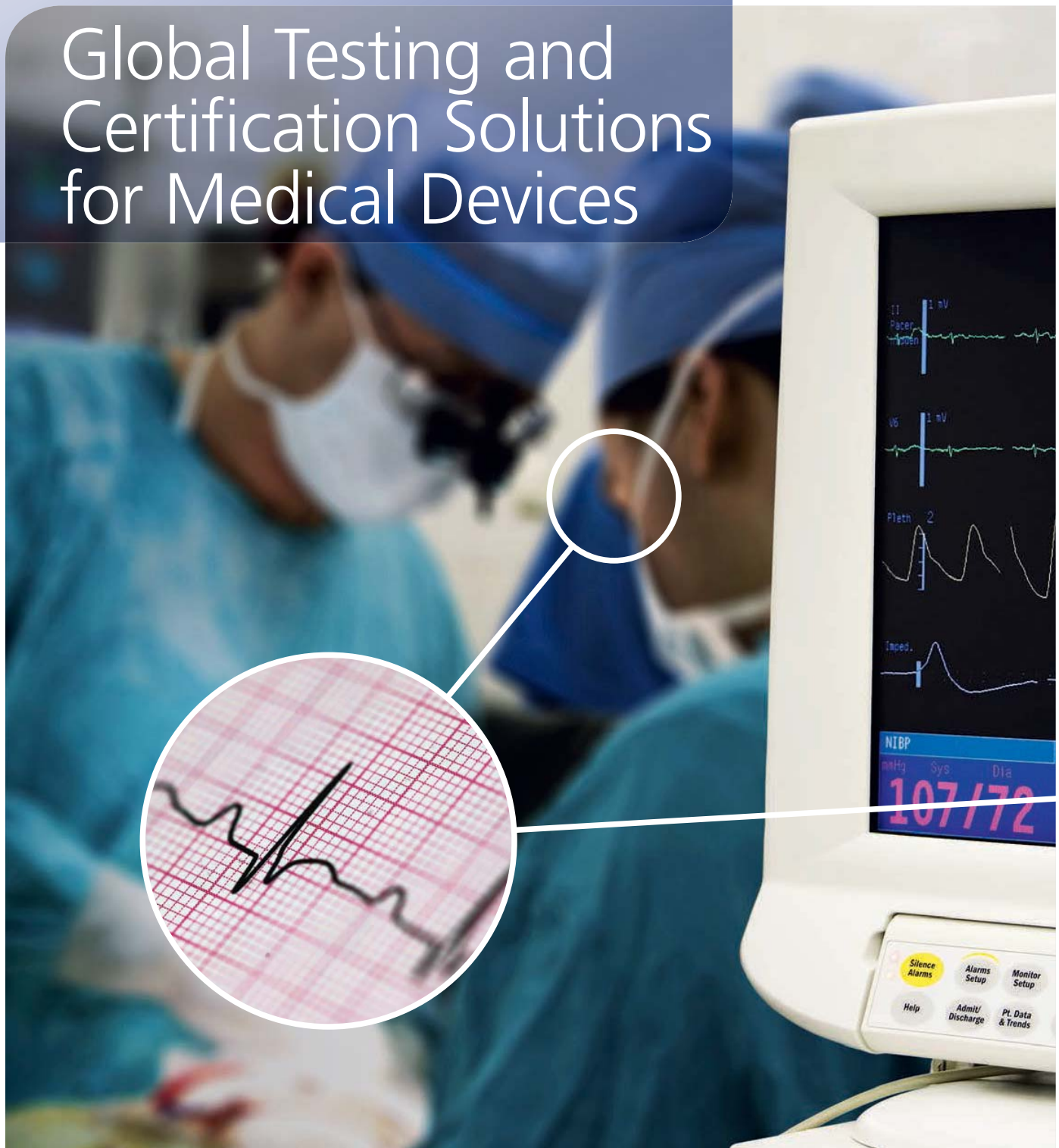
Medical Device Services

Intertek

Valued Quality. Delivered.

