SLOVENSKI STANDARD
SIST EN 301 839-2 V1.3.1:2009

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Elektromagnetna združljivost in zadeve v zvezi z radijskim spektrom (ERM) - Naprave kratkega dosega (SRD) - Aktivni medicinski vsadki ultra majhnih moļi (ULP-AMI) in pripadajoļe periferne naprave (ULP-AMI-P), ki delujejo v frekvenļnem območju od 402 MHz do 405 MHz - 2. del: Harmonizirani EN, ki zajema bistvene zahteve ļ lena 3.2 direktive R&TTE

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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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); 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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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 (as amended) [i.3] 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 [i.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") [i.1].

Technical specifications relevant to Directive 1999/5/EC [i.1] 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".

National transposition dates	
Date of adoption of this EN:	28 September 2009
Date of latest announcement of this EN (doa):	31 December 2009
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 June 2010
Date of withdrawal of any conflicting National Standard (dow):	30 June 2011

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 in table 1.

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 [i.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 [i.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 [i.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 [i.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

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.
- Non-specific reference may be made only to a complete document or a part thereof and only in the following cases:
  - if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of the referring document;
  - for informative references.

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2.1 Normative references

The following referenced documents are indispensable for the application of the present document. For dated references, only the edition cited applies. For non-specific references, the latest edition of the referenced document (including any amendments) applies.

[1] ETSI EN 301 839-1 (V1.3.1): "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".

[2] ETSI TR 100 028 (all parts) (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

2.2 Informative references

The following referenced documents are not essential to the use of the present document but they assist the user with regard to a particular subject area. For non-specific references, the latest version of the referenced document (including any amendments) applies.

[i.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).

[i.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.

[i.3] 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 [1] apply.

3.2 Abbreviations

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