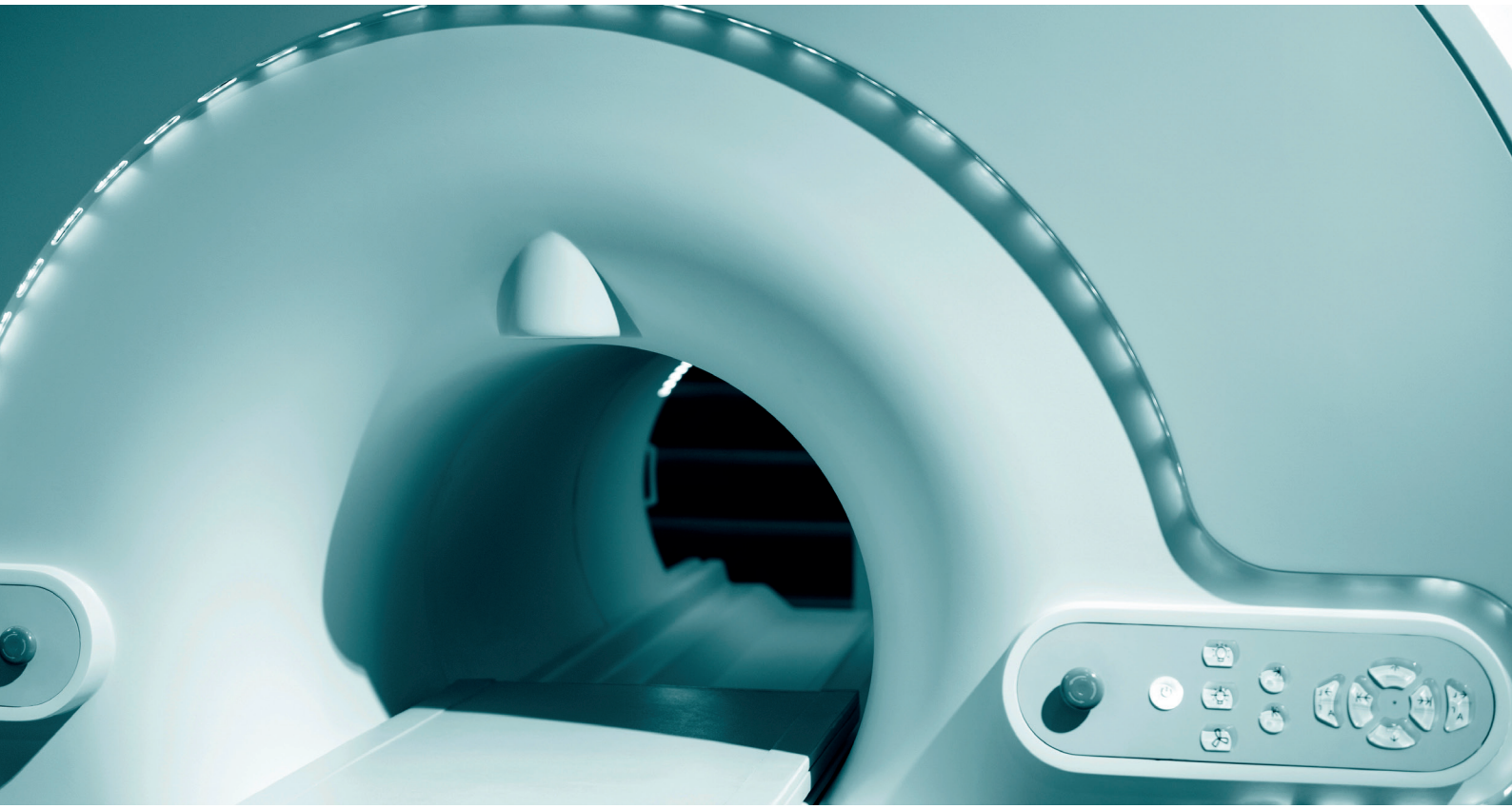
SGS Medical Device Services – Leading global testing & certification solutions

Medical device manufacturers are facing strict regulatory requirements, increasing competition, and demanding time-to-market pressures. There are a wide range of products that are classified as medical devices with huge differences in their testing and regulatory requirements. Medical device approvals and certifications differ between countries, and it is important to be aware of the various requirements. Our teams of experts are on hand to support you from both a technical and regulatory perspective, and to facilitate market access for your medical devices. We are here to provide dedicated support tailored to your type of device and your needs for all or part of the process of bringing your products to market.

