ICS 33.100.10 SLOVENSKÁ TECHNICKÁ NORMA November 2019

STN	**Elektromagnetická kompatibilita (EMC), norma na rádiové zariadenia a služby Časť 29: Osobitné podmienky na zariadenia zdravotníckej dátovej služby (MEDS) pracujúce v pásmach od 401 MHz do 402 MHz a od 405 MHz do 406 MHz Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.1(b) smernice 2014/53/EÚ**	**STN EN 301 489-29 V2.2.1** 87 1489

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services
Part 29: Specific conditions for Medical Data Service Devices (MEDS) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands
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. 10/19.

Obsahuje: EN 301 489-29 V2.2.1:2019

129298

ETSI EN 301 489-29 V2.2.1 (2019-04)

ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 29: Specific conditions for Medical Data Service Devices (MEDS) operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

Reference
REN/ERM-EMC-375

Keywords
EMC, harmonised standard, radio, regulation, short range

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Sous-Préfecture de Grasse (06) N° 7803/88

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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.7] 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 29 of a multi-part deliverable. Full details of the entire series can be found in part 1 [1].

National transposition dates	
Date of adoption of this EN:	20 June 2017
Date of latest announcement of this EN (doa):	31 July 2019
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 January 2020
Date of withdrawal of any conflicting National Standard (dow):	31 January 2021

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), Ultra Low Power Active Medical Devices (ULP-AMDs), Ultra Low Power Body Worn Devices (ULP-BWDs) and associated Ultra Low Power Active Medical Implant Peripherals (ULP-AMI-Ps), Ultra Low Power Active Medical Device Peripherals (ULP-AMD-Ps) in respect of ElectroMagnetic Compatibility (EMC).

The radio link may be part of life supporting or non-life supporting equipment and can be classified independently of the classification of the medical portion of the device.

The present document covers the EMC requirements for the radio functions of ultra low power implanted, body worn and associated ultra low power peripheral devices.

Technical specifications related to the antenna port and emissions from the enclosure port of these radio system devices 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 applies to ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P devices with RF power levels ranging up to 25 µW ERP and intended for operation in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz in accordance with the provisions of annex 12, band b) and band c), to CEPT/ERC/REC 70-03 [i.3]. Definitions of such ULP-AMI, ULP-AMD, ULP-BWD, ULP-AMD-P and ULP-AMI-P radio devices are found in the following functional radio standard:

- ETSI EN 302 537 [2]: "Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU [i.1]".

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 the 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], are aimed to cover requirements to demonstrate an adequate level of electromagnetic compatibility.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version 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 (V2.2.0) (03-2017): "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_301499/30148901/02.02.00_20/.

[2] ETSI EN 302 537 (V2.1.1) (10-2016): "Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".

[3] CENELEC 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] Void.

[i.3] CEPT/ERC/Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[i.5] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", (Physics Department, Kings College, London WC2R 2LS, UK).

[i.6] ETSI EN 301 489 (all parts): "Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services".

[i.7] 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.