

SGS ELECTRO MEDICAL DEVICES SERVICES

HELSINKI
FINLAND



INTRODUCING SGS FINLAND LAB

Established in 2012, SGS Fimko's Medical Devices testing laboratories in Helsinki and Tampere employ medical device experts that have more than twenty years of experience in standardization, regulatory requirements, testing and compliance to international medical device standards.

KEY COMPETENCES FOR ELECTRO MEDICAL DEVICES

- Patient monitoring equipment
- Dental equipment (e.g. x-ray systems)
- Mammography systems
- Hospital beds and operating tables
- MRI
- Electromagnetic Compatibility (EMC), Product Safety
- Wireless Testing/Telemedicine
- Restricted Substances Testing (including RoHS requirements)



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SGS FINLAND FEATURES



The Finland labs serve as the gateway for services in Finland for Electro Medical Devices. Accreditations and approvals received by this two facilities include:

- EN ISO 13485:2012 and EN ISO 13485:2016 by SGS Fimko
- ISO 9001:2015 in combination with ISO 13495:2016

A dedicated project engineer located close to you, will support to handle all your testing, certification and other service needs. Furthermore, we will support you by pre-testing and training in complex regulatory compliance issues, such as risk management requirements.

- Medical Device Directive 93/42/EEC
- Medical Device CE marking for the EU
- REACH, RoHS, Good Distribution Practice, BRC Consumer Products Certification, etc.

The Finish SGS labs will complete your testing to comply with relevant standards and your specific requirements by offering a wide range of marks to support you gain access to the global marketplace.

- Europe (CE, EN Standards)
- CB (Global, IEC Standards)
- Canada (CSA Standards)
- USA (NRTL, FCC)
- Canada (CMDCAS)
- Japan (JPAL)
- Brazil (INMETRO)
- Russia (EAC)
- China (CFDA)
- Third party certifications for Taiwan, Australia and Hong Kong



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