

Final draft **ETSI EN 301 839-2** V1.2.1 (2007-04)

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**



Reference

REN/ERM-TG30-002-2

Keywords

radio, regulation, SRD, testing

ETSI

650 Route des Lucioles
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
Sous-Préfecture de Grasse (06) N° 7803/88

Important notice

Individual copies of the present document can be downloaded from:

<http://www.etsi.org>

The present document may be made available in more than one electronic version or in print. In any case of existing or perceived difference in contents between such versions, the reference version is the Portable Document Format (PDF). In case of dispute, the reference shall be the printing on ETSI printers of the PDF version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at

<http://portal.etsi.org/tb/status/status.asp>

If you find errors in the present document, please send your comment to one of the following services:

http://portal.etsi.org/chaicor/ETSI_support.asp

Copyright Notification

No part may be reproduced except as authorized by written permission.
The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2007.
All rights reserved.

DECT™, **PLUGTESTS™** and **UMTS™** are Trade Marks of ETSI registered for the benefit of its Members.
TIPHON™ and the **TIPHON logo** are Trade Marks currently being registered by ETSI for the benefit of its Members.
3GPP™ is a Trade Mark of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.

Contents

Intellectual Property Rights	5
Foreword.....	5
1 Scope	6
2 References	6
3 Definitions and abbreviations.....	7
3.1 Definitions	7
3.2 Abbreviations	7
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	8
4.2.2 Frequency error.....	8
4.2.2.1 Definition	8
4.2.2.2 Limits	8
4.2.2.3 Conformance.....	8
4.2.3 Emission bandwidth.....	8
4.2.3.1 Definition	8
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 of transmitter.....	8
4.2.5.1 Definition	8
4.2.5.2 Limits	8
4.2.5.3 Conformance.....	9
4.2.6 Frequency stability under low voltage conditions	9
4.2.6.1 Definition	9
4.2.6.2 Limits	9
4.2.6.3 Conformance.....	9
4.2.7 Spurious radiation of receivers	9
4.2.7.1 Definition	9
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	10
4.2.8.2 LP/LDC spectrum access	10
4.2.8.2.1 Definition.....	10
4.2.8.2.2 Limits	10
4.2.8.3 Conformance.....	10
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.....	11
5.3.1 Frequency error.....	11
5.3.2 Emission bandwidth.....	11

5.3.3	Effective radiated power of the fundamental emission.....	11
5.3.4	Spurious emissions of transmitter.....	11
5.3.5	Frequency stability under low voltage conditions	11
5.3.6	Spurious radiation of receivers	11
5.3.7	Spectrum Access.....	12
5.3.7.1	LBT/AFA spectrum access	12
5.3.7.2	LP/LDC spectrum access	12
5.3.8	Normal and extreme test-conditions	12
5.3.9	Test power source	12
5.3.10	Choice of samples for test suites.....	12
Annex A (normative):	HS Requirements and conformance Test specifications Table (HS-RTT).....	13
Annex B (informative):	The EN title in the official languages	15
Annex C (informative):	Bibliography.....	17
History		18

Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: "*Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards*", which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (<http://webapp.etsi.org/IPR/home.asp>).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

Foreword

This 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 Vote 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].

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

The present document is part 2 of a multi-part deliverable covering 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, 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 the following radio equipment types:

- Ultra Low Power Active Medical Implants (ULP-AMI);
- and Peripherals (ULP-AMI-P).

These radio equipment types are capable of operating in all or any part of the frequency bands given below.

Table 1: Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) service frequency bands

	Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) service frequency bands
Transmit Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz
Receive Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P)	402 MHz to 405 MHz

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".

An AIMD is regulated under the AIMD Directive 90/385/EEC [2]: radio parts contained therein (referred to herein as ULP-AMI and ULP-AMI-P for peripheral devices) are regulated under the Directive 1999/5/EC [1].

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] may 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] 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 (V1.4.1): "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 interference to other equipment and services and should not receive harmful interference from other electronic devices. Transmitters and receivers may be individual or combination units.

