ETSI EN 301 489-35 V2.1.1 (2016-12)

**ElectroMagnetic Compatibility (EMC)
standard for radio equipment and services;
Part 35: Specific requirements for
Low Power Active Medical Implants (LP-AMI)
operating in the 2 483,5 MHz to 2 500 MHz bands;
Harmonised Standard covering the essential requirements
of article 3.1(b) of Directive 2014/53/EU**

Reference
REN/ERM-EMC-338

Keywords
EMC, harmonised standard, health, radio, regulation

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Contents

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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.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 35 of a multi-part deliverable. Full details of the entire series can be found in ETSI EN 301 489-1 [1].

National transposition dates	
Date of adoption of this EN:	12 December 2016
Date of latest announcement of this EN (doa):	31 March 2017
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2017
Date of withdrawal of any conflicting National Standard (dow):	30 September 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).

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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 Low Power Active Medical Implants (LP-AMIs) and associated Peripheral devices (LP-AMI-P) in respect of ElectroMagnetic Compatibility (EMC).

The present document covers the EMC requirements for the radio functions of LP-AMI and associated Peripheral devices (LP-AMI-P).

Technical specifications related to the antenna port and emissions from the enclosure port of the radio system of LP-AMI and associated Peripheral devices (LP-AMI-P) 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 of LP-AMI and associated Peripheral devices (LP-AMI-P).

Definitions of types of LP-AMIs and P-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 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], 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/.

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.

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

[3] ETSI EN 301 559 (V2.1.1) (10-2016): "Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) and associated Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".