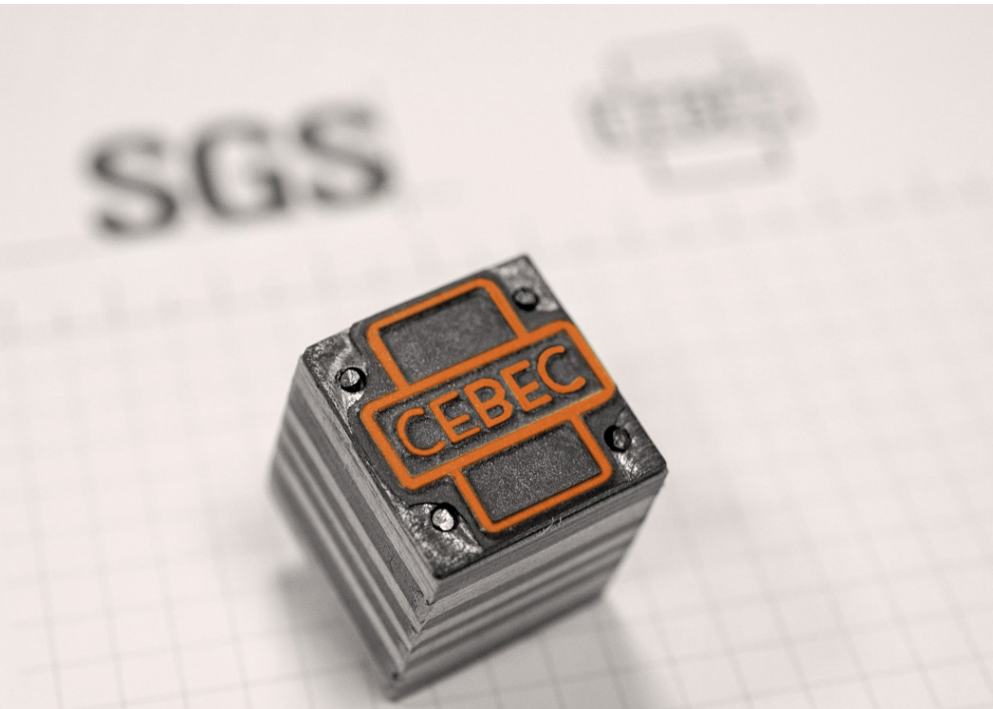


SGS ELECTRO MEDICAL DEVICES SERVICES

BRUSSELS
BELGIUM



INTRODUCING SGS CEBEC LAB

Established in 2011, SGS CEBEC provides professional one-stop testing and certification services for electrical and electronic (EE) medical devices.

Services include:

- Testing services
- Certification services
- Regulatory Compliance services

LABORATORY FEATURES

ACCREDITATIONS

SGS CEBEC'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)
- BELAC (Belgian Accreditation Body, EA, ILAC and IAF member)
- ETICS (European Testing, Inspection and Certification System)

SGS

KEY SERVICES FOR ONE-STOP MEDICAL DEVICE CERTIFICATION



QUALITY MARKS

SGS CEBEC offers a wide range of marks to support you again access to the global marketplace:

- USA NRTL (AAMI & UL Standards), SGS US/C certification mark
- USA Test Reports as part of FDA 510(k) or PMA, FCC
- Canada (CSA Standards)
- Europe (CE, EN Standards)
- Brazil (INMETRO)
- CB (Global, IEC Standards)
- SGS Fimko, SGS CEBEC
- SGS HSP SAFETY

With extensive experience in the EE medical devices sector, SGS CEBEC lab offers testing against all relevant standards, and certification against:

- IEC 60601-1 – Safety
- IEC 60601-2-XX – Performance
- IEC 60601-1-2 – EMC
- IEC 60601-1-6 & IEC 62366 – Usability
- IEC 82304-1 – Health Software Products
- IEC 62471, 60825-1 – LED & Laser
- ISO 10993 series – Biocompatibility
- RoHS & REACH Directives

FACTORY INSPECTIONS

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

- USA (NRTL)
- Brazil (Inmetro)
- Europe



CONTACT US

SGS Belgium
Division SGS CEBEC
Boulevard International 55/D
B-1070 Brussels
Belgium
t: +32 2 556 00 20
f: +32 2 556 00 36
e: cebec.info@sgs.com
www.sgs.com/cebec



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