

Turning Change into Opportunity

EMC Testing of Medical Devices – IEC 60601-1-2



Do you need help complying with Medical Directive testing standard IEC 60601-1-2? Are you meeting all requirements that were mandatory as of December 31, 2018? Are you clear on how the Edition 4 grandfather clauses vary by country?

With over 20 years of Medical Directive experience, DEKRA Product Testing and Certification helps you navigate this ever-changing standard and develop a comprehensive test strategy. Whether you need to support legacy test requirements or develop custom test plans based on specialized risk assessments, DEKRA's global network of accredited labs can help you get to market faster.



A. Canada
ISO 13485
MDSAP Medical Device
Single Audit Program

B. Brazil INMETRO

C. Europe Notified Body

- MDD 93/42/EEC
- AIMDD 90/385/EEC
- IVDD 98/79/EC
- Animal Tissue Regulation 722/2012
- Blood directive 2000/70/EC and 2001/104/EEC

D. Japan J-PMDact
Notified Body for active and non-active medical devices

E. Taiwan
TCP program

F. Australia Mutual Recognition Agreement

Impact of Edition 2 by Region



The FDA requires Edition 4 for declarations of conformity in support of premarket submissions, but some grandfathering is allowed.



The EU does not allow grandfathering of existing test results. Lack of compliance limits market access.

DEKRA service portfolio for medical devices

Safety Testing

- Electrical safety (IEC/EN 60601, IEC/EN 61010)
- Usability and functional safety
- Reliability
- Risk assessment
- Software (IEC/EN 62304)
- Chemical and material (Eco-design, REACH)
- Mechanical
- Environmental

EMC & Wireless Testing

- Electromagnetic Compatibility (EMC) (IEC/EN 60601-1-2 and IEC 61326)
- Radio Frequency (RF)
- Wireless & Mobile
- Conformance
- Interoperability
- Carriers acceptance testing
- Cyber security evaluation as well as certification acc. to well-known standards (IEC 62443, IEC 80001, IEC MEM MD CS)

Certification

- Medical Notified Body services, amongst others:
 - Medical Device Directive (MDD) (93/42/EEC)
 - Active Implantable Medical Device Directive (AIMDD) (90/385/EEC)
 - In-Vitro Diagnostic Devices Directive (IVDD) (98/79/EC)
- Wide range of Private Industry Certifications and international certification marks for wireless solutions

► IEC 60601-1-2 Key Points of Interest

You must submit a formal test plan to the test lab. Every verification/validation report must have a matching plan in accordance with ISO 13485:2016.

The Basic Safety and Essential Performance must be tested in the modes that are most likely to result in an unacceptable risk, requiring hazard analysis.

Test levels for the immunity requirements have been increased.



Let's Start a Project Together

Want more information about Edition 4?

Have a project to discuss?

Contact Us At:

DEKRA Product Testing and Certification
405 Glenn Drive #12
Sterling, VA 20164
+1 703-657-2000

Medical Device Regulatory Services:
DEKRA.us/Medical-Device-Regulatory-Services

IEC 60601 and International Type Approval:
DEKRA.us/IEC60601-ITA



Why DEKRA?

- ✓ Thorough understanding of risk-based design and testing
- ✓ FCC/ISED, CE certification, International Type Approval for 180 countries, ISO 13485 and MDSAP certification
- ✓ Validation testing of RF wireless communications equipment, including WIFI, NFC, RFID, SRD, Bluetooth and Continua Health Alliance
- ✓ Accredited labs around the world, including Sterling, VA, just minutes from Dulles Airport

About DEKRA?

Founded in 1925, DEKRA is one of the world's leading testing, inspection, and certification organizations, working to ensure safety on the road, at work, and at home. DEKRA has over 45,000 employees, operates in over 60 countries and has an annual revenue of nearly \$4 billion USD.

With over 20 years of experience with EMC/RF, DEKRA can guide you through product certifications that comply with quality and safety regulations required by international standards and regulations, specific industries, and end-users.

Our testing labs in the United States, Taiwan, Japan, and Spain offer custom solutions for a wide portfolio of testing and certification services.