4.2.1.2 Antennas

Equipment operating in the 402 MHz to 405 MHz band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, the manufacturer or provider shall make provision to prevent the use of an antenna other than that authorized by the manufacturer or provider.

4.2.1.3 Controls

Those controls that, if maladjusted, might increase the interference 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 of transmitter

4.2.5.1 Definition

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

4.2.5.2 Limits

The spurious emissions limits of transmitter 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 fulfil 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 fulfil 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 specified in EN 301 839-1 [3], clause 10 and applicable subsequent clauses.

4.2.8.2 LP/LDC spectrum access

4.2.8.2.1 Definition

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.

4.2.8.2.2 Limits

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.

4.2.8.3 Conformance

Conformance tests as defined in clause 5.3.7 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 [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

Parameter	Maximum Measurement Uncertainty
Radio Frequency	$\pm 1 \times 10^{-7}$
Adjacent channel power	± 3 dB
RF power, conducted	$\pm 0,75$ 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	$\pm 1^{\circ}\text{C}$
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 of transmitter

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 Spectrum Access

5.3.7.1 LBT/AFA spectrum access

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.

5.3.7.2 LP/LDC spectrum access

The tests for LP/LDC requirements specified in EN 301 839-1 [3], clauses 8.3.1 and 8.6.1 and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.8.2.

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): 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 301 839-2						
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	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	5.3.7

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	
Czech	Elektromagnetická kompatibilita a rádiové spektrum (ERM) - Zařízení krátkého dosahu (SRD) - Aktivní lékařské implantáty velmi nízkého výkonu (ULP-AMI) a periferní zařízení (ULP-AMI-P), pracující v kmitočtovém rozsahu 402 MHz až 405 MHz - Část 2: Harmonizovaná EN pokrývající základní požadavky článku 3.2 Směrnice R&TTE
Danish	Elektromagnetisk kompatibilitet og Radiospektrum Anliggender (ERM); Radioudstyr med kort rækkevidde (SRD); Aktive medicinske implantater med ultra lav sendeeffekt (ULP-AMI) og tilbehør (ULP-AMI-P), der benytter frekvensområdet 402 til 405 MHz - Del 2: Harmoniseret EN som dækker de væsentlige krav i R&TTE direktivets artikel 3.2
Dutch	
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	Elektromagnetilise ühilduvuse ja raadiospektri küsimused (ERM); Lähitoimeseadmed; Raadiosagedusalas 402 MHz kuni 405 MHz töötavad väga väikese võimsusega aktiivsed meditsiinilised implantaadid (ULP-AMI) ja nende lisatarvikud (ULP-AMI-P); Osa 2: Harmoneeritud EN R&TTE direktiivi artikli 3.2 põhinõuete alusel
Finnish	Sähkömagneettinen yhteensopivuus ja radiospektriasiat (ERM); Lyhyen kantaman laitteet (SRD); 402 - 405 MHz:n taajuusalueella toimivat erittäin pienitehoiset aktiiviset lääketieteelliset istutteen (ULP-AMI) ja niiden oheislaitteet (ULP-AMI-P); Osa 2: Yhdenmukaistettu standardi (EN), joka kattaa R&TTE-direktiivin artiklan 3.2 mukaiset olennaiset vaatimukset
French	Télécommunications - CEM et spectre radioélectrique (ERM) - Appareils à faible portée pour les implants et accessoires médicaux de puissance active ultra basse (ULP-AMI) et périphériques (ULP-AMI-P) opérant dans la bande de fréquence de 402 MHz à 405 MHz - Partie 2 : EN harmonisée sous couvert de l'article 3.2 de la Directive R&TTE
German	
Greek	Ηλεκτρομαγνητική Συμβατότητα και Θέματα Ραδιοφάσματος (ERM) - Συσκευές μικρής εμβέλειας (SRD) - Ενεργητικά ιατρικά εμφυτεύματα υπερχαμηλής ισχύος (ULP-AMI) και περιφερειακές διατάξεις (ULP-AMI-P) που λειτουργούν στην περιοχή συχνοτήτων από 402 MHz ως 405 MHz - Μέρος 2: Εναρμονισμένο EN για την κάλυψη των ουσιαστών απαιτήσεων του άρθρου 3.2 της Οδηγίας R&TTE
Hungarian	
Icelandic	
Italian	
Latvian	Elektromagnētiskā saderība un radiofrekvenču spektra jautājumi (ERM). Maza darbības attāluma ierīces (SRD). Ļoti zemas jaudas aktīvo medicīnisko implantu (ULP-AMI) un to perifērisko ierīču (ULP-AMI-P) radioiekārtas, kas darbojas frekvenču joslā 402 MHz līdz 405 MHz. 2.daļa: Harmonizēts Eiropas standarts (EN), kas atbilst R&TTE Direktīvas 3.2.punkta būtiskām prasībām
Lithuanian	
Maltese	
Norwegian	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
Polish	Kompatybilność elektromagnetyczna i zagadnienia widma radiowego (ERM) - Urządzenia bliskiego zasięgu (SRD) - Aktywne implanty medyczne ultra niskiego poziomu mocy (ULP-AMI) i ich urządzenia peryferyjne (ULP-AMI-P) pracujące w zakresie częstotliwości od 402 MHz do 405 MHz - Część 2: Zharmonizowana EN zapewniająca spełnienie zasadniczych wymagań zgodnie z artykułem 3.2 dyrektywy R&TTE
Romanian	
Portuguese	Assuntos de Espectro Radioeléctrico e Compatibilidade Electromagnética (ERM); Equipamentos de Curto Alcance (SRD); Implantes Médicos Activos de Ultra Baixa Potência (ULM-AMI) e Periféricos (ULP-AMI-P) operando na faixa de frequências de 402 MHz a 405 MHz; Parte 2: EN Harmonizada cobrindo os requisitos essenciais no âmbito do artigo 3.º, n.º 2, da Directiva R&TTE
Slovak	Elektromagnetická kompatibilita a závislosti rádiového spektra (ERM). Zariadenia s krátkym dosahom (SRD). Aktívne zdravotnícke implantáty s ultranízkym výkonom (ULP-AMI) a súvisiace periférne zariadenia (ULP-AMI-P) pracujúce vo frekvenčnom rozsahu od 402 MHz do 405 MHz. Časť 2: Harmonizovaná EN vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice R&TTE

