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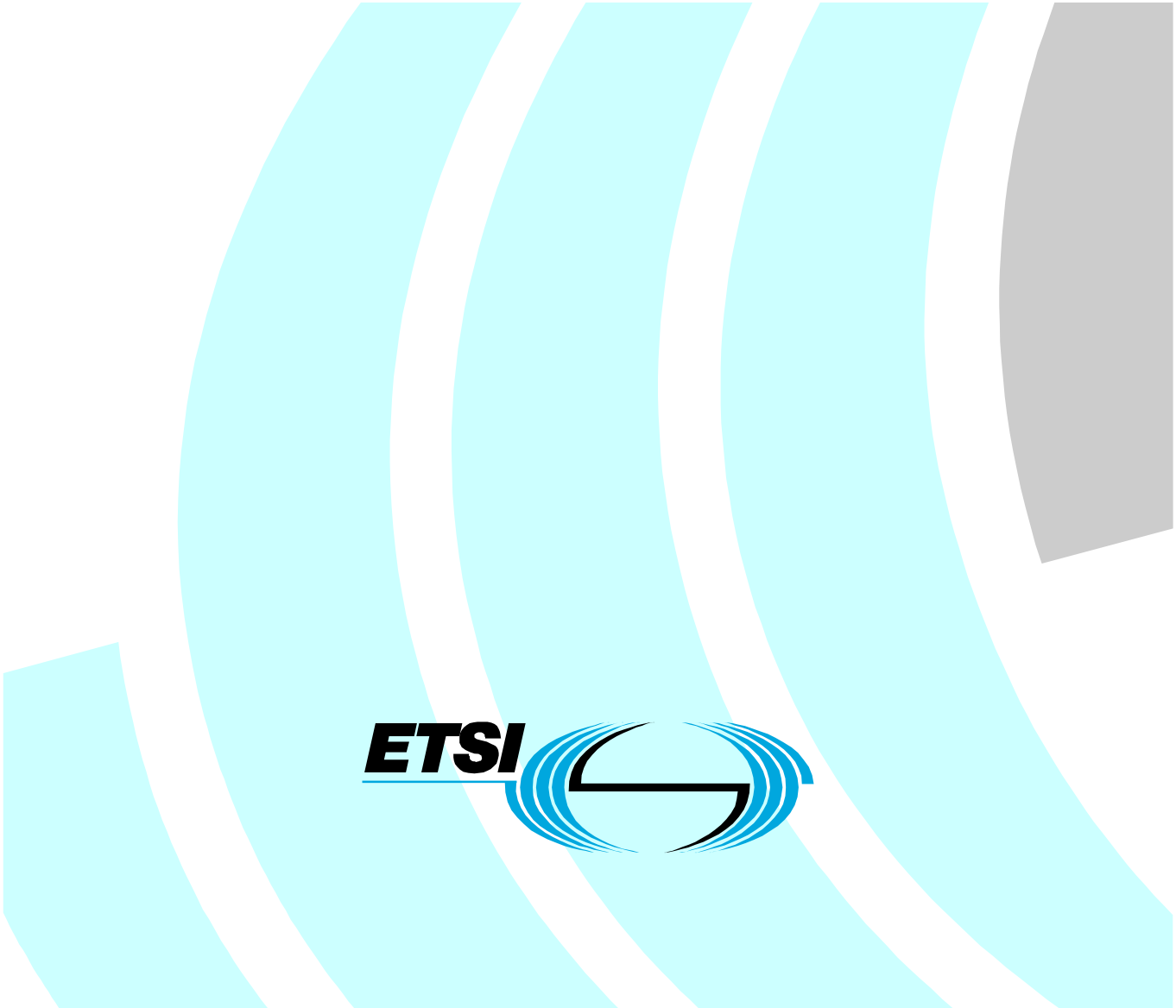
Candidate Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive



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Contents

Intellectual Property Rights 5
Foreword 5
1 Scope 6
2 References 6
3 Definitions and abbreviations 6
3.1 Definitions 6
3.2 Abbreviations 6
4 Technical requirements and specifications 7
4.1 Environmental profile 7
4.2 Conformance requirements 7
4.2.1 Mechanical and electrical design 7
4.2.1.1 General 7
4.2.1.2 Antennas 7
4.2.1.3 Controls 7
4.2.1.4 Transmitter shut-off facility 7
4.2.2 Frequency error 7
4.2.2.1 Definition 7
4.2.2.2 Limits 7
4.2.2.3 Conformance 7
4.2.3 Emission bandwidth 7
4.2.3.1 Definition 7
4.2.3.2 Limits 8
4.2.3.3 Conformance 8
4.2.4 Effective radiated power of the fundamental emission 8
4.2.4.1 Definition 8
4.2.4.2 Limits 8
4.2.4.3 Conformance 8
4.2.5 Spurious emissions 8
4.2.5.1 Definition 8
4.2.5.2 Limits 8
4.2.5.3 Conformance 8
4.2.6 Frequency stability under low voltage conditions 8
4.2.6.1 Definition 8
4.2.6.2 Limits 8
4.2.6.3 Conformance 8
4.2.7 Spurious radiation of receivers 8
4.2.7.1 Definition 8
4.2.7.2 Limits 9
4.2.7.3 Conformance 9
4.2.8 Spectrum Access 9
4.2.8.1 LBT/AFA spectrum access 9
4.2.8.1.1 Definition 9
4.2.8.1.2 Limits 9
4.2.8.1.3 Conformance 9
4.2.8.2 LP/LDC spectrum access 9
5 Testing for compliance with technical requirements 10
5.1 Environmental conditions for testing 10
5.2 Interpretation of the measurement results 10
5.3 Essential radio test suites 10
5.3.1 Frequency error 10
5.3.2 Emission bandwidth 11
5.3.3 Effective radiated power of the fundamental emission 11
5.3.4 Spurious emissions 11

5.3.5 Frequency stability under low voltage conditions 11
5.3.6 Spurious radiation of receivers 11
5.3.7 LBT/AFA Monitoring system....11
5.3.8 Normal and extreme test-conditions 11
5.3.9 Test power source 11
5.3.10 Choice of samples for test suites....11

Annex A (normative): The EN Requirements Table (EN-RT) 12

Annex B (informative): The EN title in the official languages 15

Annex C (informative): Bibliography....16

History 17

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Foreword

This Candidate Harmonized European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Public Enquiry phase of the ETSI standards Two-step Approval Procedure.

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC (as amended) [5] 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 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 ("the R&TTE Directive") [1].

The present document is part 2 of a multi-part deliverable covering Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Peripherals, 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".

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	6 months after doa
Date of withdrawal of any conflicting National Standard (dow):	18 months after doa

1 Scope

The present document applies to Ultra Low Power-Active Medical Implants (ULP-AMI) and accessories as described in Directive 90/385/EEC [2], operating in a Medical Implant Communications System (MICS) in the frequency band 402 MHz to 405 MHz.

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.

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.

[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] 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.

[3] ETSI EN 301 839-1 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods".

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

[5] 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.

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in EN 301 839-1 [3], clause 3.1 apply.

3.2 Abbreviations

For the purposes of the present document, the abbreviations given in EN 301 839-1 [3], clause 3.3 apply.

4 Technical requirements and 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 Frequency error

4.2.2.1 Definition

The frequency error shall be as defined in EN 301 839-1 [3], clause 8.1.1.

4.2.2.2 Limits

The frequency error limits shall be as defined in EN 301 839-1 [3], clause 8.1.2.

4.2.2.3 Conformance

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

4.2.3 Emission bandwidth

4.2.3.1 Definition

The emission bandwidth shall be as defined in EN 301 839-1 [3], clause 8.2.1.

4.2.3.2 Limits

The emission bandwidth limits shall be as defined in EN 301 839-1 [3], clause 8.2.2.

