CITC Technical Specification

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Specification for Medical Devices

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This publication is a translation. In case of divergence; the original Arabic text shall prevail.
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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:

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