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STN	**Elektromagnetická kompatibilita (EMC), norma na rádiové zariadenia a služby Časť 27: Osobitné podmienky na aktívne zdravotnícke implantáty s ultranízkym výkonom (ULP-AMI) a súvisiace periférne zariadenia (ULP-AMI-P) Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.1(b) smernice 2014/53/EÚ**	**STN EN 301 489-27 V2.1.1** 87 1489

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); Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/18

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.4] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.1].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

The present document is part 27 of a multi-part deliverable. Full details of the entire series can be found in ETSI EN 301 489-1 [1].

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Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2017
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Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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1 Scope

The present document together with ETSI 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 B.

In case of differences (for instance concerning special conditions, definitions, abbreviations) between the present document and ETSI 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 ETSI EN 301 489-1 [1], except for any special conditions included in the present document.

The present document, together with ETSI EN 301 489-1 [1], contains requirements to demonstrate an adequate level of electromagnetic compatibility as set out in Directive 2014/53/EU [i.1].

2 References

2.1 Normative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at https://docbox.etsi.org/Reference/.

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The following referenced documents are necessary for the application of the present document.

[1] ETSI EN 301 489-1 (V2.1.1) (11-2016): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU".

NOTE: Available at http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.01.01_30/en_30148901v020101v.pdf.

[2] ETSI EN 301 839 (V2.1.1) (04-2016): "Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".

[3] IEC EN 60601-1-2 (2007): "Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests".

[4] IEC EN 61000-4-5 (2006): "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

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The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Directive 2014/53/EU of the European Parliament and of the council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

[i.2] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.3] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", Physics Department, King's College, London WC2R 2LS, UK. February 1996.

NOTE: Available at http://www.dtic.mil/dtic/tr/fulltext/u2/a305826.pdf.

[i.4] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.5] Italian National Research Council, Institute for Applied Physics.

NOTE: Available at http://niremf.ifac.cnr.it/.