4.2.3.3 Conformance

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

4.2.4 Effective radiated power of the fundamental emission

4.2.4.1 Definition

The effective radiated power shall be as defined in EN 301 839-1 [3], clause 8.3.1.

4.2.4.2 Limits

The effective radiated power limits shall be as defined in EN 301 839-1 [3], clause 8.3.2.

4.2.4.3 Conformance

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

4.2.5 Spurious emissions

4.2.5.1 Definition

The spurious emissions shall be as defined in EN 301 839-1 [3], clause 8.4.1.

4.2.5.2 Limits

The spurious emissions limits shall be as defined in EN 301 839-1 [3], clause 8.4.2.

4.2.5.3 Conformance

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

4.2.6 Frequency stability under low voltage conditions

4.2.6.1 Definition

The frequency stability under low voltage conditions shall be as defined in EN 301 839-1 [3], clause 8.5.1.

4.2.6.2 Limits

The frequency stability under low voltage conditions limits shall be as defined in EN 301 839-1 [3], clause 8.5.2.

4.2.6.3 Conformance

Conformance tests as defined in clause 5.3.5 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 301 839-1 [3], clause 9.1.1.

4.2.7.2 Limits

The spurious radiation of receivers limits shall be as defined in EN 301 839-1 [3], clause 9.1.2.

4.2.7.3 Conformance

Conformance tests as defined in clause 5.3.6 shall be carried out.

4.2.8 Spectrum Access

It is mandatory that the manufacturer declares a spectrum access method. At least one of the following methods shall be chosen. A manufacturer may choose to implement both methods in his equipment, however, he may operate using both access methods if the total emission bandwidth does not exceed 300 kHz.

- LBT/AFA requirements for the monitoring system are specified in EN 301 839-1 [3], clause 10. Manufacturers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.8.1 of the present document, and are not obliged to fulfill the requirements of clause 4.2.8.2 of the present document.
- LP/LDC requirements are specified in EN 301 839-1 [3], clauses 8.3.2 and 8.6.3. Manufacturers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.8.2 of the present document, and are not obliged to fulfill the requirements of clause 4.2.8.1 of the present document.

4.2.8.1 LBT/AFA spectrum access

4.2.8.1.1 Definition

Under this method, spectrum access is based on the technical requirements of EN 301 839-1 [3], clause 10. A monitoring system is the circuitry in a medical implant transmitter or an ULP-AMI-P that assures conformity with the essential requirement for use of the spectrum access protocol specified EN 301 839-1 [3], clause 10 by use of LBT and AFA.

4.2.8.1.2 Limits

The ULP-AMI-P/ULP-AMI requirements are as specified in EN 301 839-1 [3], clause 10 and applicable subsequent clauses.

4.2.8.1.3 Conformance

Conformance tests as defined in clause 5.3.7 shall be carried out.

4.2.8.2 LP/LDC spectrum access

The maximum power for low duty cycle operations as defined in EN 301 839-1[3], clause 8.3.1 shall not exceed the limit in EN 301 839-1 [3] clause 8.3.2.

The maximum duty cycle, as defined in EN 301 839-1 [3], clause 8.6.1, shall not exceed the limits in EN 301 839-1 [3], clause 8.6.3.

This requirement only applies to ULP-AMI accessing the 403,5 MHz to 403,8 MHz band as described in EN 301 839-1 [3], clause 8.6.

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 [4] 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	$\pm 1 \times 10^{-7}$
Adjacent channel power	±3 dB
RF power, conducted	±0,75 dB
Conducted emission of transmitter	±4 dB
Conducted emission of receivers	±3 dB
Radiated emission of transmitter, valid up to 4 GHz	±6 dB
Radiated emission of receiver, valid up to 4 GHz	±6 dB
Conducted monitoring test system	±4 dB
Radiated monitoring test system	±6 dB
Temperature	±1°C
Humidity	±5 %

5.3 Essential radio test suites

5.3.1 Frequency error

The test for frequency error specified in EN 301 839-1 [3], clause 8.1 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 Emission bandwidth

The test for emission bandwidth specified in EN 301 839-1 [3], clause 8.2.1.1 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 Effective radiated power of the fundamental emission

The test for effective radiated power of the fundamental emission specified in EN 301 839-1 [3], clause 8.3.1.1 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 Spurious emissions

The test for spurious emissions specified in EN 301 839-1 [3], clause 8.4.1.1 appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.5.2 in order to assess compliance with the requirement.

