TECHNICAL SPECIFICATION

FOR

MEDICAL APPLICATIONS

ISSUED BY

BOTSWANA COMMUNICATIONS REGULATORY AUTHORITY

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Technical Specification for Medical Applications

Contents

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Scope

This specification applies to any equipment for medical applications.

Where terminal equipment supports more than one interface type, each interface must meet the requirements applicable to it. It may therefore be necessary to make reference to additional specifications.

Entry into Force

This specification shall enter into force on 15/01/2016.

Document History

Description	Status	Date
Medical Applications	Original V1	11/12/2015

Health, Safety, and Generic Emissions

The following universal specifications shall be applied.

TS0001: Health, Safety and Generic Emissions of Radio and Telecommunications Terminal Equipment.

Technical Requirements

The following specifications shall be applied.

ETSI EN 301 489-27 V1.1.1
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)

ETSI EN 301 489-29 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); 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

ETSI EN 301 489-31 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 31: Specific conditions for equipment in the 9 kHz to 315 kHz band for Ultra Low Power Active Medical Implants (ULP-AMI) and related peripheral devices (ULP-AMI-P)

ETSI EN 301 489-35 V1.1.2
Electromagnetic compatibility and Radio spectrum Matters (ERM); 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

ETSI EN 301 559-1 V1.1.2
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part 1: Technical characteristics and test methods

ETSI EN 301 559-2 V1.1.2
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Part

2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

ETSI EN 301 839-1 V1.3.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP-AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 1: Technical characteristics and test methods

ETSI EN 301 839-2 V1.3.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Active Medical Implants (ULP-AMI) and Peripherals (ULP- AMI-P) operating in the frequency range 402 MHz to 405 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

ETSI EN 302 195-1 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 1: Technical characteristics and test methods

ETSI EN 302 195-2 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP- AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

ETSI EN 302 510-1 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 1: Technical characteristics and test methods

ETSI EN 302 510-2 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 30 MHz to 37,5 MHz for Ultra Low Power Active Medical Membrane Implants and Accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

ETSI EN 302 537-1 V1.1.2
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 1: Technical characteristics and test methods

ETSI EN 302 537-2 V1.1.2
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Ultra Low Power Medical Data Service Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive

ETSI EN 303 203-2 V1.1.1
Electromagnetic compatibility and Radio spectrum Matters (ERM); Short Range Devices (SRD); Medical Body Area Network Systems (MBANSs) operating in the 2 483,5 MHz to 2 500 MHz range; Part 2: Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

Important Note: The revision numbers of the documents given in the approval standard are the minimum standards that apply. Should updated versions of these documents be published, the latest version will always apply. This also applies to documents where no revision number is currently quoted.

Obtaining Technical Standards

ETSI technical standards may be obtained free of charge for individual use from the ETSI web site. www.etsi.org

CENELEC, IEC and CISPR standards may be obtained at cost from, or through www.cenelec.org and from www.iec.ch respectively.