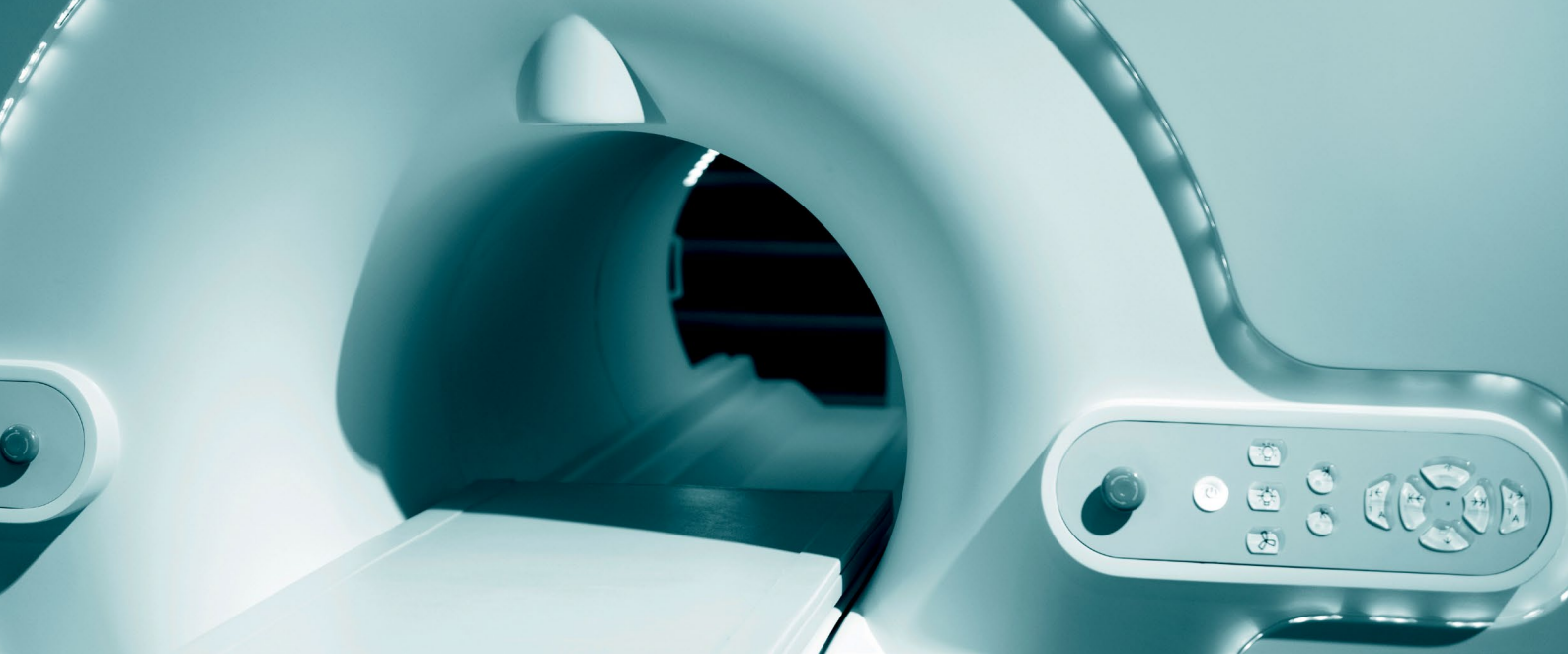
SGS testing & certification solutions for medical devices

SGS



SGS MEDICAL DEVICE SERVICES

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

Medical device manufacturers are facing strict regulatory requirements, increasing competition, and demanding time-to-market pressures. There is a wide range of products classified as medical devices, with significant differences in their testing and regulatory requirements. Medical device approvals and certifications differ between countries, making it essential to be aware of the various requirements.

Our teams of experts are on hand to support you from both a technical and a regulatory perspective, and to facilitate market access for your medical devices. We provide dedicated support tailored to your type of device and your specific needs, covering all – or part – of the process of bringing your products to market.

