هيئة الإتصالات وتقنية المعلومات
Communications and Information Technology Commission

CITC Technical Specification

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Specification for Medical Devices

Issued by The Communications and Information Technology Commission of Saudi Arabia in accordance with article 89 of the Telecommunications Bylaw.

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Contents

This document comprises the following sections:

Scope

This document applies to Medical Devices.

All telecommunications and radio terminal equipment must comply with the relevant technical specifications established by CITC. In addition, such equipment may be subject to regulations for Declaration of Conformity or registration. See http://www.citc.gov.sa/ for details.

If more than one interface type is offered by a piece of equipment, each interface must meet the applicable technical specifications.

Entry into force

This specification shall enter into force on 10/01/2010 G

Frequency of operation

Following table is showing information on frequency bands, maximum output power and applicable specifications:

Frequency band	Maximum Output Power or Magnetic Field	ETSI Standard
9-315 kHz	30 dBμA/m at 10m	EN 302 195
30.0-37.5 MHz	1 mW e.r.p.	EN 302 510
402-405 MHz	25 μW e.r.p.	EN 301 839
401-402 MHz	25 μW e.r.p.	EN 302 537
405-406 MHz	25 μW e.r.p.	EN 302 537

Proof of compliance

It is recommended that test reports are obtained from a laboratory that has been accredited by a body that is a member of the ILAC Mutual Recognition Arrangement.

Technical requirements

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.

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).

General
In addition to meeting the above requirements, all equipment must comply with the requirement of CITC specification GEN001, be safe and must not adversely affect other electrical equipment.

Obtaining technical standards

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

Network information (only for network interfaces)

Further information on the characteristics and presentation of network interfaces can be found by visiting operator's website.

Document history

Description	Status	Date
	Issue 1	10/01/2010 G