SGS MEDICAL DEVICE SERVICES

Achieving a fast time to market requires comprehensive regulatory knowledge and a flexible approach in establishing the most suitable assessment procedure. With an efficient combination of tests and audits SGS can ensure compliance with requirements of multiple certifications at the same time.



TESTING SERVICES FOR ELECTROMEDICAL DEVICES

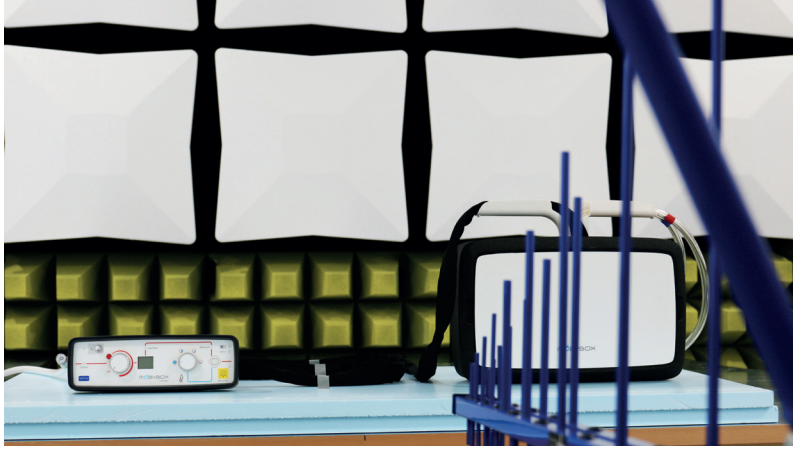
- Electrical Safety Testing according IEC 60601-1 standard series
- Electromagnetic compatibility Testing (EMC)
- Environmental simulation testing
- "Out of hospital" Testing (IEC 60601-1-12, EN 1789, EN 13718, RTCA DO-160G)
- Wireless testing & certification incl. RED (Radio Equipment Directive)
- Battery Testing (IEC 62133-1, IEC 62133-2)
- Functional Safety
- Cybersecurity

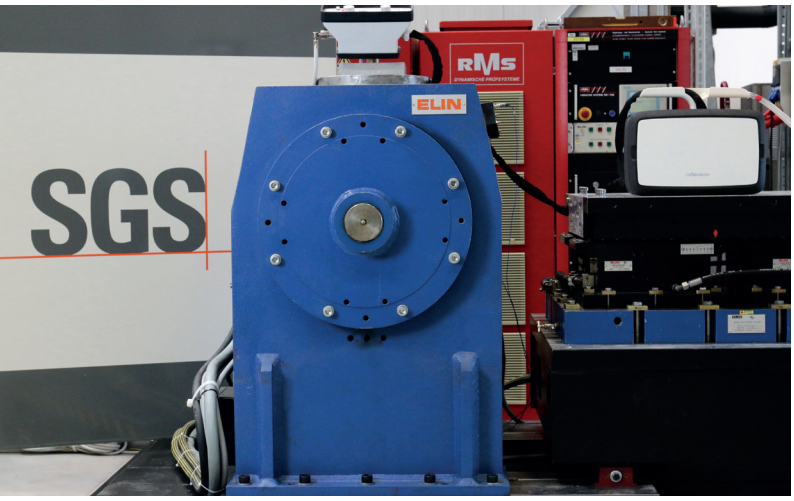
GLOBAL ACCESS SERVICES FOR MEDICAL DEVICES

