

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 high frequency electromagnetic fields. Besides CTC advanced's contribution to ensure radiation protection compliance, CTC advanced supports the Medical Industry with expert consulting (except design consulting), testing and certification solutions to ensure that your product meets the required quality, health, environmental and safety standards for a smooth market access.



ELECTRICAL (BASIC) SAFETY & EMC

CTC advanced has many years of experience in Electrical Safety and EMC testing and is recognized as test service provider for medical device testing according to the medical directive 2017/745 (MDR) and 2017/746 (IVDR).

CTC advanced is accredited according to DIN/ISO/IEC 17025 by the National German Accreditation Authority DAkkS and is recognized by the ZLG (ZLG is the central coordination unit in Germany regarding medicinal products for human and animal use). We can support you with a large portfolio, e.g.:

For safety testing:

- EN/IEC 60601-1 / -8 / -11
- EN/IEC 61010-2-66
- including the required technical documentation as risk management (ISO 14791), usability (EN/IEC 60601-1-6), software-documentation (EN 62304), ...
- EN/IEC 61010-1
- EN/IEC 61010-2-040 / -081 / -101
- IEC 61010-031

For EMC testing:

- EN/IEC 60601-1-2
- EN/IEC 60118-13
- EN/IEC 61326-2-6

Furthermore, CTC advanced is an accredited CB testing lab for **CB Scheme in Electrical Safety and EMC**. We are also NRTL for North America. For further accreditations please check our website.

DOES YOUR MEDICAL DEVICE USE RADIO TECHNOLOGIES?

Medical devices that incorporate RF wireless technology, such as e. g. BT, WIFI, DECT, Radar, NFC etc., have to fulfill the requirements of both Medical and Radio Equipment Directive (2014/53/EU).

The Radio Equipment Directive of the European Union (RED; replacing R&TTE) applies to all electrical and electronic equipment which intentionally emits and/or receives radio waves.

FURTHER SERVICES AT CTC IN MEDICAL ISSUES

- Electro-acoustic measurements of hearing aids for the Nordic, North American and European market
- Co-existence tests for the FDA
- Environmental tests (e.g. vibration, shock, climatic, IP-classification)
- Battery testing
- Telecommunication Certification Body for USA, Canada
- Radio Equipment Certification Body for Japan
- International Type Approval services around the world

Our experts would be pleased to advise you and find out solutions tailored to your needs.

