Medical Testing

The field of medical technology is diverse and highly innovative. The technologies used in medical devices have multiplied over the last few years at a breathtaking pace. It is necessary to ensure that mobile communication technologies in medical devices do not have harmful effects on health due to radio-frequency electromagnetic fields.
Besides CTC advanced's contribution to ensure radiation protection compliance, CTC advanced supports the Medical Industry with expert consulting, testing and certification solutions to ensure that your product meets the required quality, health, environmental and safety standards for a smooth market access.

SAFETY & EMC FOR MEDICAL DEVICES

CTC advanced has many years of experience in safety and EMC testing and is recognized as test service provider for medical device testing according to the medical directive 93/42 EWG (Medical Device Directive) and 98/79 EG (In Vitro Diagnostic Medical Devices).
The accreditation according to DIN/ISO/IEC 17025 by the ZLG (ZLG is the central coordination unit in Germany regarding medicinal products for human and animal use) allows CTC advanced the performance of a large portfolio of standards:

For safety testing:
- DIN/EN/IEC 60601-1
- DIN/EN/IEC 60601-1-8
- DIN/EN/IEC 60601-1-11
- DIN/EN/IEC 61010-2-040
- DIN/EN/IEC 60601-2-66
- DIN/EN/IEC 61010-2-101

For EMC testing:
- DIN/EN/IEC 60601-1-2
- DIN/EN/IEC 60118-13
- DIN/EN/IEC 61326-2-6

Furthermore, CTC advanced is an accredited test lab for **CB Scheme in Safety and EMC**.

ELECTRO ACOUSTIC HEARING AID MEASUREMENTS

CTC advanced is accredited for the performance of hearing aid electro-acoustic measurements. The state-of-the-art test lab including fully- and hemi-anechoic chamber, audiology room and audiology booth are equipped with professional measurement analyzers, microphones and audio sources. The scope of acoustical measurements includes the below mentioned standards:

- IEC/EN 60118-0 / -1 / -2 / -6 / -7 / -13
- NSH 7th edition (Nordic Requirements)
- NSH 7.0 Annex A
- ANSI C63.19 clause
- AS/NZS 1088.9

Further tests can be carried out on demand, please do not hesitate to contact us with your special request.

RE DIRECTIVE

The Radio Equipment Directive of the European Union (RE Directive – RED; succeeding R&TTE) applies to electrical or electronic products which intentionally emit and/or receive radio waves.
Radio waves describe electromagnetic waves of frequencies lower than 3.000 GHz.
CTC advanced is able to support you in every part of the RED:

- Radio
- EMC
- Safety

This applies to all medical devices that incorporate RF wireless technology, such as:

- Wireless Medical Telemetry Service (WMTS)
- Medical Device Radiocommunication Service (MedRadio)
- Medical Implant Communication Service (MICS)
- Medical Micropower Network (MNN)
- Medical Body Area Network (MBAN)
- Cellular communication chipsets
- RF identification (RFID) products

CTC advanced GmbH as Telecommunications Certification Body for USA, Canada and Japan offers support for the market access of radio equipment in more than 150 countries.

COEXISTENCE TESTING FOR WIRELESS MEDICAL DEVICES

The U. S. Food and Drug Administration (FDA) regulates the safety of medical devices and defines risk criteria.
If an RF wireless medical device is expected to be used in proximity to another RF wireless inband source, FDA recommends to avoid such risks through testing for coexistence of the device wireless system.
The wireless coexistence standard ANSI C 63.27 describes such requirements regarding coexistence testing of wireless devices.

CTC advanced is able to support you anytime your product's quality and performance are to be optimized.

CTC advanced GmbH
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