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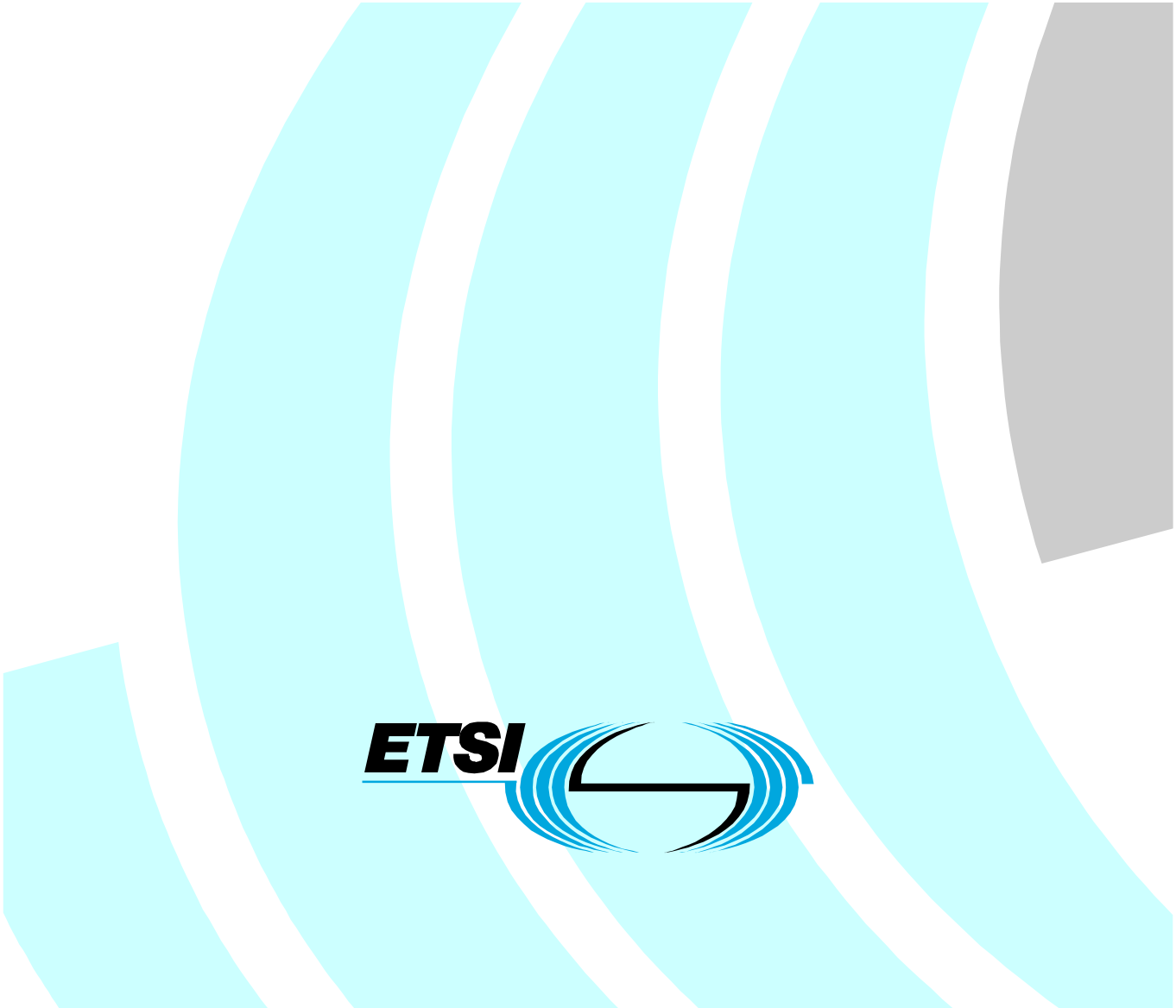
Candidate Harmonized European Standard (Telecommunications series)

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 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 [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.

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

Introduction

The present document is part of a set of standards designed to fit in a modular structure to cover all radio and telecommunications terminal equipment under the R&TTE Directive [1]. Each standard is a module in the structure. The modular structure is shown in figure 1.

