

# Problem-Solving and Testing Services

for the Medical Device Industry

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.





Our laboratories are accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. Contact Intertek for a scope of accreditation.

### **Our Services**

- R&D Analytical Support
  - Polymeric mechanical property understanding through rheology and molecular weight differences
  - Trace metals, degradants, residual solvents, and volatile organic compounds (VOCs) in polymers and plastics
  - Connecting polymer chemistry with device performance
- Material Characterization/QC and Failure **Analysis** 
  - Quick turn, accredited data generationmechanical, physical, electrical, optical,

- Analytical, rheology, weathering, thermal, flammability (ASTM, ISO)
- Fracture and failure analysis
- Surface chemistry and adhesion
- Microstructure and mechanical property relationships
- Material deformulation
- Stability and Medical Device Testing
  - Elution and dissolution
  - Stability and storage
  - Extractables and leachables

## **Our Experience**

Examples span areas from polymeric components to electrical medical devices as well.

- Flectrical Medical Device
  - Benchmark new materials of construction
  - Identify unexpected residues on circuit boards, electrodes, syringes and other devices to determine cause of failure or source of contamination
  - Identify undesirable chemicals or metals in coatings or on surfaces
  - Characterize contaminants on seals or surfaces
  - Corrosion evaluation
  - Evaluate effect of environment factors (cleaning solutions, sterilization protocol) on device integrity

- Polymers (such as catheters, molded parts, device cases, seals, valves, dental, drug delivery devices, labels and packaging)
  - Batch-to-batch variability of polymer molecular weight and composition
  - Mechanical property impact in polymers with molecular weight changes, nanoparticle levels, API loading levels or other formulation changes
  - The effect of chemical exposure or environmental conditioning (heat and humidity) on impact resistance, rupture, or other failure modes for the device
  - Packaging and labeling evaluations including blocking or adhesion problems
  - Identification of unknown residues, impurities and fibers.

## The Intertek Advantage

Intertek supports the broad needs of the medical device industry through a global network of expertise delivering:

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

# **About Intertek**

Intertek is a leading provider of quality and safety solutions serving a wide range of industries around the world. From auditing and inspection, to testing, quality assurance and certification, Intertek people are dedicated to adding value to customers' products and processes, supporting their success in the global marketplace. Intertek has the expertise, resources and global reach to support its customers through its network of more than 1,000 laboratories and offices and 30,000 people in over 100 countries around the world.

7201 Hamilton Blvd.

Intertek

Allentown, PA 18195 **USA** 

291 RT 22 East, PO Box 470 Whitehouse, NJ 08888 USA

50 Pearl Street Pittsfield, MA 01201 USA

For urgent failure analysis testing needs in the US, please call 610-295-0148. For more information email us at: mddevice.testing@intertek.com.