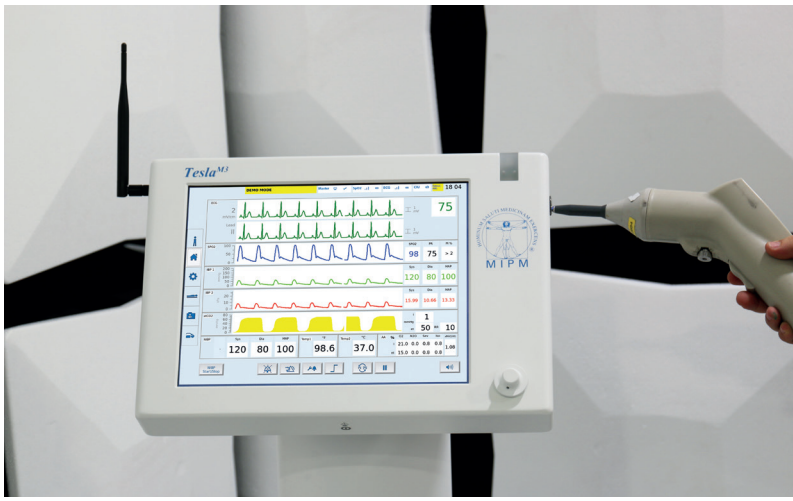
- Global: IECEE CB scheme (IEC Standards)
- Europe (CE, EN Standards)
- USA (NRTL, FCC)
- Canada (CSA standards & CMDCAS)
- Japan (JPAL)
- Brazil (INMETRO)
- Russia (EAC)
- China (CFDA)
- Taiwan (ILAC, TAF)

AND MUCH MORE

- Package Testing (ISTA series)
- RoHS2 (2011/65/EU)
- Chemical Testing
- Biocompatibility Testing
- Material characterization
- Toxicology reports
- Microbiological Testing
- Training courses







SGS ELECTRO-MEDICAL TEST LAB SERVICES

PRODUCT SAFETY TESTING SERVICES

- Safety evaluation according to IEC 60601/80601 standard series for electro-medical equipment
- Testing solution for in vitro diagnostic (IVD) medical equipment using IEC 61010-1 and IEC 61010-2-101
- IECEE CB Scheme testing and certification
- US-NRTL certification according to ANSI/AAMI ES60601-1 and CAN/CSA-C22.2 No. 60601-1
- Pre-compliance evaluation, Evaluation of constructional requirements
- IEC 60601-1:2020 Amendment 2 Gap Analysis program
- ISO 17025 accredited evaluation to meet INMETRO requirements
- Test program for Medical devices used in the home health care environment (IEC 60601-1-11)
- Test program for Medical devices used for road and air ambulances (IEC 60601-1-12, EN 1789, EN 13718, RTCA DO-160G)
- Individual product safety workshops

ELECTROMAGNETIC COMPATIBILITY SERVICES

- Training for contents and application of IEC 60601-1-2 incl. test plan, EMC risk management, news and additional actual/future global requirements
- Testing acc. IEC 60601-1-2 with pass/fail-criteria referencing to Basic Safety and Essential Performance together with IEC TR 60601-4-2 concerning the performance of Medical Systems
- Testing of the influence from RFID/EAS-systems relating to the new testing procedures concerning proximity to magnetic fields (30 kHz, 134.2 kHz, 13.56 MHz) referencing to IEC 60601-1-2:2014 + AMD1:2020 and AIM 7351731
- Testing “out of hospital” for operation in home healthcare environment incl. emergency car (CISPR 25, ISO 7637-2), air ambulance (RTCA DO-160G)
- Evaluation of requirements for “combined equipment” of Medical System incl. wireless-function acc. ETSI EG 203 367 with reference to EN 301 489-x and e.g. EN 300 220 or EN 300 328

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DAkkS Deutsche Akkreditierungsstelle D-PL-11020-03-02

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CYBERSECURITY

SGS offers a tailored cybersecurity service portfolio for manufacturers and hospitals helping them to comply with regulations and corresponding standards, and to generate requested evidence and proof points that cybersecurity related risks have been considered, evaluated and mitigated for the complete life cycle for devices, systems and networks.
We provide training, assessment and certification services, paying special attention on the intertwined relationship of cybersecurity and functional safety.

