

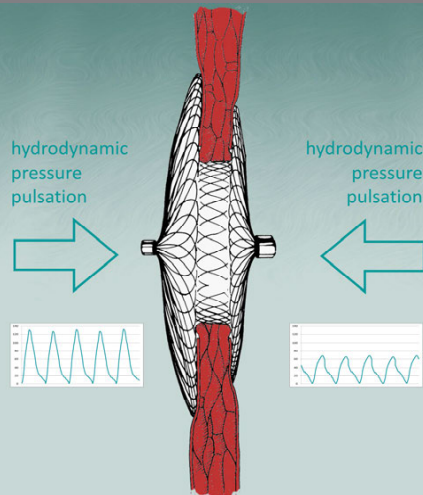
## The Company

**Questmed** offers specialized laboratory services for medical device manufacturers, focusing on the evaluation of *occluder performance*, *cardiac implants*, *ion release* and *surgical implants*. With over a decade of experience in the industry, we provide comprehensive static and dynamic testing of medical implants, including precise ion release assessments. Our expertise extends to the analysis and documentation of mechanical durability and functional integrity of *occluders*, *stents*, and *surgical implants* and *ion release behavior*.

As an international accredited test laboratory under ISO 17025, we ensure the highest standards of quality and reliability in our testing processes. Whether it's assessing the long-term stability of materials, simulating clinical conditions, or ensuring compliance with regulatory requirements, Questmed delivers accurate, detailed, and timely results tailored to your needs.



Deutsche  
Akkreditierungsstelle  
D-PL-18753-02-00



### Questmed GmbH (Headquarter)

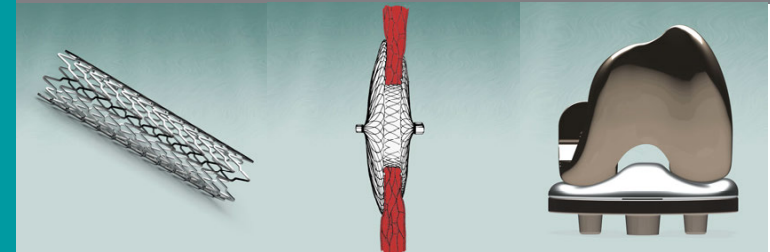
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questmed 



Testing of Medical Devices

## Methods

At **Questmed**, all ion release, occluder, stent, dental and surgical implant tests are conducted with the latest scientific and technological advancements.

We continually adapt our testing protocols to align with the newest international standards, ensuring that our procedures remain at the forefront of the industry.

Our testing processes are designed to replicate in-vivo conditions as closely as possible, providing reliable data on the performance and safety of medical devices under realistic scenarios.

We believe that rigorous testing, especially in areas like ion release behavior and mechanical integrity of occluders and surgical implants, is essential to enhancing patient safety. Furthermore, thorough testing can contribute to cost reductions in healthcare by preventing device failures and extending implant longevity.

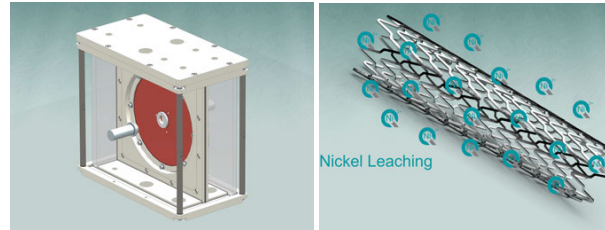
**Questmed** is committed to support manufacturers in delivering high-quality, reliable implants that meet the highest standards of safety and efficacy.

### Occluder

with experience since 2011 for testing of durability under axial and hydrodynamic load:

- Left Atrial Appendage Occluder (LAA)
- Atrial Septal Occluder (ASD)
- Patent Foramen Ovale Occluder (PFO)
- Patent Ductus Arteriosus Occluder (PDA)
- Ventricular Septal Occluder (VSD)
- Paravalvular Leak Occluder (PVL)
- Interatrial Shunt Device (IASD)
- Cardiac Patches or Strips

1.2 to 99 Hz, 10 to 400 million cycles, saline solution, up to 30 samples per test system, 6 test systems

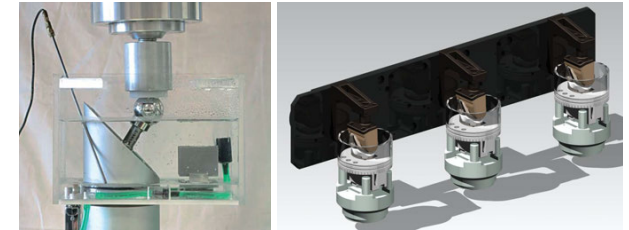


### Cardiovascular Implants

- ISO 22679: Occluder - Durability under axial and hydrodynamic load
- ISO 25539-1, ISO 25539-2: Stent – Fatigue and Durability
- ISO 25539-3: Vena Cava Filter IVC – Fatigue and Durability:
- ASTM F3211: Fatigue-to-Fracture

### Ion release - Nickel leaching - Corrosion

- ASTM F3306: Ion release - Nickel leaching of medical implants like cardiovascular devices, endovascular devices, orthopedic implants and more
- ASTM F2129: Cyclic Potentiodynamic Polarization
- ASTM F3044: Galvanic Corrosion of two dissimilar metal components in contact with one another
- ISO 10271: Corrosion test of Dental Implants



### Joint Replacement

- Knee, Ankle, Shoulder, Hip, Elbow, Finger: Wear, Fatigue, Durability, Strength

### Spinal Implants

- ASTM F1717: Spinal Implant Constructs
- ASTM F2077: Intervertebral Body Fusion Device
- ASTM F2193: Spinal Surgical Fixation

### Osteosynthesis

- ASTM F382: Bone Plate
- ASTM F543: Bone Screws
- ASTM F3437: Small Bone Plates
- ASTM F1264: Intramedullary Rods

### Dental implants

- ISO 14801: Fatigue of Endosseous Dental Implants
- ISO 13017: Magnetic Attachments

1 N to 10 kN, up to 90 Hz, 18 test systems