

Medical Testing

Medical devices are designed for the use in a wide variety of situations and environments where they must meet basic safety and performance requirements.

There are more and more mobile medical devices, which are battery or accumulator powered and therefore have to fulfill specific requirements. Medical applications which utilize Bluetooth®, WLAN or other wireless transmission technologies such as contactless power transmission fall within the scope of radio equipment directive (RED) and have to comply with it. Depending on the application and environment, these items often have to withstand extreme environmental conditions such as temperature, shock, vibration or tightness requirements.

To demonstrate conformity with these stringent requirements, we provide comprehensive testing services in the above-mentioned fields and consequently assist our customers in the elaborate and complex process of bringing their medical device to market.



ELECTRICAL (BASIC) SAFETY & EMC

cetecom 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).

cetecom 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 Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices). We can support you with a large portfolio, e.g.:

For Safety testing:

- EN/IEC 60601-1 including the required technical documentation as risk management (ISO 14791), usability (EN/IEC 60601-1-6), software-documentation (EN 62304), etc.
- EN/IEC 60601-1-8 /-11 /-12
- EN/IEC 60601-2-4 /-18 /-25 /-35 /-66
- EN/IEC 80601-2-30
- EN/IEC 61010-2-040 /-101

For EMC testing:

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

Furthermore, cetecom advanced is an accredited CB testing lab for **CB Scheme in Electrical Safety and EMC**. Since we are a Partner Test Laboratory (PTL), we can also offer NRTL approval with our network.

DOES YOUR MEDICAL DEVICE USE RADIO TECHNOLOGIES?

Medical devices that incorporate RF wireless technologies, 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 electrical and electronic equipment that intentionally emits and/or receives radio waves.

FURTHER SERVICES IN MEDICAL ISSUES AT CETECOM ADVANCED

- Co-existence tests for the FDA
- Environmental tests (e.g. vibration, shock, climatic, IP-classification)
- Battery testing
- Telecommunication Certification Body (TCB) for USA
- Foreign Certification Body (FCB) for Canada
- Registered 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.