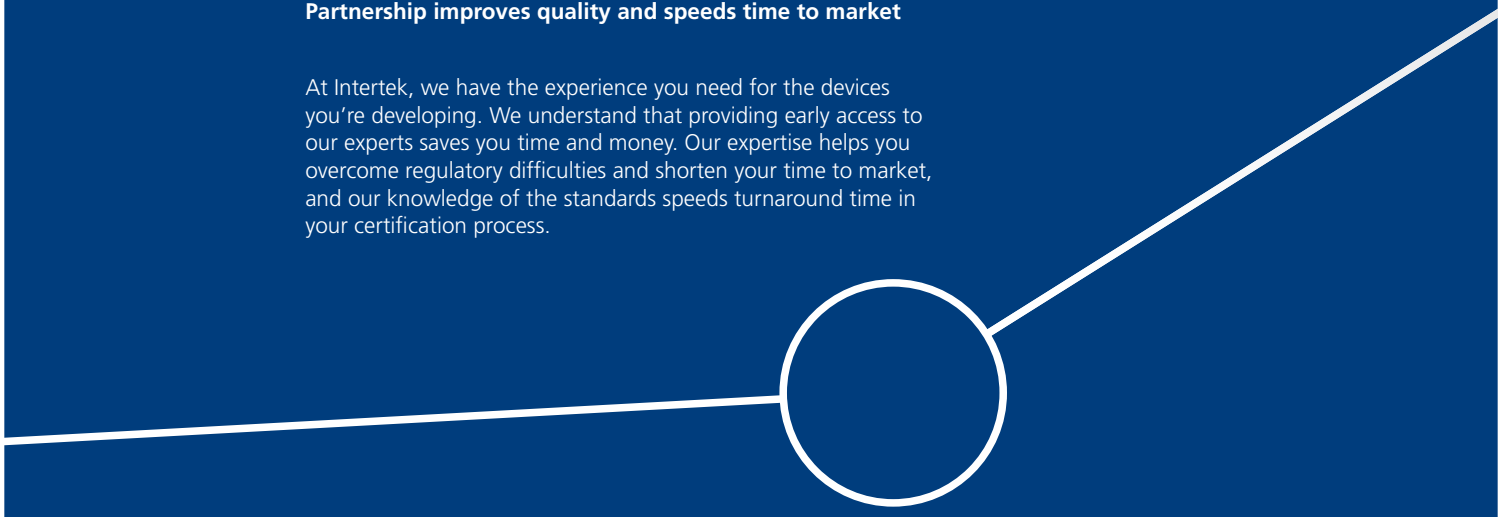
Global Testing and Certification Solutions for Medical Devices



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.

Partnership improves quality and speeds time to market

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.



Intertek guides you through every step of the regulatory process

Our expertise in medical device testing goes above and beyond standard reviews. We provide our clients with support, guidance and partnership throughout all phases of design and production. Our market-entry expertise and globally recognized programs assist you with international requirements. Intertek is your partner from start to finish.

Global Accreditations

Our broad scope of global accreditations supports your entry in to markets around the world. Intertek is an OSHA accredited NRTL (Nationally Recognized Testing Laboratory) in the US. In Canada, we are accredited by the Standards Council of Canada (SCC) as a Testing Organization and Certification Body, as well as a Health Canada (CMDCAS) recognized registrar. For market access to the European Union, we have three Notified Bodies for CE Marking.

Worldwide Accommodations

Intertek has a global network of auditors and engineers, ready to work with you wherever you are. Our global network of 11 Medical Device Centers of Excellence and 23 Electromagnetic Compatibility (EMC) labs boasts state-of-the-art equipment for Safety, EMC and Performance testing for medical devices.

Education Programs

As a premier educational resource for manufacturers around the world, we keep you informed and prepared for changing standards, market entry requirements, and upcoming changes to industry regulations. Through training seminars, webinars, and white papers, Intertek is a leading voice in the medical industry for technical and regulatory insight.

Depth of Field

The range and depth of our testing and certification experience provides the expertise necessary to do the job right the first time. Our program managers, engineers, and auditors have the experience to help you determine what to assess, how to test, and what standards apply - saving time, reducing costs, and increasing speed to market. As active participants in standards writing committees, Intertek excels in the latest testing methods to provide outstanding service.

