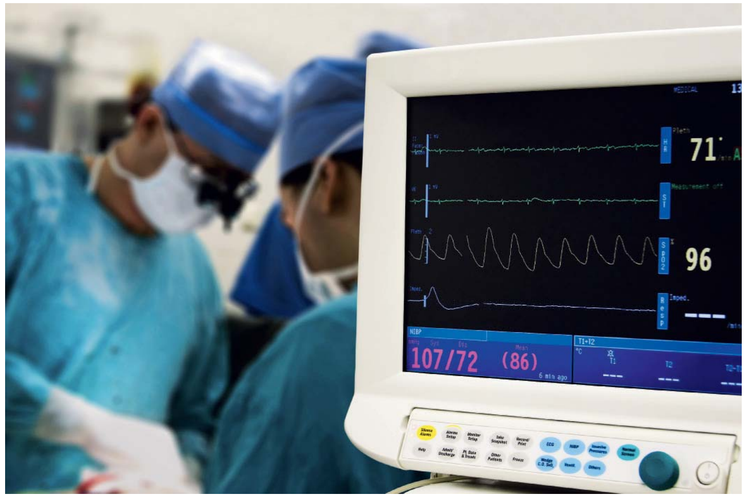

AUDIT AND CERTIFICATION SERVICES

ISO13485:2016：The ISO 13485 standard provides manufacturers, operators, and suppliers to the medical device industry with a framework necessary to demonstrate compliance to regulatory requirements and mitigate risks to stakeholders. It places more emphasis on risk-based thinking and decision-making while it also offers stronger intra-operability between the clauses and requirements.

Management System Certification
Beyond opening doors to new markets, a third-party certified management system can improve your operational processes and give you a competitive advantage in the marketplace. We offer registration to ISO 9001, ISO 13485, ISO 14001, ISO 45001, and ISO 14971, among other standards.

Second-Party Auditing
Evaluating your suppliers or facilities against your own quality, safety, or security requirements will bring your entire supply chain to a higher level of reliability. When you outsource this process to Intertek, you gain access to our global network of over 1,000 qualified auditors – not only freeing up your personnel for other tasks, but also significantly reducing the travel time and cost of each audit.

*Intertek does not provide consulting services for management systems certification. Any consulting activities provided by Intertek are separate and independent from certification activities.

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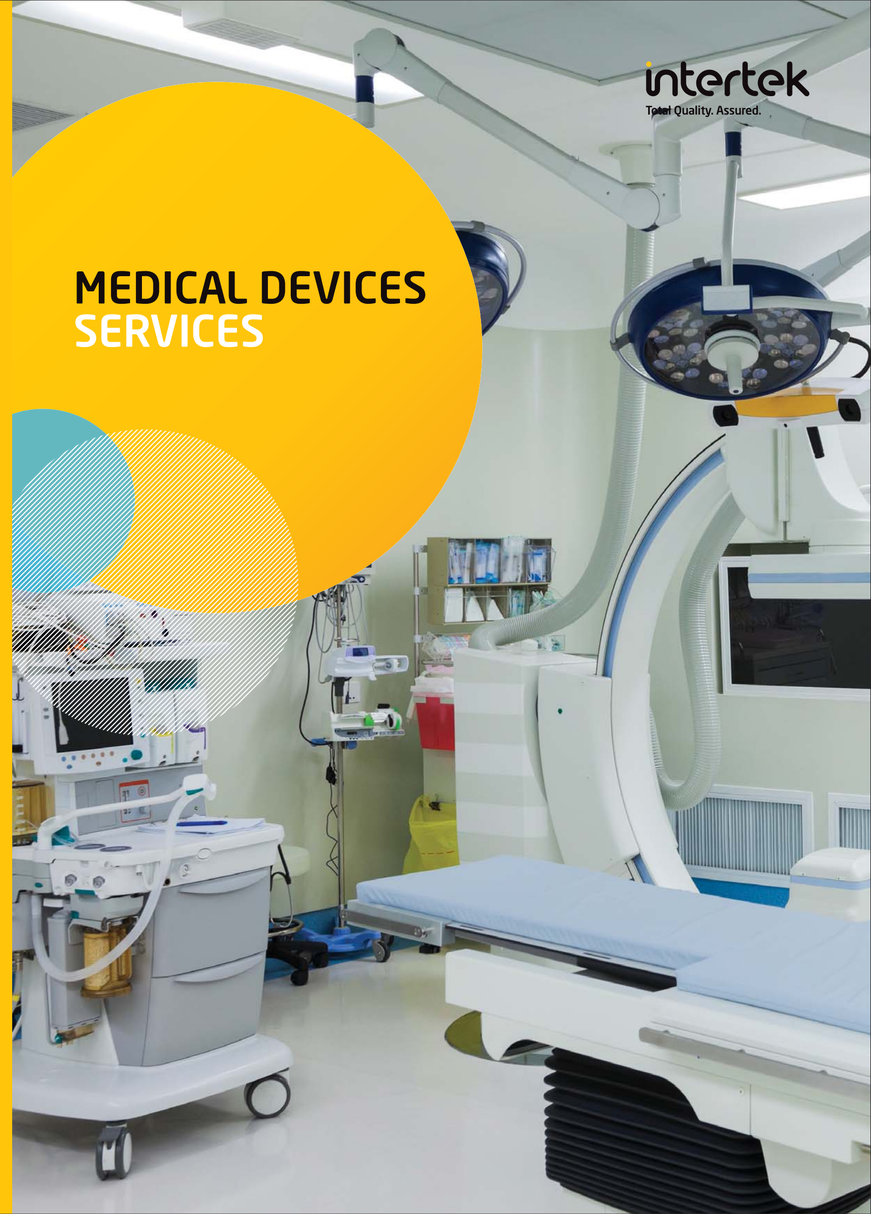

