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STN	**Zariadenia s krátkym dosahom (SRD). Aktívne zdravotnícke implantáty s ultranízkym výkonom (ULP-AMI) a príslušenstvo (ULP-AMI-P), pracujúce vo frekvenčnom rozsahu od 9 kHz do 315 kHz. Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.2 smernice 2014/53/EÚ.**	**STN EN 302 195 V2.1.1** 87 2195

Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz Harmonised Standard covering the essential requirements of article 3.2 of the 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. 02/17

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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.6] 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.2].

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.

National transposition dates	
Date of adoption of this EN:	14 June 2016
Date of latest announcement of this EN (doa):	30 September 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	31 March 2017
Date of withdrawal of any conflicting National Standard (dow):	31 March 2018

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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

Introduction

The present document covers Ultra Low Power Active Medical Implant (ULP-AMI) and any associated non-implantable Peripherals (ULP-AMI-P) equipment incorporating low frequency technology, which is designed to operate in the frequency range of 9 kHz to 315 kHz for the purpose of providing a digital communication link.

The present document includes methods of measurement for ULP-AMI and ULP-AMI-P incorporating attachable/detachable antenna connector(s) and/or integral antenna(s). Equipment designed for use with an integral antenna may use a temporary or permanent internal connector for the purpose of testing, provided the characteristics being measured are representative of the final product placed on the market.

If equipment already placed on the market is required to be inspected it should be tested in accordance with the methods of measurement specified in the present document.

Clauses 1 through 3 provide a general description on the types of equipment covered by the present document and the definitions, symbols and abbreviations used.

Clause 4 provides the technical requirements specifications, limits and conformance relative to transmitter and receiver function.

Clauses 5.1 and 5.2 specify the conditions for testing of the equipment and interpretation of the measurement results with the maximum measurement uncertainty values.

Clause 5.3 specifies the required measurement methods.

Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU [i.2].

Annex B (normative) provides specifications concerning radiated measurements.

Annex C (normative) provides procedures for H-field measurements at other distances than 10 m.

Annex D (informative) bibliography; provides additional information.

1 Scope

The present document applies to ULP-AMI equipment operating in the frequency range from 9 kHz to 315 kHz and any associated Peripherals (ULP-AMI-P) transmitters and receivers operating in the frequency range of 9 kHz to 315 kHz including external programmers and patient related telecommunication devices using digital modulation techniques such as, but not limited to, FSK or pulse position modulation. Analogue voice modulation is not within the scope of the present document.

The present document applies to ULP-AMI/ULP/AMI-P transmitters and receivers:

- transmitters operating in range from 9 kHz to 315 kHz with power levels ranging up to 30 dBuA/m at 10m;
- receivers operating in the range from 9 kHz to 315 kHz.

The present document applies to ULP-AMI devices:

- either with a Radio Frequency (RF) output connection and dedicated antenna, or with an integral antenna;
- for telecommand, telemetry etc. applications;
- for all types of digital modulation.

The present document covers ULP-AMI-P fixed stations (physician programmer/controllers), mobile stations (patient programmers, handheld or otherwise) and portable stations (implanted devices providing medical benefit to the implanted patient).

The present document contains the technical requirements for characteristics of ULP-AMI/ULP-AMI-P radio equipment which are aligned with annex 12 Sub-band (a) of CEPT/ERC Recommendation 70-03 [i.1].

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 9 kHz to 315 kHz *"shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference"* (article 3.2 of the Directive 2014/53/EU) [i.2]. It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

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 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.

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

Not applicable.

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.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

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

[i.2] 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.3] 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".

[i.4] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.5] Air Force Technical Report AL/OE-TR-1996-0037: "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies", Camelia Gabriel.

[i.6] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardization request to the European Committee for Electrotechnical Standardization 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.