Failure Analysis Services

Intertek provides failure analysis and investigatory services for materials failures of medical devices. We have state-of-the-art microscopy and materials analysis facilities, together with extensive finite element analysis expertise. We offer litigation support related to failures of medical devices such as stents, hip joints, catheters, scoliosis rods, etc. We provide engineering assistance, support and training throughout the product's development and life cycle.

Intertek provides complete global testing and certification solutions for Medical Devices

The ETL Mark

Intertek's ETL Mark is the fastest growing safety certification mark in North America. More than 8,400 manufacturers already place their trust in ETL. Offering both ETL Listed and ETL Classified Marks, Intertek gives you the opportunity to choose the best market access option for your product. The advantages of an ETL listing do not end at certification. Intertek's network of local auditors provides cost-effective inspections, charging by site rather than by product to potentially save you tens of thousands of dollars each year.

CE Marking for the European Union

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

The S Mark

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

The Green Leaf Mark

The Green Leaf Mark is proof that a product has been independently tested and found to conform to multiple existing environmental regulations, such as RoHS, REACH and Eco Design requirements. With this single mark, you can provide independent proof and assurance to consumers that your product lives up to its environmental claims through point of purchase displays, advertising, and literature, all of which substantiate your product's credentials.

CB Scheme

Intertek stamps your passport to international markets with the CB Scheme. With three National Certification Bodies (NCB) and a global network of CB Testing Laboratories, Intertek saves you time and money by providing access to the 40-plus countries of the CB Scheme with a single set of tests.

> Intertek's ETL Mark is the fastest growing safety certification mark in North America. More than 8,400 manufacturers already place their trust in ETL.

Intertek's expertise and experience translates into global success for you and your Medical Device

Our unique, multi-faceted offering of global product, process and management system certification enables you to get your medical device to market faster than ever before.

Performance Testing

As leaders in the testing, inspection and certification industry, Intertek offers a wide scope of custom performance testing services. We 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.

FDA 510(k) Third Party Reviews

As an FDA-accredited third-party reviewer for 510(k) services, Intertek can shave as much as 50 days off the average turnaround time, getting you to market sooner. We are able to complete your 510(k) review and submit our findings to the FDA within 10 days, while delivering a higher probability of success for clearance on the first pass. Intertek's scope of device eligibility includes approximately 670 product types. Our expertise, combined with the FDA's comfort in our findings and accurate results, mean you can reach your market faster.

Satellite™

Satellite™ is Intertek's revolutionary approach to data acceptance programs. We perform testing and certification on-site at your facility, and in accordance with your schedule, allowing us to speed up certification, time to market, and increase your revenue potential. Furthermore, Satellite™ allows you to choose the marks and markets you need to meet or exceed your sales and business goals.

When it comes to Risk Management, Intertek has you covered

IEC 60601-1, 3rd Edition

With the increased emphasis on risk management in the 3rd Edition of IEC 60601-1, Intertek is prepared to partner with you from the early product development cycle through certification to ensure your success in meeting the Risk Management requirements of the 3rd Edition.

intertek.it/dispositivi-medicali/

Education to Certification – A four step process

- Education through Intertek Academy, Compliance to the 3rd Edition
- Audit to ISO 14971, which may increase your Risk Management pass rate by up to 80%
- Preliminary design package review of the product and the Risk Management File
- Final testing to IEC 60601-1 3rd Edition

