FACT SHEET

MEDICAL DEVICE TESTING & SCIENTIFIC SUPPORT

CHEMICALS & MATERIALS SCIENCES

With over 30 years of experience in materials analysis and physical testing, we support medical device product development, regulatory submissions, and production. Our team of scientists and regulatory experts collaborate with global developers and manufacturers at every stage of a product's lifecycle, serving as a flexible, knowledgeable resource to advance your business.

Medical device testing, chemical analysis, and scientific support are essential throughout the lifecycle of medical devices, from clinical research and product development to regulatory submission and production. Medical device companies face numerous challenges in bringing safe and effective products to market, including materials characterization, contamination control, stability testing, problem-solving, failure resolution, and manufacturing quality control. As medical device innovation continues to advance to address the needs of an aging population, increased life expectancy, and chronic diseases, the integration of new technologies, materials, and scientific support solutions will be critical for a successful product launch.

Our medical device testing experts provide scientific solutions for wound care, stents, cardiovascular implants, dermal fillers, orthopaedic implants, bone cement, biomaterials, catheters, in vitro diagnostics, combination products such as pre-filled syringes or inhaled drug products, and dental or surgical instruments. With over 30 years of experience in materials science, mechanical testing, and chemical testing, our laboratories (GLP, GMP, and ISO 17025), as well as our scientists and engineers, provide lab service solutions to drive insight into your products and processes. Through the considered application of analytical methods, robust data generation and experienced data interpretation, our approach and scientific rationale can accelerate your product development and enable your regulatory submission. Our medical device testing network reacts rapidly and efficiently to resolve manufacturing issues or in-field customer complaints.

Material Characterization and Failure Analysis

Our materials scientists conduct comprehensive analytical studies on component and material microstructures, adhesives, and raw materials. We examine property relationships and perform mechanical testing on materials, devices, and packaging, including failure-in-service analysis. This materials analysis helps clients understand how raw materials affect product properties and provides a thorough understanding of structure-property-processing relationships. Microscopy, mechanical testing of device materials and packaging, and evaluate rheological properties and performance. Additional services include chemical imaging, fracture and failure investigation, contamination analysis, as well as metallurgy, corrosion, and chemical resistance studies. Intertek ensures compliance with ASTM and ISO standards for raw material validation.

We go beyond just "testing", responding accurately to your needs to help you to mitigate risks to your business

Manufacturing Crisis and Rapid Response

Our scientists strengthen 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.

Typical examples of how we can support medical device development and production include:

- Causes of material failure in devices and components
- Cleaning validation analysis support for medical device production
- Understanding of the distribution of drugs and excipients in materials and on surfaces
- Competitive analysis
- Migration of actives either by design or unintentional
- Contamination studies in devices and packaging
- Chemical and physical characterisation of development materials and surfaces

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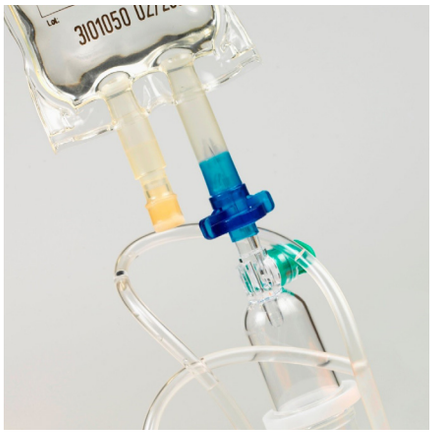
ISO 10993 Part 18 Chemical Characterisation of Medical Device Materials

The European Medical Device Regulation (EU MDR) came into force in 2021, bringing an increased focus on chemical characterisation testing of medical devices including extractables and leachables. In addition, the EU MDR regulations highlight the need for identification of carcinogenic, mutagenic and reprotoxic (CMRs) substances in extractions from the medical device in control and mitigate potential release of hazardous CMR substances during intended clinical exposure.

Supplier and raw material data help assess chemical composition, however processing aids, contaminants, and residues can all impact composition during production and storage. Innovators and manufacturers will need to characterize materials and constituents, with a particular focus on identifying potential risks to patient health including risks due to CMR substances.

ISO 10993 Part 18 outlines steps to identify and quantify extractables and leachables from medical devices. Extraction studies aim to create an extractables profile similar to the leachables profile. Study design depends on device class, usage, and contact time, with extraction conditions tailored to the "contact category." Methods include exhaustive, exaggerated, or simulated conditions, balancing between sufficient and overly aggressive extractions. Expertise is crucial for a scientifically sound study.

Leachables studies per ISO 10993-18 estimate actual chemical release using real or accelerated conditions (e.g., elevated temperatures). Substances identified in extractables studies are targeted, with additional screening for leachables using sensitive methods. Quantification uses multiple techniques for different compounds. Intertek's lab employs LC-MS for semi and non-volatiles, GC-MS/MS and Headspace GC-MS for volatiles, and ICP-MS for elemental analysis. Our consultants are experienced in toxicity risk assessments. The toxicological risk analysis (TRA) uses allowable limits, Safety Concern Thresholds (SCT), and Analytical Evaluation Thresholds (AET) for regulatory submission.



Our strength derives from the ability to combine an appropriate set of measurements for any given situation. Across a breadth of industries we apply these strengths to investigate and test, to bring you the insight you need to address quality, performance, failure, litigation, contamination, and regulatory issues.

Stability, Performance, Extractables and Leachables for Combination Devices

Our laboratories (GLP/GMP if required) provide assay development and validation for pharmaceutical drug product-device interactions and material compatibility, the evaluation of product interactions with packaging materials, and the identification of trace impurities or degradation pathways. We have world-leading expertise in orally inhaled and nasal drug product development, formulation, stability and assessment of device performance related to delivered dose.

Our expertise

Materials Science Research

We have the facility to work with you on longer-term materials research projects, for example targeted at the development or optimisation of new materials. Our materials characterisation, chemical imaging, measurement and processing expertise complement your internal strengths allowing you to focus on your core business needs.

Problem Solving

We apply our problem-solving skills where there is a need to investigate a material related problem such as product quality, performance or processability. Our scientists define an appropriate set of measurements, conduct often multi-discipline analysis programs to derive data-driven intelligence to help you identify and understand underlying issues or source of risks.

Method Development

Our highly skilled method development scientists have acquired years of experience, working across many types of products, methods and analytical technologies to ensure that the method for application to specific customer problems will be 'fit for purpose'. This has ranged from the adaptation of 'routine' measurements for novel sample types through to major projects on the development of on-line measurement tools.

CONTACT OUR EXPERTS NOW TO FIND OUT HOW WE CAN SUPPORT YOUR MEDICAL DEVICE DEVELOPMENT OR PRODUCTION.

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