5.3.5 Frequency stability under low voltage conditions

The test for frequency stability under low voltage conditions specified in EN 301 839-1 [3], clause 8.5.1.1 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.

5.3.6 Spurious radiation of receivers

The test for spurious radiation of receivers specified in EN 301 839-1 [3], clause 9.1.1.1 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.

5.3.7 LBT/AFA Monitoring system

The tests for monitoring system requirements specified in EN 301 839-1 [3], clause 10 and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.1.2.

5.3.8 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 301 839-1 [3], clauses 5.3 and 5.4.

5.3.9 Test power source

The test power source shall meet the requirements of EN 301 839-1 [3], clause 5.2.

5.3.10 Choice of samples for test suites

Measurement shall be performed, according to the present document, on samples of equipment defined in EN 301 839-1 [3], clauses 4.2.1, 4.2.2 and 4.2.3.

Annex A (normative): The EN Requirements Table (EN-RT)

The EN Requirements Table (EN-RT) 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 in the present document or to a specific clause in a specific referenced document;
- it provides a statement of all the test procedure corresponding to those essential requirements by cross reference to specific clause(s) in the present document or to a specific clause(s) in 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 dependent on the supplier 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;
- when the schedule is completed in respect of a particular equipment including the testing outcomes, including a completed version of table A.1 it provides a means to assert the "presumption of conformity" with the HS.

Table A.1: EN Requirements Table (EN-RT)

Harmonized Standard EN 301 839-2 The following technical requirements and test specifications are relevant to the presumption of conformity under Article 3.2 of the R&TTE Directive							
Technical Requirement reference			**Technical Requirement Conditionality**		**Test Specification**		
No	**Description**	**Reference: Clause No**	**U/ C**	**Condition**	**E/O**	**Reference: Clause No**	**Observations**
1	Mechanical and electrical design	4.2.1	U		X		
2	Frequency error	4.2.2	U		E	**5.3.1**	
3	Emission bandwidth	4.2.3	U		E	**5.3.2**	
4	Effective radiated power of the fundamental emission	4.2.4	U		E	**5.3.3**	
5	Spurious emissions (of transmitters)	4.2.5	U		E	**5.3.4**	
6	Frequency stability under low voltage conditions	4.2.6	C	Only applies to all battery operated equipment	E	**5.3.5**	
7	Spurious radiation of receivers	4.2.7	U		E	**5.3.6**	
8	Spectrum Access	4.2.8	U		E		

Key to columns:

Essential Requirement:

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

Description A textual reference to the Essential Requirement.

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

Conditionality:

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

Condition Explains the conditions when the requirement shall or shall not be applicable for a 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 essential requirements. Tests designated "E" collectively make up the Essential Radio Test Suite; those designated "O" make up the Other Test Suite. For those requirements for which no test specification applies are designated "X". All tests classified "E" shall be performed as specified with satisfactory outcomes in order to allow a presumption of conformity. Requirements associated with tests classifies "O" or "X" must be complied with although the requirement shall be complied with as demonstrated by an equivalent test or by assertion by the supplier and asserted to be complied with to allow presumption of conformity.

Reference: 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.

Observations: Remains blank in the HS but is available for use for users of the standard to record the outcome of tests against each requirement.

