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Elektromagnetna združljivost (EMC) in zadeve v zvezi z radijskim spektrom (ERM) - Standard elektromagnetne združljivosti (EMC) za radijsko opremo in storitve - 27. del: Posebni pogoji za aktivne medicinske vsadke ultra majhnih moči (ULP-AMI) in pripadajoče periferne naprave (ULP-AMI-P)

Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

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Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 27: Specific conditions for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

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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 the Council Directive 98/34/EC [4] (as amended) laying down a procedure for the provision of information in the field of technical standards and regulation.

The present document, together with EN 301 489-1 [1], 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") (89/336/EEC [3] as amended), and 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" [2]).

The present document is part 27 of a multi-part deliverable. Full details of the entire series can be found in part 1 [1].

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1 Scope

The present document together with EN 301 489-1 [1], covers the assessment of all radio transceivers associated with Ultra Low Power Active Medical Implants (ULP-AMIs) and associated Peripheral ULP-AMI-Ps) in respect of ElectroMagnetic Compatibility (EMC).

The present document covers the EMC requirements for the radio functions of ULP-AMI and ULP-AMI-P devices.

Technical specifications related to the antenna port and emissions from the enclosure port of the ULP-AMI and ULP-AMI-P devices radio system are not included in the present document. Such technical specifications are found in the relevant product standards for the effective use of the radio spectrum.

The present document specifies the applicable test conditions, performance assessment, and performance criteria for ULP-AMIs and associated Peripheral devices (ULP-AMI-Ps).

Definitions of types of ULP-AMIs and ULP-AMI-Ps covered by present document are given in annex A.

In case of differences (for instance concerning special conditions, definitions, abbreviations) between the present document and EN 301 489-1 [1], the provisions of the present document take precedence.

The environmental classification and the emission and immunity requirements used in the present document are as stated in the EN 301 489-1 [1], except for any special conditions included in the present document.

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] ETSI EN 301 489-1 (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements".

[2] 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).

[3] 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).

[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] 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 EN 301 839-2 (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 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[7] EN 60601-1-2: "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests".

[8] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[9] EN 61000-4-5: "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

3 Definitions and abbreviations

3.1 Definitions

For the purposes of the present document, the terms and definitions given in EN 301 489-1 [1] and the following apply:

Ultra Low Power Active Medical Implant (ULP-AMI): transmitter or receiver or transceiver forming part of an active medical implant, that is used in a medical implant communications system radio link set up by the peripheral device (ULP-AMI-P)

Ultra Low Power Active Medical Implant Peripheral device (ULP-AMI-P): radio part of equipment outside the human body, including body worn devices, used to program and/or control an ULP-AMI by means of a Medical Implant (radio) Communications Link (MICL), such as an external programmer or control transceiver

environmental profile: range of environmental conditions under which equipment within the scope of EN 301 489-27 is required to comply with the provisions of EN 301 489-27

life supporting equipment: equipment whose continued normal operation is required in order to sustain life

Medical Implant Communications Link (MICL): collections of transmission that may or may not be continuous, between co-operating medical implant devices and accessories, including programmer/controllers, transferring patient related information in communications service

Medical Implant Communications System (MICS): specific system providing radiocommunications between an ULP-AMI and an associated ULP-AMI-P

Active Medical Implant (AMI): 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

3.2 Abbreviations

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

AC	Alternating Current
AIMD	Active Implantable Medical Device
AMI	Active Medical Implant
DC	Direct Current
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
MICL	Medical Implant Communications Link
MICS	Medical Implant Communications System
R&TTE	Radio and Telecommunications Terminal Equipment
RF	Radio Frequency
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral device

4 Test conditions

For the purposes of the present document, the test conditions of the EN 301 489-1 [1], clause 4, shall apply as appropriate. Further product related test conditions for ULP-AMI and associated ULP-AMI-P are specified in the present document.

4.1 General

For emission and immunity tests the normal test modulation, test arrangements, etc., as specified in the present document, clauses 4.1 to 4.5 shall apply.

Whenever the Equipment Under Test (EUT) is provided with a detachable antenna, the EUT shall be tested with the antenna fitted in a manner typical of normal intended use, unless otherwise specified. If the EUT can be used with several types of antenna the test shall be repeated for each type of antenna.

