TDRA | هيئة تنظيم الاتصالات والحكومة الرقمية
TELECOMMUNICATIONS AND DIGITAL GOVERNMENT REGULATORY AUTHORITY

United Arab Emirates

TECHNICAL SPECIFICATION

Requirements for Medical Devices

TS RE 038, Version 1.0

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Telecommunications Regulatory Authority (TDRA)
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1 General requirements

Technical specification has been prepared and approved by the Telecommunications Regulatory Authority (TDRA) based on the Telecommunication apparatus Type Approval Regime.

Several technical specifications may apply to the equipment. If equipment within the scope of this technical specification also incorporates functions that are covered by another technical specification, the relevant technical specification is applied to each function separately. The influence of one function on the other is taken into account.

2 Scope

This technical specification applies to Medical Devices.

This technical specification defines minimum technical requirements for health and safety, electromagnetic compatibility, efficient use of radio spectrum and additional essential requirements based on the Telecommunication apparatus Type Approval Regime.

Unless the context requires otherwise, the expressions and wordings appearing in the Telecommunication apparatus Type Approval Regime shall have the same meaning described thereto.

3 Technical Requirements

3.1 Efficient use of radio spectrum

The equipment shall comply with allocated frequency bands given in the National Frequency Allocation Table (NFAT), UAE 8.

The equipment shall meet the requirements of following standard(s):

EN 301 839-2 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.

EN 302 195-2 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: Harmonize EN covering essential requirements of article 3(2) of the R&TTE directive.

EN 302 510-2 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.

EN 302 537-2 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.

3.2 Electromagnetic compatibility

The equipment shall meet the requirements of following standard(s):

EN 301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements.

EN 301 489-27 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).

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

3.3 Health and safety

The equipment shall meet the requirements of Technical specification TS HS 001.

3.4 Additional essential requirements

No additional requirements.

3.5 Validity of standards

If no issue or revision number is quoted along with the title of a standard, the valid edition should be used. The valid of the standard can be checked on:

- For EN standards: http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/rtte/index_en.htm;