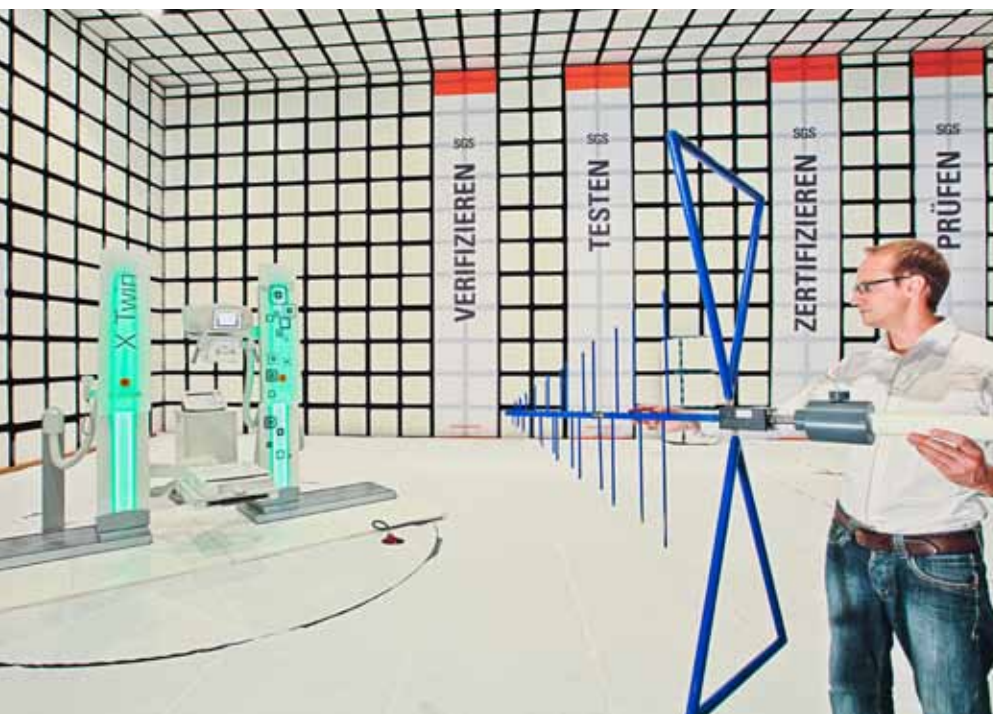


# SGS ELECTRO MEDICAL DEVICE SERVICES

MUNICH, GERMANY



## INTRODUCING SGS MUNICH LAB

- Established: 1921
- Employees: 140

The SGS Munich Lab was originally founded as Siemens "Institut für Qualität" in 1921 and became part of SGS Group in 2008. The Munich lab now serves the following key competences for Electro Medical Devices:

- Electromagnetic Compatibility (EMC), Product Safety
- Environmental Engineering, Qualification of Components
- SGS TÜV Saar GmbH Functional Safety, Homologation
- Battery Testing

## SGS MUNICH FEATURES

EMC Chamber: Radiated Emission testing of an X-ray System

The Munich lab serves as the gateway for services in Germany for Electro Medical Devices. Furthermore, the SGS Munich facility incorporates Test- and Simulationlabs, covering an area of over 5,500m<sup>2</sup>. Accreditations and approvals received by this facility include:

- DIN EN ISO/IEC 17025
- KBA Notification (e/E Mark)
- Notified Body for EMC and R&TTE Directives
- CBTL-Testlab

## KEY TYPES OF SERVICES



- EMC Testing e.g. IEC EN 61326, IEC EN 60601-1-2 (10m chamber, 2 x 3m Chamber, 3 x shielded room)
- Product Safety Testing e.g. IEC EN 61010, 60601-x Series, IEC EN 60825-1
- Environmental Simulation Testing
- Functional Safety e.g. IEC EN 61508, ISO 26262, ISO13849/IEC EN 62061, IEC EN 62304
- RoHS & WEEE
- Notified Body and Quality Management System (9001, 13485) CE0120, CE0598

- MTBF Calculation, FIT Rates (IEC EN 61709, SN 29500, MIL-HDBK-217F,..)
- Failure and Damage Analysis
- Biocompatibility Testing (e.g. ISO 10993), Microbiological Tests
- Validation of Cleaning, Reprocessing and Sterilisation
- Virological Testing
- Stability Testing of Packages and Materials

Our technical team has experts in all Electro Medical Device Testing services, for example X-Ray Testing, as well as all other services needed for product safety.

The Munich SGS lab offers a wide range of marks to help you gain access to the global marketplace

- Europe (CE, EN Standards)
- CB (Global, IEC Standards)
- USA (FDA, UL Standards, FCC)
- Canada (CSA Standards)
- Brazil (INMETRO)
- Japan (JPAL)
- China (CFDA, CCC)
- Belarus, Kasachstan (TR EAC)
- SGS Fimko, SGS CEBEC, SGS US/C



**SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY.**

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**WHEN YOU NEED TO BE SURE**

**SGS**