ULP-AMI devices (active medical implants) are designed to be implanted within a human body. These radio systems are isolated from disturbances by the surrounding body tissue. In order to adequately assess the EMC characteristics of active medical implants devices , the use of a simulated man is necessary. See annex B for additional details. The provisions of annex B are intended to provide an operational environment that simulates, to the extent possible, actual usage conditions for internal implanted devices. It is necessary to use this or another appropriate special fixture when making emission measurements and immunity tests with radiated RF fields.

4.2 Arrangements for test signals

The provisions of the EN 301 489-1 [1], clause 4.2 shall apply.

4.2.1 Arrangements for test signals at the input of the transmitter

The provisions of the EN 301 489-1 [1], clause 4.2.1 shall apply with the following modifications:

The transmitter shall be modulated with normal test modulation as specified for that type of equipment (see clause 4.5). Where transmitters do not have a modulation input port, the internal equipment modulation shall be used.

4.2.2 Arrangements for test signals at the output of the transmitter

The provisions of the EN 301 489-1 [1], clause 4.2.2 shall apply with the following modification:

The manufacturer may provide a suitable companion receiver or another device that can be used to set up a communications link and/or to receive messages.

4.2.2.1 ULP-AMI transmitters

For ULP-AMI transmitters the test fixture described in annex B shall be used.

The manufacturer shall provide a suitable receiver that can be used to monitor the medical implant communications link.

4.2.2.2 ULP-AMI-P transmitters

The provisions of EN 301 489-1 [1], clause 4.2.2 shall apply with the following modifications:

- ULP-AMI-P devices are designed to be used externally to a human body;
- the manufacturer shall provide a suitable receiver that can be used to monitor the medical implant communications link.

4.2.3 Arrangements for test signals at the input of the receiver

The provisions of EN 301 489-1 [1], clause 4.2.3 shall apply with the following modifications:

- the wanted RF input signal, coupled to the receiver, shall be modulated with normal test modulation as specified for that type of equipment (clause 4.5);
- the level of the wanted RF input signal shall be 20 dB above the threshold sensitivity level of the receiver, but in all cases it shall be below the overload characteristics of the receiver;
- the manufacturer shall provide a suitable transmitter that can be used to set up the medical implant communications link.

4.2.4 Arrangements for test signals at the output of the receiver

The provisions of EN 301 489-1 [1], clause 4.2.4 shall apply with the following modification, if appropriate:

- if direct access to the receiver output of the ULP-AMI and associated ULP-AMI-P is not possible, then the manufacturer shall provide the method by which the receiver's functionality can be monitored during the immunity tests.

4.2.5 Arrangements for testing transmitter and receiver together (as a system: ULP-AMI together with an associated ULP-AMI-P)

The provisions of EN 301 489-1 [1], clause 4.2.5 shall apply with the following modification:

- the transmitter of an ULP-AMI and the receiver of an associated ULP-AMI-P or the receiver of an ULP-AMI and the transmitter of an associated ULP-AMI-P may be tested together, if appropriate and agreed by the manufacturer and the test laboratory (size of devices etc.).

In this case both EUTs shall be located in their respective test environment and exposed simultaneously to the EMC phenomena.

4.3 Exclusion bands

The emission measurement and immunity test exclusions are referred to as "exclusion bands" and are defined in the clauses 4.3.1 and 4.3.2 of the present document.

The frequencies on which the EUT is intended to operate, shall be excluded from conducted and radiated RF immunity tests.

The frequencies on which the transmitter part of the EUT is intended to operate shall be excluded from emission measurements when performed in transmit mode of operation.

During emission measurements, a frequency exclusion band does not apply for the receiver part of ULP-AMIs and/or associated ULP-AMI-Ps.

4.3.1 Exclusion bands for receivers

The exclusion band for receivers (including receivers that are part of transceivers) is determined as follows:

- for receivers capable of operating on 9 or more channels within the frequency band specified in table 1 and not having an alignment range, the lower frequency of the exclusion band is the lower frequency of the used frequency channel minus the extension value given in table 1, and the upper frequency of the exclusion band is the upper frequency of the used frequency channel plus the extension value given in table 1. The calculated extension value shall be based on the operating frequency;