



MEDICAL DEVICE EMC TESTING AND ELECTRICAL SAFETY CERTIFICATION

ACCREDITED TESTING AND CB SCHEME CERTIFICATION FOR THE US AND CANADIAN MARKETS

Medical electronic devices sold in the US, Canada, or Europe must meet IEC 60601-1-2 EMC requirements and IEC 60601-1 electrical safety standards before it can enter the market. Devices with wireless modules require FCC and ISSED Canada authorization as well. QAI provides all of this from accredited labs under a single project scope, so you are not coordinating between multiple facilities or managing separate timelines. We work with you to develop a test plan that covers your target markets before testing begins, so scope and cost are clear from the start.

TESTING AND EVALUATION INCLUDES

- Radiated and conducted emissions per IEC 60601-1-2 Ed. 4
- ESD, RF immunity, EFT, surge, and conducted RF immunity
- Wireless coexistence testing per AIM 735731
- Electrical safety evaluation per IEC 60601-1 (3rd edition)
- Pre-compliance review before formal testing begins
- CB Test Report for IECEE CB Scheme certificate issuance
- FCC Part 15/18 and ISSED Canada wireless authorization

WHAT THIS MEANS FOR YOUR PROJECT

- Results accepted by FDA, Health Canada, and IECEE national bodies in 50+ countries
- One point of contact for EMC, electrical safety, and wireless
- A2LA-accredited EMC lab, registered with FCC and ISSED Canada
- Clear test plan and cost estimate before work begins

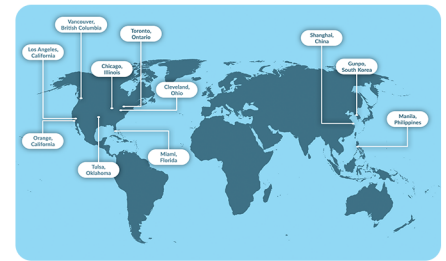
Contact us at info@qai.org to visit: qai.org/electromagnetic-compatibility/medical-device-emc-testing



Accredited EMC testing per IEC 60601-1-2



Pre-compliance through CB certification



Global network of laboratories

About QAI

Founded in 1995, QAI is a testing, inspection, and certification body (CB) that holds accreditations with IAS and the Standards Council of Canada (SCC), and is recognized by OSHA as a Nationally Recognized Testing Laboratory (NRTL). From initial planning through final approval, QAI provides a structured and efficient certification process.

QAI's EMC lab is accredited by A2LA to ISO/IEC 17025 and recognized by the IECEE as a CB Testing Laboratory (CBTL), with registration held by the FCC and ISSED Canada.