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MEDICAL DEVICES SERVICES

At Intertek, time to market starts with partnership. With over 110 years of experience, we combine our expertise with our passion for solutions that guide your products through today' s constantly changing regulatory process and into the hands of customers faster than ever before.

At Intertek, we have the experience you need for the devices you're developing. We understand that providing early access to our experts saves you time and money. Our expertise helps you overcome regulatory difficulties and shorten your time to market, and our knowledge of the standards speeds turnaround time in your certification process.

KNOWLEDGE-BASED SERVICES

We partner with you to share our knowledge, keeping you on the cutting edge of latest regulatory requirements.

Education and Training

We're proud to be a leading educational resource for manufacturers around the world. Through our seminar, webinar, and white paper programs, we strive to keep you informed and prepared for changing standards, market entry requirements, and upcoming industry regulations. MedTech Info, our magazine and web portal, is the leading voice for technical and regulatory insight for medical professionals.

Design for Market Entry Services

Including Intertek earlier in the design process will help you gain a better understanding of how to design your medical device with current standards and requirements in mind. This will ensure a well-planned market entry and reduce costly re-designs and delays.

Process Design for Risk Management

Intertek has substantial expertise in risk management principles and tools. At each point of the product life cycle, our services can assist you to identify the different scenarios in which the end user of your product could be harmed. If a concerning level of risk is identified, Intertek can help in objectively evaluating available options that will help you determine what steps could be taken to reduce the risk of predictable future problems.

GMAP (GLOBAL MARKET ACCESS PROGRAM)

Medical Device Directive (MDD 93/42/EEC)

Before you can market your medical device in the EU, your product must meet the essential requirements of the Medical Devices Directive (MDD/93/42/EEC), as well as the standards related to your device type.

Intertek SEMKO AB (NB 0413) is a member of the Team-NB and a signatory of the Code of Conduct for Notified Bodies in Europe.

Medical Device Regulation (MDR 2017/745)

The new Medical Device Regulation will enter into force on May 26, 2021. This means that the market access framework for all member countries of the European single market (27 EU member states including the members of the EEA – Iceland, Lichtenstein and Norway, and through bilateral treaties Switzerland) will change significantly.

Medical Device certification under the new Medical Device Regulation, MDR (2017/745) will be offered through our new legal entity Intertek Medical Notified Body AB (IMNB AB, No. 2862). The headquarters for this Notified Body will remain in Stockholm, Sweden.

Medical Device Single Audit Program (MDSAP)

The Medical Device Single Audit Program was developed by a group of medical device regulators to allow recognized third-party auditors to conduct a single audit of a medical device manufacturer that will cover ISO 13485:2016 and their respective regulatory requirements. The regulatory authorities that are currently participating in the MDSAP Pilot Program are Australia – TGA, Brazil – ANVISA, Canada - Health Canada, U.S. – FDA, Ministry of Health, Labour and Welfare (MHLW) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA).

North America

Intertek is an OSHA approved NRTL (Nationally Recognized Testing Laboratory), which is authorized to test products and enrolling them into proprietary certification program (ETL). Intertek's proprietary ETL Mark has become the fastest growing medical devices safety Certification Mark in North America.

Brazil

Intertek's São Paulo office was accredited by the National Institute of Metrology, Quality, and Technology (INMETRO) as a certification body (OCP 0090). Intertek could conduct product testing, inspection and issues INMETRO certification.

