SLOVENSKI STANDARD
SIST EN 302 510-2 V1.1.1:2007

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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Radijska oprema v frekvenļnem območju od 30 MHz do 37,5 MHz za aktivne membranske medicinske vsadke ultra majhnih moļi in pribor - 2. del: Harmonizirani EN, ki zajema bistvene zahteve ļlena 3.2 direktive R&TTE

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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33.060.20	Sprejemna in oddajna oprema	Receiving and transmitting equipment
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

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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.