran-implantat med extrem låg effekt samt kringutrustning; Del 2: Harmoniserad EN omfattande väsentliga krav enligt artikel 3.2 i R&TTE-direktivet

Annex C (informative): Bibliography

CEPT/ERC/Recommendation 70-03 (2006): "Relating to the use of Short Range Devices (SRD)".

Radiofrequency Radiation Dosimetry Handbook (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

ETSI EN 301 489: "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (LV Directive).

History

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