Australia

Intertek is the CB/ILAC approved laboratories for the medical devices, could help our customer access Australian market with the Australian standard test report.

Nigeria

As a partner of the Nigeria Bureau of standards (SON), Intertek has the full capability of Nigeria product inspection and certification, issued certificate of clearance for the medical devices.

Our Product Conformity for Exports and Pre-Shipment Inspection Programs

Help you to comply with the requirements of the following countries: Kuwait, Nigeria, Algeria, Bangladesh and Uzbekistan. Additionally, we can help you trading with those countries around the world that have strict safety, performance, or pre-shipment inspection requirements for imports.

SAFETY AND PERFORMANCE TESTING

IEC 60601-1,3rd Edition

With the increased emphasis on risk management in the 3rd Edition of IEC 60601-1, there are a variety of routes to demonstrate compliance. Intertek will partner with you for an interactive risk management approach to your 3rd Edition certification.

From beginning of your product development cycle through certification, our medical device experts will partner with you on the development and review of your Risk Management File (RMF), Electrical Safety, and Electromagnetic Compatibility (EMC) testing and Performance assessment.

Our accreditations cover all the key marks for your global trade and we can support you in getting them in the most suitable combination to your marketing needs:

ETL Listed Mark for North America

Our ETL Listed Mark, the leading safety mark for medical devices in North America, indicates that your product has been independently tested by Intertek, an OSHA-recognized Nationally Recognized Testing Laboratory (NRTL), found to be in compliance with applicable safety standards, and meets the minimum requirements for sale of distribution within North America.

CE Marking for the European Union

We can assist you with the mandatory CE Marking for both the Medical Device Directive (MDD) and the In-Vitro Diagnostic Directive (IVDD), ensuring European Union market access.

S Mark

The S Mark is our recognized voluntary, European mark, additional to the CE Marking, which provides evidence to professional buyers that your product' s compliance to applicable European safety requirements has been independently tested and certified by Intertek.

CB Scheme

As a National Certification Body (NCB) and CB Testing Laboratory (CBTL), Intertek can guide you through the entire testing process, and help you meet the requirements of the more than 54 countries that participate in the CB Scheme for medical devices.

Performance Testing

We can test well beyond mandatory requirements by performing a range of accelerated stress tests to determine the effects certain stresses (such as temperature, vibration, humidity, or water spray) have on your product during life cycle. Collecting this data prior to marketing your product will help you to better assess risk and avoid costly field failures.

RoHS Directive for hazardous substances

Intertek provides complete RoHS testing service, including Wet-Chemical Analysis, XRF screening, RoHS product compliance assessment, RoHS Product Certification Scheme (PCS), RoHS legislation consulting and training service, etc.

CE Intertek Intertek Intertek

SCIENTIFIC SUPPORT SERVICES

Intertek is a leading provider of scientific support services, having both the specialist instrumentation and expert capability for the chemical and physical analysis of medical devices at all stages of the design, trial and manufacturing process. Our scientific capability uniquely covers the fields of metals, polymers and pharmaceuticals with over 1000 expert scientists and 28 research laboratories worldwide. Intertek provides long term scientific research and rapid response problem solving with GLP certification, cGMP compliance and ISO 17025 accreditation.

R&D Analytical Support

Includes assay development for API's, impurities and degradants, determination of residual solvents such as volatile organic compounds (VOCs) and organic volatile impurities (OVIs), assessment of physical chemical properties and extensive capabilities for extractables and leachable testing including polymer components and evaluation of packaging laminates and materials.

Material Characterization and Failure Analysis for Medical Devices

Intertek's materials sciences laboratory provides analysis and expertise for implantable medical devices and related healthcare products with experience in solving a wide range of material-related problems associated with the manufacture and use of medical devices such as catheters and stents. Typical analytical approaches to problem-solving include fracture and failure analysis, surface chemistry and adhesion, microstructure and mechanical property relationships, chemical imaging and materials de-formulation.

Interaction Assessments in Combination Devices

Includes assay development for API-device interactions and material compatibility, evaluation of interaction with packaging materials and identification of Impurities and degradation pathways.

Stability and Medical Device Testing

Comprehensive capabilities to evaluate batch release, slow elution, low solubility dissolution and controlled drug release patterns (DRP) with onsite stability and storage facilities that include walk-in chambers for ICH conditions and reach-in chambers for special storage conditions.

Intertek is a true "one-stop-shop" of auditing, certification and review services for the medical industry. Our unique combination of expertise has brought confidence and assurance to thousands of organizations all over the world.