SLOVENSKI STANDARD
SIST EN 301 839-2 V1.1.1:2003

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Elektromagnetna združljivost (EMC) in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenļnem obmoļju od 402 MHz do 405 MHz za aktivne medicinske implantate ultra majhnih moļi in pribor - 2. del: Harmonizirani evropski standard (EN), ki zajema bistvene zahteve ļlena 3.2 direktive o radijski in telekomunikacijski terminalski opremi (R&TTE)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

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Candidate Harmonized European Standard (Telecommunications series)

Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical 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).

The present document has been produced by ETSI in response to a mandate from the European Commission issued under Council Directive 98/34/EC [7] (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 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") [1].

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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 Accessories, as identified below:

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Part 1: "Technical characteristics, including electromagnetic compatibility requirements, 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:	7 June 2002
Date of latest announcement of this EN (doa):	30 September 2002
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2003
Date of withdrawal of any conflicting National Standard (dow):	31 March 2004

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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.

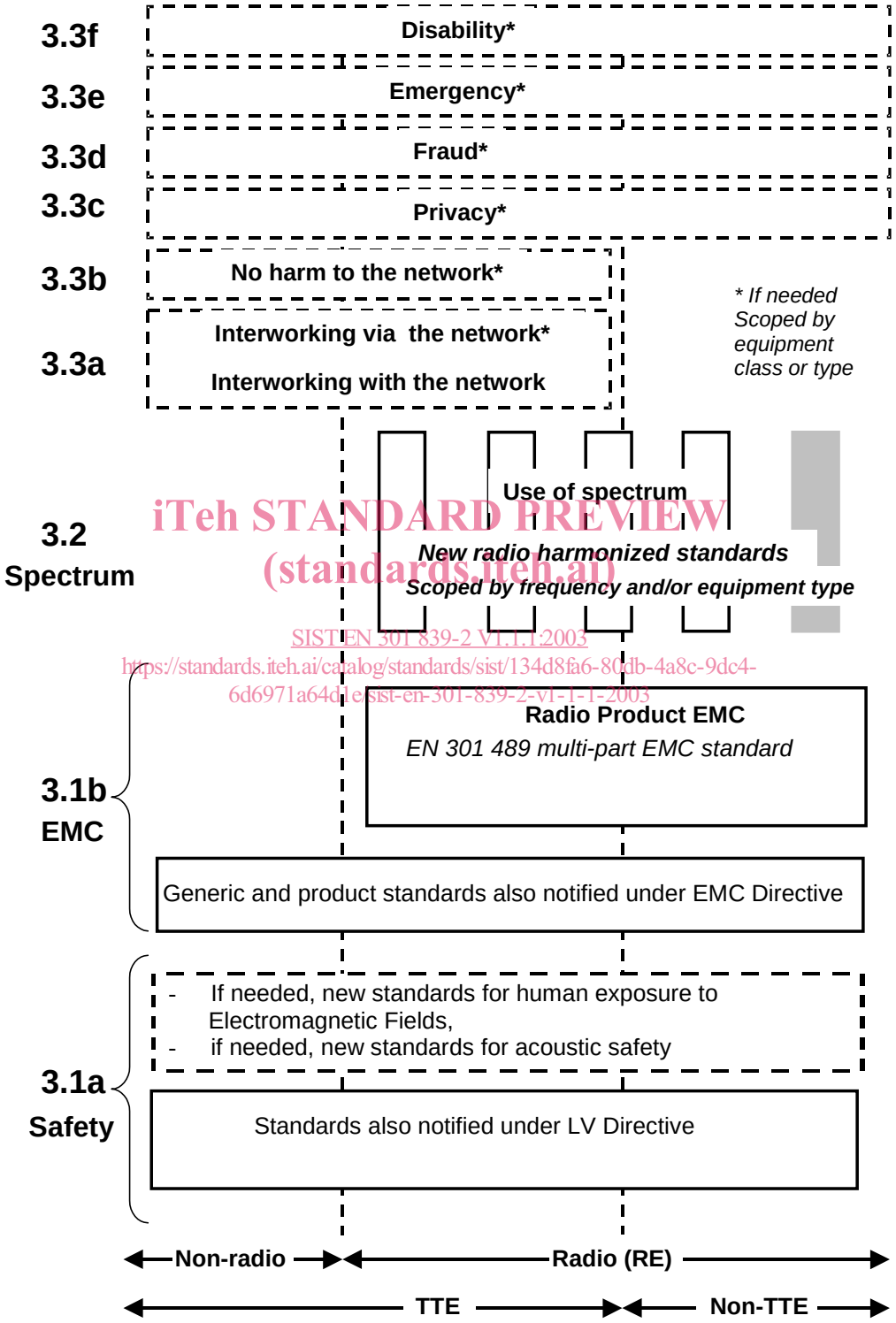

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Figure 1: Modular structure for the various standards used under the R&TTE Directive

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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, the multi-part product EMC standard for radio used under the EMC Directive [2].

For article 3.1a the diagram shows the existing safety standards currently used under the LV Directive [3] 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 [1] 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 [1] 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.

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1 Scope

The present document applies to Ultra Low Power-Active Medical Implants (ULP-AMI) and accessories as described in Directive 90/385/EEC [4], operating in a Medical Implant Communications System (MICS) in the frequency band 402 MHz to 405 MHz.

NOTE 1: The present document applies to operation in the band 402 MHz to 405 MHz only; devices that can also operate in spectrum outside this band should also meet any applicable requirements for operation in such bands.

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 2: 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.

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- 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.

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[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 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (EMC Directive).

[3] 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).

[4] 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.

[5] ETSI EN 301 839-1 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 402 MHz to 405 MHz for Ultra Low Power Active Medical Implants and Accessories; Part 1: Technical characteristics, including electromagnetic compatibility requirements, and test methods".

[6] ETSI ETR 028 (Edition 2): "Radio Equipment and Systems (RES); Uncertainties in the measurement of mobile radio equipment characteristics".

[7] 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.

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3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in the R&TTE Directive [1], and the following apply:

active medical implant: diagnostic or therapeutic device designed to be implanted in a human body containing a power source and a transceiver using the 402 MHz to 405 MHz frequency band for the purpose of providing a two way digital communications link

environmental profile: range of environmental conditions under which equipment within the scope of EN 301 839-2 is required to comply with the provisions of EN 301 839-2

Medical Implant Communications System (MICS): system specifically for the purpose of providing two way non-voice digital communications between an external programmer/control transceiver and an active medical implant transceiver or between active medical implant transceivers placed in a human body

medical implant device: apparatus that includes a transmitter with an integral receiver that operates in the ULP-AMI band from 402 MHz to 405 MHz that is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

Ultra Low Power Active Medical Implant (ULP-AMI): active medical implant transmitter or medical implant programmer/control transmitter that is designed to radiate RF energy in accordance with the provisions of annex 12 to CEPT/ERC/REC 70-03 and EN 301 839-2

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3.2 Abbreviations

For the purposes of the present document, the following abbreviations apply:

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AMI	Active Medical Implant
EMC	Electro-Magnetic Compatibility
EUT	Equipment Under Test
LV	Low Voltage
MICS	Medical Implant Communications System
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
SRD	Short Range Device
TTE	Telecommunications Terminal Equipment
ULP-AMI	Ultra Low Power Active Medical Implant