



WHO WE ARE

We are Element, one of the world's leading independent providers of testing, inspection and certification services to a diverse range of industries, where failure "in service" is simply not an option.

We exist to help all of our customers to make certain that the materials and products that they make are safe, quality, compliant and ultimately fit for purpose using our 200 years of testing experience and our global testing capabilities.

That is the Certainty of Element.

OVERVIEW

UNIQUELY QUALIFIED

With over 190 laboratories worldwide and more than 6,700 experts, Element offers medical device product evaluation and mechanical testing services to medical device manufacturers.

In our ISO 17025 accredited medical laboratories, we work with medical device and pharmaceutical companies to complete everything from initial research and development studies to testing for full regulatory submissions and post market validations.

Element provides a comprehensive range of material, electrical and design characterization testing on orthopedic, cardiovascular, raw materials, and implantable, diagnostic and therapeutic equipment. Our engaged experts have experience in every stage of the process, understanding that decreasing time to market is key. As a result, we have designed our services as a partnership with our customers – driving down lead time, minimizing vendor management and working as an extension of your R&D and manufacturing teams. With the broadest range of technical services in the medical industry alongside a global platform, Element delivers solutions when and where you need them.

With changing regulatory environments in Europe and the US, our experts can help navigate questions, protocols, and provide regulatory submission support both internally and through our testing partners. We understand the challenges it takes to bring your device to market and our expertise can mitigate risk which results in better decisions, improved planning, and prevents delays and regulatory questions. Our experts routinely participate in ASTM, ISO and other technical committees, ensuring Element is at the forefront of the newest methods and trends.

OUR TESTING SERVICES

ORTHOPEDIC, SPINE & TRAUMA IMPLANT TESTING

- Static and fatigue loading
 - Axial
 - Torsional
 - Bending
 - Multi-axis
- Wear testing
- Biomechanical studies

CARDIOVASCULAR DEVICE TESTING

- Pulsatile fatigue
- Durability testing
- Radial force
- Peripheral stent gait motion simulation
- Nickel ion leaching

PACKAGING AND ENVIRONMENTAL TESTING

- ISTA shipping
- Accelerated aging
- Shelf life

PRODUCT TESTING

- Chemical resistance
- Foam testing (wheelchairs, gurneys, etc)
- Medical bed testing

EMC/EMI TESTING

- IEC 60601 & IEC 60601-1-2
- ANSI C63.27 wireless coexistence
- AIM 7351731 RFID immunity
- OTA 3D antenna testing & SAR
- Wireless testing & global approvals

MATERIALS TESTING

- Chemical analysis
- Microstructure
- Hardness
- SEM/EDS
- Tensile testing
- HCF/LCF
- Fracture mechanics
- Creep and rupture
- Non-destructive testing

MICROBIOLOGICAL TESTING

- Endotoxin
- Bioburden
- Cytotoxicity
- TOC (Total Organic Compound)
- Gravimetric Cleanliness Testing (Residual & Particulate)
- Water Analysis (HPC< LAL, RO/DI)

OTHER TESTING

- Corrosion
- Coatings and Adhesives
- Polymer testing
- Analytical testing
- Extractables and leachables
- Failure analysis
- Pharmaceutical method development and research
- Wear debris analysis particle counting
- Tissue and cadaveric testing
- Trace Metals Analysis

TYPES OF DEVICES TESTED

- Knee
- Spine
- Hip
- Extremity & trauma
- Dental
- Coatings
- Stents & grafts
- Heart valves
- Catheters
- Occluders and closure devices
- Pacemakers
- Stimulator leads
- Animal and human tissue
- Diagnostic equipment
- Therapeutic equipment
- Wireless equipment
- Pharmaceuticals
- Combination products
- Implantable Equipment

MATERIALS

- Titanium
- Stainless steel
- Cobalt chrome
- Nitinol
- Ceramics
- Polymers
- Composites
- Other materials

ADDITIVE MANUFACTURING SUPPORT

- Coupon testing
- Powder characterization
- Device validation

REGULATORY SERVICES

- Early Stage Qualification (ESQ)
- Regulatory Submission Support