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

Language	EN title
Czech	
Danish	Elektromagnetisk kompatibilitet og Radiospektrum Anliggender (ERM); Radioudstyr I frekvensområdet 402 til 405 MHz med ultra lav effekt, som benyttes I aktive medicinske implantater og hjælpeudstyr; Del 2: Harmoniseret EN son dækker de væsentlige krav I R&TTE direktivets artikel 3.2.
Dutch	Elektromagnetische compatibiliteit en radiospectrum zaken (ERM); Radio apparatuur, werkend in de frequentieband 402 - 405 MHz voor actieve medische implantaten en accessoires met ultra klein vermogen; Deel 2: Geharmoniseerde EN welke invulling geeft aan de wezenlijke vereisten, neergelegd in artikel 3.2 va de R&TTE Directive.
English	Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive.
Estonian	
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); Erittäin pientehoiset radiolaiteet taajuusalueella 402 - 405 MHz aktiivisille lääketieteellisille siirrännäisille ja niiden lisälaitteille; Osa 2: Yhdenmukaistettu standardi (EN), joka kattaa R&TTE direktiivin artikla 3.2 mukaiset olennaiset vaatimukset.
French	CEM et spectre radioélectrique (ERM); Service Mobile Terrestre; Equipements radio dans la bande de fréquence 402 MHz à 405 MHz pour les implants médicaux actifs d'ultra faible puissance et accessoires; Partie 2: Norme harmonisée couvrant les exigences essentielles de l'article 3.2 de la Directive R&TTE.
German	Elektromagnetische Verträglichkeit und Funkspektrumangelegenheiten (ERM); Funkeinrichtungen für den Einsatz im Frequenzbereich 402 MHz bis 405 MHz für aktive medizinische Implantate und Zubehör mit sehr geringer HF-Leistung; Harmonisierte Europäische Norm (EN) mit wesentlichen Anforderungen nach R&TTE-Richtlinie Artikel 3.2.
Greek	Ηλεκτρομαγνητική συμβατότητα και Θέματα Ραδιοφάσματος (ERM) - Ραδιοεξοπλισμός στην περιοχή συχνοτήτων από 402 MHz έως 405 MHz για Ενεργητικά Ιατρικά Εμφυτεύματα και Παρελκόμενα υπερχαμηλής ισχύος - Μέρος 2: Εναρμονισμένο EN για την κάλυψη των ουσιωδών απαιτήσεων του άρθρου 3.2 της Οδηγίας R&TTE.
Hungarian	
Icelandic	
Italian	Compatibilità elettromagnetica e Questioni relative allo spettro delle radiofrequenze (ERM); Apparecchiature radio nella gamma di frequenza 402 MHz fino a 405 MHz per accessori ed impianti medicali attivi di bassissima potenza; Parte 2: Norma armonizzata relativa ai requisiti essenziali dell'articolo 3.2 della direttiva R&TTE.
Latvian	
Lithuanian	
Maltese	
Norwegian	
Polish	
Portuguese	Assuntos de Espectro Radioelictrico e Compatibilidade Electromagnıtica (ERM); Equipamento rαdio de muito pequena potκncia para implantes mıdicos activos e seus acessσrios, operando na faixa de frequκncias de 402 MHz a 405 MHz; Parte 2: EN harmonizada cobrindo os requisitos essenciais no βmbito do Artigo 3.2 da Directiva R&TTE.
Slovak	
Slovenian	
Spanish	Compatibilidad electromagnıtica y cuestiones de espectro de radiofrecuencia (ERM); Equipos radio en el rango de frecuencia entre 402 MHz y 405 MHz para Implantes y Accesorios medicos activos de potencia ultra baja; Parte 2: EN armonizada cubriendo los requisitos esenciales según el artículo 3.2 de la directiva de R&TTE.
Swedish	Elektromagnetisk kompatibilitet och radio-spektrum frågor (ERM); Radioutrustning i frekvensområdet 402 till 405 MHz för aktiva medicinska implantat och tillbehör med ultralåg effekt; Del 2: Harmoniserad EN omfattande väsentliga krav enligt artikel 3.2 i R&TTE-direktivet.

Annex C (informative): Bibliography

CEPT/ERC/REC 70-03: "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.

History

Document history		
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