TESTING SERVICES FOR ELECTROMEDICAL DEVICES

- Electrical safety testing according to the IEC 60601-x standard series
- "Out of hospital" testing (IEC 60601-1-12, EN 1789, EN 13718, RTCA DO-160G)
- Safety of Active Implantable Medical Devices (AIMD) according to the ISO 14708 standard series
- Electromagnetic Compatibility testing (EMC)
- Environmental simulation testing
- Wireless testing and certification including RED (Radio Equipment Directive)
- Battery testing (IEC 62133-1/-2)
- Functional Safety
- Cybersecurity

GLOBAL ACCESS SERVICES FOR MEDICAL DEVICES

- Global: IECEE CB Scheme (IEC standards)
- ISO 13485
- Europe (MDR CE, EN standards)
- USA (NRTL, FCC)
- Canada (CSA standards and CMDCAS)
- Japan (JPAL)
- Brazil (INMETRO)
- China (CFDA)
- Taiwan (ILAC, TAF)

AND MUCH MORE

- Package testing (ISTA series)
- RoHS for EU (2011/65/EU), China, and many other countries
- Chemical testing
- Biocompatibility testing
- Material characterization
- Toxicology reports
- Microbiological testing
- Training courses
- Evaluation of breathing gas pathways (DIN ISO 18562-2/-3/-4)
- Failure and damage analysis

SGS electromedical test lab services

PRODUCT SAFETY TESTING SERVICES

- Safety evaluation according to IEC 60601/80601 standard series for electromedical equipment
- Safety of Active Implantable Medical Devices (AIMD) according to ISO 14708 standard series
- Testing solutions 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 healthcare 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 on the content and application of IEC 60601-1-2 incl. test plans, EMC risk management, news, and additional current/future global requirements
- Testing according to 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 the influence from RFID/EAS systems relating to new testing procedures concerning proximity to magnetic fields (30 kHz, 134.2 kHz, 13.56 MHz) referencing IEC 60601-1-2:2014 + AMD1:2020 and AIM 7351731
- "Out of hospital" testing for operation in the home healthcare environment incl. emergency vehicles (CISPR 25, ISO 7637-2) and air ambulances (RTCA DO-160G)
- Evaluation of requirements for "combined equipment" of medical systems incl. wireless functions according to ETSI EG 203 367, with reference to EN 301 489-x and, e.g., EN 300 220 or EN 300 328

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 throughout the complete life cycle of devices, systems, and networks. We provide training, assessment, and certification services, paying special attention to 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 and coding principles, security assessment, and testing
- Communication and 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., according 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 applications) and against relevant standards

CERTIFICATION

- Independent conformity assessments against cybersecurity guidance documents issued by the FDA or in connection with the European MDR/IVDR regulations
- Independent conformity assessments against the standards AAMI TIR57, AAMI TIR97, AAMI SW96, UL 2900- 2-1, IEC TR 60601-4-5, IEC 81001-5-1 (SGS Cybersecurity Mark)
- Security evaluation and certification according to the upcoming BSZ Certification Scheme governed by the BSI in Germany
- Security evaluation and certification according to the SESIP scheme
- Security evaluation and certification according to Singapore's Cybersecurity Labeling Scheme for Medical Devices – CLS (MD)

Biocompatibilitity test biological safety assessment

BIOCOMPATIBILITY. NON-ANIMAL ALTERNATIVE METHODS

In vitro methods are fast, reliable, reproducible, and cost-effective. They help suppliers and manufacturers choose the most suitable materials for medical applications. Our laboratories are ISO 17025-accredited and provide tests under Good Laboratory Practices (GLP). SGS Institut Fresenius GmbH supports the 3R principles whenever possible by developing and implementing non-animal alternative methods to reduce the number of animal trials. The combination of in vitro methods and chemical characterization (Extractables & Leachables) of materials, together with a subsequent toxicological risk assessment, is ideal for complying with regulatory challenges and minimizing the risks of your product.

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 to ISO 10993-17
- USP <1663> and <1664> for pharmaceuticals
- USP <1665> and <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 according to ASTM F 1980

BIOLOGICAL ENDPOINTS

- In vitro cytotoxicity – ISO 10993-5 and USP 87 (extraction + ISO 10993-12, direct and indirect contact, filter and agar diffusion)
- In vitro irritation (ISO 10993-23) (intact skin, mucosal membrane, vaginal and intestinal tissues, cornea-epithelium)
- In vitro hemocompatibility (ISO 10993-4)
- In vitro genotoxicity, carcinogenicity (ISO 10993-3)
- Microbial purity Ph. Eur. 2.6.12, USP <61>
- Identification of various species Ph. Eur. 2.6.13, USP <61>
- Chemical/thermal disinfection verification, USP <61>
- 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>

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When you need to be sure