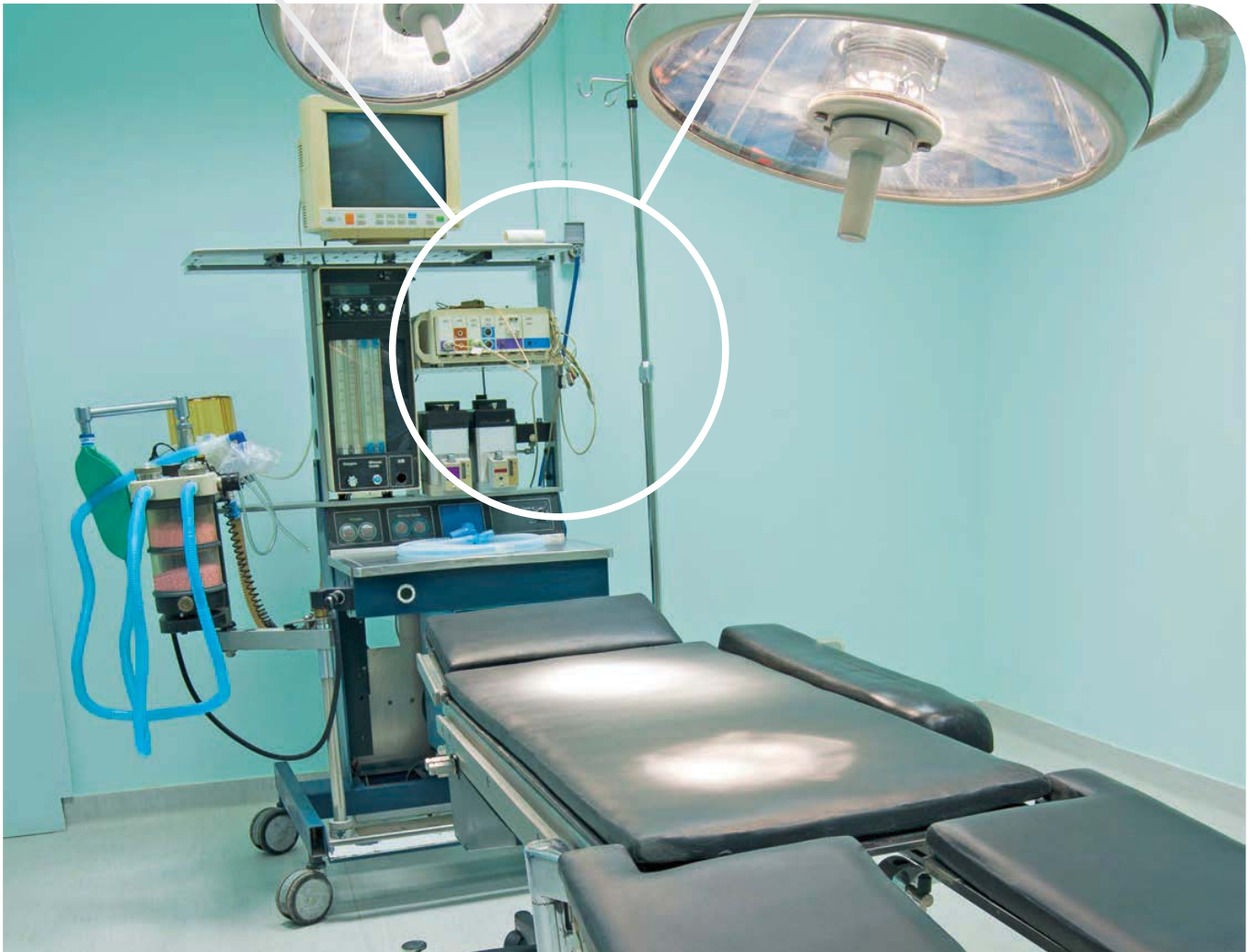
Progress with Confidence

Our approach streamlines your overall certification process, avoiding time-consuming and costly setbacks.

The Largest Independent Global Network of EMC Test Laboratories

Our EMC labs offer state-of-the-art three, five and ten meter semi-anechoic chambers as well as open area test sites (OATS). A full range of EMC services for Medical Devices includes pre-scans, flicker and harmonics, radiated RF, burst, surge, and electrostatic discharge (ESD), and conducted RF immunity.

> Intertek is prepared to partner with you from the early product development cycle through certification to ensure your success in meeting the Risk Management requirements.



Comprehensive audit, certification and review services

Intertek can partner with you during the audit, certification, and review process with precision

a complete source for auditing, certification and review services, our unique combination of expertise brings confidence and assurance to thousands of organizations all over the world. Our expert team of management system auditors worldwide provide a coordinated, committed, and consistent approach to serve your global needs.

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 14971, and DAMAS, among other standards.

CMDCAS Program

For manufacturers applying for device licenses in Canada, Intertek is recognized by Health Canada to provide the ISO 13485 certification required under the Canadian Medical Device Conformity Assessment System (CMDCAS) program. For Canadian manufacturers, certificates issued by Intertek under the CMDCAS program are also recognized by the Australian TGA (Therapeutic Goods Administration).

