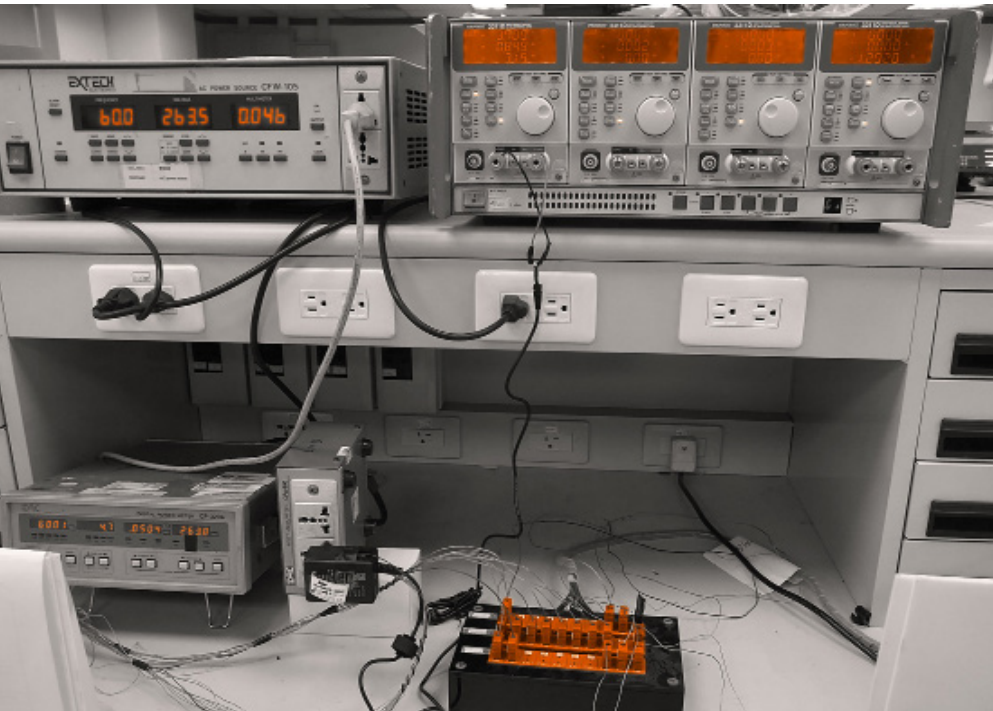


SGS ELECTRO MEDICAL DEVICES SERVICES

NEW TAIPEI CITY
TAIWAN



INTRODUCING SGS TAIWAN LAB

Established in 1996, SGS Taiwan Lab provides professional one-stop testing and certification services for electrical and electronic (EE) medical devices. Services include:

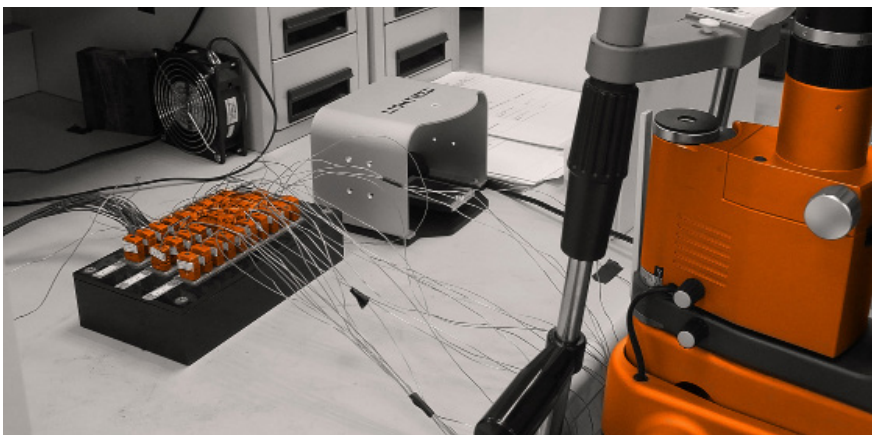
- Regulatory Compliance Services
- Testing services

LABORATORY FEATURES

Accreditations

SGS Taiwan's EE medical devices lab supports speed products' route to market and is accredited to both national and international certification schemes and standards bodies, including:

- IECEE (IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components)
- ILAC (International Laboratory Accreditation Cooperation)
- TAF (Taiwan Accreditation Foundation)



SGS

KEY SERVICES FOR ONE-STOP MEDICAL DEVICE CERTIFICATION



With extensive experience in the EE medical devices sector, SGS Taiwan offers testing against all relevant standards, including:

REGULATORY COMPLIANCE:

- ISO 13485
- CE MDD 93/42/EEC
- CE IVD 98/79/EC
- JPAL (Japan)
- Inmetro (Brazil)
- CMDCAS (Canada)

TESTING & CERTIFICATION AGAINST:

- IEC 60601-1 – safety
- IEC 60601-2-XX – performance
- IEC 60601-1-2 – EMC
- IEC 60601-1-6 & IEC 62366 – usability
- IEC 62304 – software
- IEC 62471, 60825-1 – LED & laser
- ISO 10993 series – biocompatibility
- RoHS & REACH directives
- Mechanical testing against medical device standards
- Reliability testing

FACTORY INSPECTIONS

We are qualified to conduct factory inspections to demonstrate compliance with certification schemes including:

- USA & Canada (SGS Q mark)
- Brazil (Inmetro)

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WHEN YOU NEED TO BE SURE

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