

Testing and certification services for in vitro diagnostic (IVD) medical devices

SGS



SGS offers comprehensive testing and certification services for in vitro diagnostic (IVD) medical devices. We support manufacturers in meeting national and international regulatory requirements and bringing their products successfully to global markets.

OUR SERVICES AT A GLANCE

- Product safety testing according to IEC 61010-1 and IEC 61010-2-101
- Electromagnetic compatibility (EMC) testing according to IEC 61326-1 and IEC 61326-2-6
- IVDR certification according to ISO 13485 through SGS Fimko as a Notified Body
- Testing and certification for global market access
- Chemical testing for hazardous or undesirable substances
- Environmental simulation testing and mechanical stability testing
- Development-supporting testing and design reviews
- Training on regulatory requirements
- Biocompatibility testing according to ISO 10993, USP Class I-VI, and/or JP 7.02
- Medical device certification in accordance with Regulation (EU) 2017/745 (MDR)

YOUR PARTNER FOR GLOBAL MARKET ACCESS

SGS supports you to fulfill the national and international requirements for in vitro diagnostic medical devices, enabling you to bring your products to market quickly, efficiently, and safely. Benefit from our many years of expertise and our global network of experts, testing laboratories, and certification bodies.

SGS C US

ilac-MRA

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

IECEE



Analyses of blood, tissue, and other human specimens are now largely performed using automated systems. Modern in vitro diagnostic medical devices and systems are technologically advanced and play a central role in medical diagnostics. Therefore, users must be able to rely on the safety, reliability, and performance of these products at all times, whether they are used in healthcare settings, laboratories, or at home.

Our testing laboratory in Puchheim, near Munich, accredited to ISO 17025, is also recognized as a CB testing laboratory under the IECEE CB scheme and offers you a comprehensive range of services from a single source.

- Product safety testing for in vitro diagnostics according to IEC 61010-1 and IEC 61010-2-101. This includes the assessment of electrical, thermal, and mechanical hazards, among others, to reliably prevent potential risks such as electric shock, burns, or mechanical hazards during equipment operation.
- Electromagnetic compatibility (EMC) testing according to IEC 61326-1 and IEC 61326-2-6. This includes radiated and conducted emissions and immunity testing, taking integrated wireless technologies into account.
- Review of product-related documentation with reference to ISO 14971, including instructions for use, technical documentation, and risk analyses.
- Support for global market access, including CB test reports and CB certificates for EMC and product safety testing, as well as supplementary SGS North America product safety certification for the USA and Canada.
- Environmental simulation and reliability testing, including ingress protection (IP) testing, mechanical shock and vibration testing, as well as verification of functionality and safety under varying climatic conditions.



CONTACT

SGS Germany GmbH
Benzstrasse 26/28
82178 Puchheim, near Munich

+49 (0) 89 787 475-222
de.medical@sgs.com

www.sgs.com
www.sgs-cqe.de/en

© SGS Société Générale de Surveillance SA (2026)

WE ARE SGS – THE WORLD'S LEADING TESTING, INSPECTION AND CERTIFICATION COMPANY.

SGS

When you need to be sure