



PRODUCT TESTING

What is Product Testing?

Laboratory product testing is a means of characterizing a medical device under simulated conditions. Characteristics evaluated can vary from electrical to mechanical to chemical, depending on the type of device or criteria under assessment.

What is Product Testing Used For?

The most common reason for product testing is to verify that a medical device meets the defined product design specifications. Specifications are set to ensure that safety, efficacy, and reliability requirements are adequately addressed. Tests are prescribed by notified bodies with reference to international standards.

Our product testing services include:

- Electrical safety (IEC 60601/61010)
- Luer connector (ISO 80369-7)
- Fatigue/life cycle testing
- Dimensional verification
- Horizontal force testing:
 - Deployment
 - Delivery
 - Retrieval
 - Frictional mapping

- Trackability
- Environmental simulation
- Tensile/torque strength
- Balloon and tubing burst pressure

Benefits of Product Testing

Testing a product through an independent laboratory helps ensure conformance to international standards and industry best practices. Customers can expect the following benefits with STERIS:

- Testing support services
- Verification of all applicable test standards
- Ability to tailor standardized tests to specific product requirements
- Advanced custom test development capabilities
- Wide range of ISO17025 accredited tests
- In-house 3D printing capability

STERIS provides support throughout medical device research and development as well as qualification activities. Support begins with early-stage technical feasibility assessments, throughout the research and development phases, device verification and validation (V&V), manufacturing, market approval and post-market surveillance.



FOR MORE INFORMATION

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