Language	EN title
Slovenian	Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) – Naprave kratkega dosega (SRD) – Aktivni medicinski vsadki ultra majhnih moči (ULP-AMI) in pripadajoče periferne naprave (ULP-AMI-P), ki delujejo v frekvenčnem območju od 402 MHz do 405 MHz – 2. del: Harmonizirani EN, ki zajema bistvene zahteve člena 3.2 direktive R&TTE
Spanish	Cuestiones de compatibilidad electromagnética y espectro de radiofrecuencia (ERM); Dispositivos de Corto Alcance (SRD); Equipos radioeléctricos en la gama de frecuencias de 402 MHz a 405 MHz para Implantes Médicos Activos de Membrana de Potencia Ultra Baja (ULP-AMI) y Periféricos (ULP-AMI-P); Parte 2: Norma Europea (EN) armonizada cubriendo los requisitos esenciales según el artículo 3.2 de la Directiva R&TTE
Swedish	Elektromagnetisk kompatibilitet och radiospektrumfrågor (ERM); Kortdistansutrustning (SRD); Aktiva medicinska implantat med extrem låg effekt (ULP-AMI) och kringutrustning (ULP-AMI-P) arbetande i frekvensområdet 402 MHz till 405 MHz; 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		
V1.1.1	June 2002	Publication
V1.2.1	May 2006	Public Enquiry PE 20060929: 2006-05-31 to 2006-09-29
V1.2.1	April 2007	Vote V 20070629: 2007-04-30 to 2007-06-29