Notified Body Reviews for the Medical Device Directive

Countless medical device manufacturers have relied on Intertek to gain market access into the European Union under the Medical Device Directive (MDD). Intertek provides a standard turnaround time of thirty calendar days on Notified Body technical review reports. With three EU-based Notified Bodies, and the proven competence of our highly experienced review team, we are able to deliver fast and technically reliable review services.

Our Notified Body can also perform a pre-assessment review of your clinical data. This step is optional, but it is extremely helpful in identifying potential problem areas, increasing your likelihood of meeting the CE Marking requirements on the first attempt.

TCP & PAL

To enhance manufacturers' market access in Taiwan, Intertek, as a designated Notified Partner, offers ISO 13485 Certification recognized under the Technical Cooperation Program (TCP). Additionally, through our cooperation with a Japanese certification body, Intertek can perform audits according to Japan's adaptation of ISO 13485, per the Pharmaceutical Affairs Law (PAL).

Restricted Substances Compliance Assurance

Intertek's compliance assurance service gives manufacturers access to experts on RoHS compliance and a proven documentation process, helping ensure products are 100% RoHS compliant and demonstrating due diligence. Medical devices were initially exempt from the RoHS Directive. However, they will be included effective July 22, 2014 (medical devices) and July 22, 2016 (In-Vitro devices).

FDA Accredited Persons (AP) Inspection Program

In the US, Intertek is accredited to conduct medical device facility inspections of eligible manufacturers on behalf of the FDA. The "AP Inspection Program" is a voluntary program where you can use a third party for the equivalent of an FDA Quality System inspection. This gives you the ability to plan the timing of the inspection and also combine it with other QMS audits.

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.

Product Conformity for Exports and Pre-Shipment Inspection Programs

Intertek helps you comply with the requirements of the following countries: Kuwait, Kenya, Nigeria, Algeria, Bangladesh, Ecuador, Mozambique, Sierra Leone and Uzbekistan. Additionally, we can help you when trading with those countries around the world that have strict safety, performance, or pre-shipment inspection requirements for imports.

Intertek Intertek CE 0359 CE 0413 CE 0473

Scientific Support Services

Intertek is a leading provider of scientific support services, having both the specialized instrumentation and expert capability to conduct chemical and physical analysis of medical devices at all stages of the design, trial and manufacturing processes. Our scientific services uniquely address the fields of metals, polymers and pharmaceuticals, and provide both long term scientific research and rapid response problem solving, including GLP certification, cGMP compliance and ISO 17025 accreditation.

R&D Analytical Support

Intertek's significant expertise in bioanalysis and clinical pharmacokinetic studies allows us to support medical device companies working in the areas of preclinical and clinical drug development. Our support services include assay development for API's, impurities, trace metals and degradants. We help determine residual solvents such as volatile organic compounds (VOCs) and organic volatile impurities (OVIs). We assess physical / chemical properties and have extensive capabilities for extractables and leachables testing - including metals, polymer components and the evaluation of packaging materials.

Material Characterization and Failure Analysis

Intertek's extensive materials science laboratories offer analytical services for implantable medical devices and healthcare products. 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

Intertek offers assay development for API-device interactions and material compatibility, the evaluation of product interactions with packaging materials, and identification of trace impurities or 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 on-site stability and storage facilities that include walk-in chambers for ICH conditions and reach-in chambers for special storage conditions. Intertek laboratories are equipped to detect the smallest traces of substances of concern in both drug compounds and polymeric materials.

Regulatory, Auditing and Microbiology Services

Intertek pharmaceutical and clean air services provides clean room validation, cGMP QA Auditing and instrument validation / calibration services. We also cover the biocide directive, carry out cGMP microbiological evaluations and assess antimicrobial efficacy at a number of locations worldwide. Our toxicological experts work in close collaboration with our pharmaceutical and materials scientists to provide a truly comprehensive expert service.

Manufacturing Crisis and Rapid Response

Our scientists and auditors extend your local problem-solving capability by having corrosion scientists, metallurgists, polymer scientists and pharmaceutical specialists on call. Intertek's medical device network reacts exceptionally quickly and efficiently to manufacturing issues or in-field customer complaints. And being truly independent our clients find our patent infringement investigations and scientific legal advisory services highly informative and readily submissible to both customers and regulatory bodies alike.