TRAINING

- Introductory cybersecurity training for medical device manufacturers introducing the current market situation, incidents, threats and risks, regulations, standards, certifications and best practices
- Cybersecurity risk management for medical device manufacturers according to ISO 14971, AAMI TIR57 or AAMI SW 96
- Cybersecurity-related post market activities
- Secure hardware/software development life cycle
- Training covering secure design & coding principles, security assessment and testing
- Communication & network security

ASSESSMENT

- Cybersecurity threat and risk analysis for medical devices, hospital networks, policies and processes
- Security capability/maturity assessments for organizations and business processes
- Security-related gap assessments and design reviews for medical devices covering the complete product life cycle
- Review and assessment of applied cybersecurity risk management for medical devices (e.g. acc. to ISO 14971, AAMI TIR57 or AAMI SW 96)
- Vulnerability assessments for hardware and software, as well as network and cloud solutions
- Customized security assessment and test campaigns in preparation for product approvals (e.g. FDA 510k application) and against relevant standards

CERTIFICATION

- Independent conformity assessments against cybersecurity guidance documents issued by the FDA or issued in connection to the European MDR/IVDR regulations
- Independent conformity assessments against the standards AAMI TIR57, AAMI TIR97, AAMI SW96, UL2900-2-1, IEC TR 60601-4-5
- Security evaluation and certification according to the upcoming BSZ Certification Scheme governed by the BSI in Germany (in preparation)
- Security evaluation and certification according to the SESIP scheme (provisionally licensed)

SGS

BIOCOMPATIBILITITY TEST
BIOLOGICAL SAFETY ASSESSMENT

BIOCOMPATIBILITY

NON-ANIMAL ALTERNATIVE METHODS

In vitro methods are fast, reliable, reproducible and cheap. They may help suppliers and manufacturer choose the most suitable material for medical applications. Our laboratories are ISO 17025 accredited and provide tests under Good Laboratory Practises (GLP). SGS Institut Fresenius GmbH supports when possible the 3R-Principles with the development and implementation of non-animal alternative methods to reduce the number of animal trials. The combination of in vitro methods and chemical characterization (Extractables & Leachables) of materials with a subsequent toxicological risk assessment is ideal to comply with regulatory challenges and to minimize the risks of your product.

- In vitro cytotoxicity – ISO 10993-5 (direct and indirect contact + ISO 10993-12, filter- and agar- diffusion)
- In vitro irritation (ISO 10993-10). Intact skin, mucosal membrane, vaginal and intestinal tissues, cornea-epithelium
- In vitro hemocompatibility (ISO 10993-4)
- In vitro genotoxicity, carcinogenicity (ISO 10993-3)

CHEMICAL ENDPOINTS

- Method development and validation of Extractables & Leachables studies under GMP/cGMP (ISO 10993-18) and toxicological risk assessment
- Determination of biologically safe levels according ISO 10993-17
- USP <1663> and <1664> for Pharmaceuticals
- USP <1665> und <665> for Single Use Systems

PHYSICO-CHEMICAL ENDPOINTS

- Characterization of impurities in metals, solutions and other materials
- Material defects and damage analysis
- Particle size distribution and particle identification
- Chemical surface purity
- Morphology characterization (DSC)
- Aging ASTM F 1980

BIOLOGICAL ENDPOINTS

- Microbial purity Ph. Eur. 2.6.12, USP <61>
- Identification of various species Ph. Eur. 2.6.13, USP <61>
- USP <61> chemical – chemical/thermal disinfection verification
- Bioburden, ISO 11737, USP <1115>
- Mycoplasma Ph. Eur. 2.6.7, USP <63>
- Sterility Ph. Eur. 2.6.1, USP <71>
- Endotoxin Ph. Eur. 9 (2.6.14) and USP <85>

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

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WHEN YOU NEED TO BE SURE

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