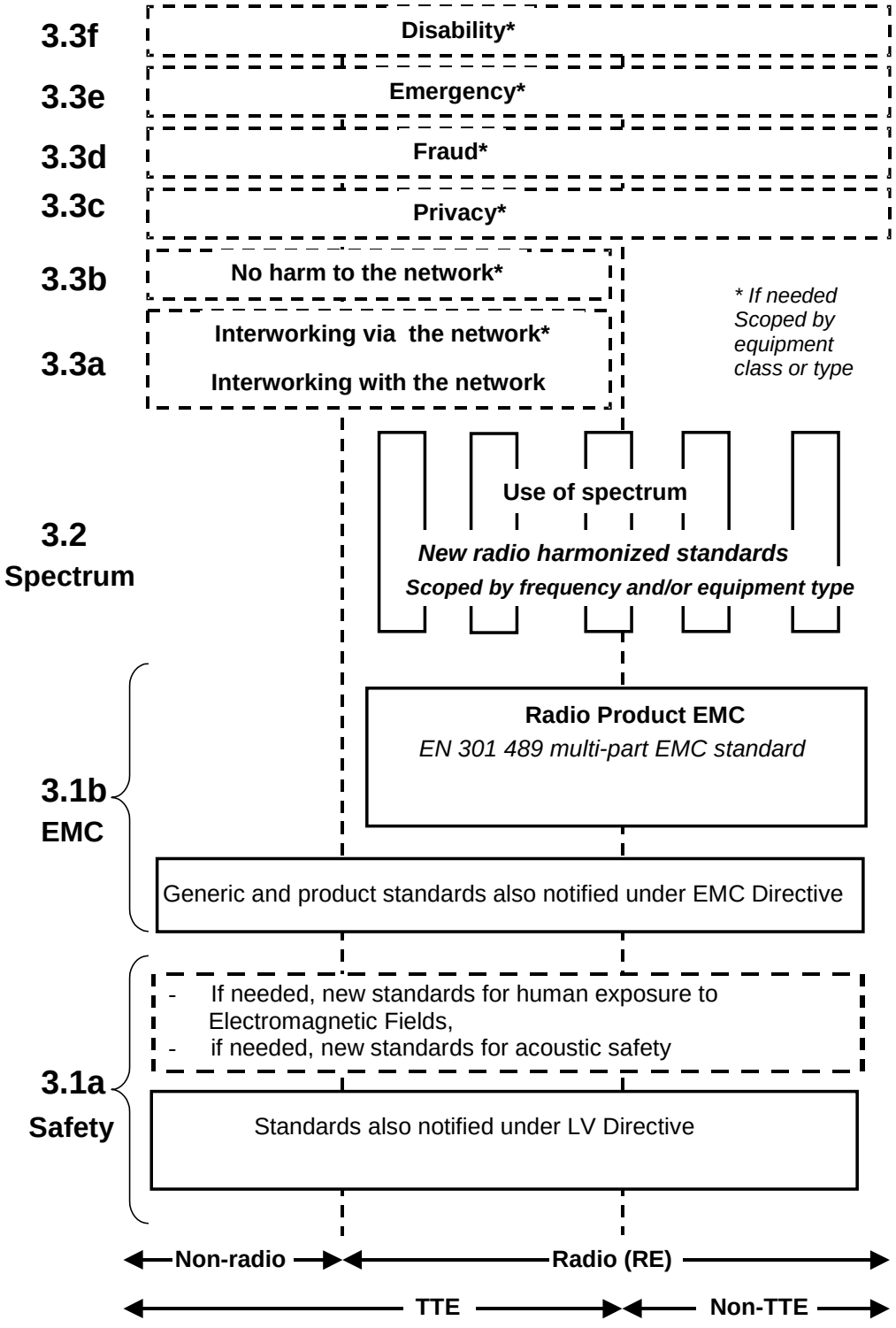

Figure 1: Modular structure for the various standards used under the R&TTE Directive [1]

The left hand edge of the figure 1 shows the different clauses of Article 3 of the R&TTE Directive [1].

For article 3.3 various horizontal boxes are shown. Dotted lines indicate that at the time of publication of the present document essential requirements in these areas have to be adopted by the Commission. If such essential requirements are adopted, and as far and as long as they are applicable, they will justify individual standards whose scope is likely to be specified by function or interface type.

The vertical boxes show the standards under article 3.2 for the use of the radio spectrum by radio equipment. The scopes of these standards are specified either by frequency (normally in the case where frequency bands are harmonized) or by radio equipment type.

For article 3.1b the diagram shows EN 301 489 (see bibliography), the multi-part product EMC standard for radio used under the EMC Directive [5].

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive (see bibliography) and new standards covering human exposure to electromagnetic fields. New standards covering acoustic safety may also be required.

The bottom of the figure shows the relationship of the standards to radio equipment and telecommunications terminal equipment. A particular equipment may be radio equipment, telecommunications terminal equipment or both. A radio spectrum standard will apply if it is radio equipment. An article 3.3 standard will apply as well only if the relevant essential requirement under the R&TTE Directive is adopted by the Commission and if the equipment in question is covered by the scope of the corresponding standard. Thus, depending on the nature of the equipment, the essential requirements under the R&TTE Directive may be covered in a set of standards.

The modularity principle has been taken because:

- it minimizes the number of standards needed. Because equipment may, in fact, have multiple interfaces and functions it is not practicable to produce a single standard for each possible combination of functions that may occur in an equipment;
- it provides scope for standards to be added:
  - under article 3.2 when new frequency bands are agreed; or
  - under article 3.3 should the Commission take the necessary decisions

  without requiring alteration of standards that are already published;
- it clarifies, simplifies and promotes the usage of Harmonized Standards as the relevant means of conformity assessment.

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.

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.

[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 Implants and Accessories; Membrane Implants; 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".

[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 Effective radiated power of the fundamental

4.2.2.1 Definition

The 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 Spurious emissions

4.2.4.1 Definition

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

4.2.4.2 Limits

The spurious emissions 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

The maximum duty cycle, as defined in EN 302 510-1 [2], clause 7.5.1, shall not exceed the limits in EN 302 510-1 [2], clause 7.5.3.

This requirement applies to all transmitters.

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 7.

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}
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 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 Spurious emissions

The test for effective radiated power of spurious emissions 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): 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 302 510-2 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	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	Spurious emissions (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 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 (normative): The EN title in the official languages

Language	EN title
Czech	
Danish	
Dutch	
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	
Finnish	
French	
German	
Greek	
Hungarian	
Icelandic	
Italian	
Latvian	
Lithuanian	
Maltese	
Norwegian	
Polish	
Portuguese	
Slovak	
Slovenian	
Spanish	
Swedish	

Annex C (informative): Bibliography

CEPT/ERC/Recommendation 70-03 (1997): "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

Document history			
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