Savings from proficiency

Services & Sector Index

The services that Intertek provides meet the needs of all kinds of organisations working in the widest range of fields, markets and geographies. Whatever safety or quality issues you face, we have the flexibility and the experience to deliver the right solutions for your business.

A list of the services we offer and the sectors that we serve within each industry area, as well as our cross-industry services, can be found below.

The broad categories that cover these individual services are explained in detail on p02–03.

In summary, we offer:

- **Testing** services to help you protect your reputation
- **Inspection services** to help you manage risk
- **Certification services** to help you reach new markets
- **Auditing services** to help you control operations
- **Outsourcing services** to help you focus on core activities
- **Advisory services** to help you advance your business
- **Training services** to help you improve your performance
- **Quality Assurance** services to help you meet expectations

Cross industry services
Advisory Services
Analytical Problem Solving
Auditing Services
Certification
Climate Change
Consulting Services
Corporate Social & Environmental Responsibility
Corrosion Measurement & Consultancy
End of Life & Waste Compliance
Engineering Consultancy
Environmental Compliance
Expert Legal Witness
Laboratory Design & Consulting
Laboratory Outsourcing
Laboratory Services
Legal & Insurance
Life Cycle Assessment
Management Systems Auditing & Certification
Materials Analysis & Consultancy
Outsourcing
Quality Assurance
REACH & RoHS Compliance Services
Registration & Certification
Regulatory Services
Restricted & Controlled Substances
Retail, Distribution Import
Risk Management
Second Party Auditing
Supply Chain Management
Sustainability
Technical Staffing
Training
Toxicology

Aerospace & Automotive
Airbags
Ballistics
Batteries Testing
Catalyst Testing & Optimisation
Composites Testing (NADCAP Certified)
Durability
EV Battery
EV Component
EV Charge Station
Engine Emissions Testing
Engine Services
Fuel System Services
Lighting
Lubricant Services
Marine
Metallurgy & Materials
Personal Protective Equipment
Plastics Testing
Used Oil Analysis
Vehicles
VOC Testing

Building Products
Construction Products
Door & Openings
Fenestration
Fire Doors
Fire Testing
Furniture
Hardware
Hearth Products
Manufactured Wood
Plumbing
Roofing Products

Chemicals
Additive Analysis
Advanced Materials
Air Pollution Consultancy
Analysis & Testing
Cargo Inspection & Testing
Catalysts
Chemicals Analysis
Coatings, Inks & Adhesives
Engineering & Consulting
Environmental, Regulatory & Safety
Industrial Inspection
Inline & PAT Services
Pilot Plant Services
Plastics & Polymers
Power Handling Safety Testing
Print & Paper Testing
Registration & Notification
Speciality Chemicals
Waste Water Treatment Consultancy
Water Services
UN Transportation Testing

Consumer Goods & Retailers
Accessories
Apparel
Chemicals
Cosmetics
Deformulation and Product Analysis
Electronic & Electrical Products
Food & Beverage
Footwear
Furnishings & Furniture
Gifts & Premiums
Hardlines
Healthcare & Beauty
Home & Personal Care
Home Appliances
Juvenile Products
Leather goods & Luggage
Packaging & Packaging Materials
Product & Packaging Testing & Certification
Product, Process & System Inspection
Product Safety Training
Quality Management & Outsourcing
Soft Home Furnishings
Textiles
Toys & Games

Electrical & Electronic
Commercial Kitchen Ventilation
Components
Energy Storage
Food Equipment
Hazardous Locations
Home Appliances
HVAC
Industrial Machinery
Life Safety
Luminaires & Lighting
Multimedia & AV
Pool & Spa
Power Tools
Renewables
Semiconductor
Toys & Gaming
Wire & Cable

Energy
Biofuels & Alternative Fuels
Cargo Inspection & Testing
Coal & Pet-Coke
Distribution & Retail
Engineering & Consulting
Environmental & Safety
Exploration & Production
Flow Assurance
Industrial Inspection
Integrity Management
Loss Control
Materials Consultancy & Testing
Metrology
Microbiology Consultancy
Nuclear
Oil & Gas
Power Systems
Petroleum
Photovoltaic & Solar
Pilot Plant Services
Production Assurance
Production Chemistry
Refining
Renewable Energy
Wind

Intertek – the mark of quality

For more than a 100 years, Intertek has guided clients through the challenging certification process. Offering the broadest range of certification and accreditation marks accepted in markets around the world, Intertek can help clients to succeed in new and existing markets, meet evolving regulatory requirements and win new customers.

Food & Agriculture
Cargo Inspection & Certification
Chemicals
Claim Substantiation
Customs & Excise Support
Environmental Standards
Exposure Assessments
Feed Additive & Approval
Food Contact Migration Testing
Food Packaging Testing
Food Testing
Health Claims
Label Verification
New Food Ingredient Safety Assessment & Regulatory Support
Product & Process Inspections
Product Contamination & Safety
Quality & Safety Compliance Assessments
Quantity Determination
Study Monitoring
Traceability
Transport, Distribution & Handling

Government and Trade Services
Government Institutions
Cargo Scanning
Certification of Origin for Exports
Certificate of Quality for Exports
Destination Inspection of Imports
Pre-shipment Inspection for Exports
Product Conformity Programme for Exports
Supply Chain Security Services
Verification Services for Container, Production, Exporter/ Importer & Donor Organisation

Industrial
3D Laser Scanning
3D Modelling
Asset Integrity Management
Capability Assessment
Civil & Construction
Condition Assessment
Dimensional Control
Education & Training
Engineering, Procurement & Construction
Failure Analysis & Forensic Investigation
Industrial Manufacturing Infrastructure
Maintenance In-Service Inspection
Non-Destructive Evaluations
Oil & Gas Technical Training
Operational Performance Improvement & QHSE Training & Consulting
Photogametry
Risk-based Inspection
Topographic Survey
Vendor Assessment
Vendor Inspection & Expediting

IT & Telecom
Central Office Equipment
Outside Plant Equipment
Mobile
Radio
Software
Wired Equipment
Wireless Equipment

Medical & Pharmaceutical
Accelerated Stress Testing (AST)
Accredited Persons (AP) Inspection Programme
Bioanalysis
CE Marking
cGMP Biopharmaceutical Analysis
cGMP Pharmaceutical Analysis
Electrical Safety Testing
Electromagnetic Compatibility (EMC) Testing
Environmental Compliance Services
Environment Qualification
Extractable Leachables Testing
FDA 510(k) Third Party Reviews
GLP Chemical, Pharmaceutical & Immunochemistry Investigation
Immunochemistry
In-Vitro Diagnostic Directive
KineticsTM (Integrated Clinical Bioequivalence & PK Programme)
Mechanical Testing of Medical Devices
Medical Device Directive
Metals & Inorganic Bioanalysis
Microbiology of Medical Devices to GMP
On-site Manufacturing Support & In-Service Failure Investigation
Performance & Benchmarking Testing
Pharmaceutical Auditing & Compliance
Pharmaceutical Process Safety Testing
Process Qualification Documents & Tests
Star of Life Ambulance Certification
Toxicology & Exposure Risk Assessment
Validation Services

Minerals
Mineral Sample Preparation
Precious Metals Analysis
Exploration Geochemistry
Minerals Environmental Services
Ore Grade Analysis
Mine-Site Laboratories
Coal Inspection & Testing
Minerals Cargo Inspection
Robotics & Automated Minerals Laboratory Systems

Textiles, Apparel & Footwear
Accessories
Apparel
Care Labelling
Chemicals
Footwear
Leather goods & Luggage
Product & Packaging Testing
Product, Process & System Inspection
Soft Home Furnishings
Textiles

Toys, Games & Hardlines
Accessories
Chemicals
Electronic & Electrical Products
Furnishings & Furniture
Gifts & Premiums
Hardlines
Home Appliances
Juvenile Products
Packaging & Packaging Materials
Premiums Testing
Product & Packaging Testing
Product, Process & System Inspection
Toys & Games

Intertek

Valued Quality. Delivered.

At Intertek, our time-tested service, wealth of experience, and depth of knowledge allow us to offer solutions dedicated to helping you navigate the regulatory process. Intertek delivers the precision you need, with the speed to market you are looking for.

For more information
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