# Reusable Device Testing

### What is Reusable Device Testing?

Reusable device testing is a regulatory requirement for reusable medical devices, and single-use medical devices that are prepared at the point of use prior to patient use. Reusable device testing demonstrates that:

- Reusable medical devices can be safely and effectively processed between patient use
- Single-use devices can be safely and effectively processed at the point of use prior to patient use

### What is Reusable Device Testing Used For?

Reusable device testing is used to demonstrate the efficacy of recommended cleaning, disinfection, and/or sterilization processes indicated by the device manufacturer in their device instructions for use (IFU). By complying with the validation testing indicated in industry standards and guidance, medical device manufacturers and their regulatory bodies can be assured these types of medical devices can be effectively cleaned, disinfected, and/or sterilized between patient uses.

Some examples of products tested include:

- Instruments used for:
  - o Orthopedic procedures
  - o Dental procedures
  - o Laparoscopic procedures
  - o Cardiac procedures
  - o ENT procedures
  - o OB-GYN procedures
- Ultrasound probes
- Electrical and fiberoptic cables
- Medical equipment:
  - o Screens and monitors
  - o Light sources
  - o Infusion pumps
  - o Pulse-ox and glucose sensors

### Standards

STERIS complies with the following industry standards and guidance for reusable device testing including:

- ISO 17664-1
- ISO 17664-2
- ANSI/AAMI ST98
- AAMI TIR12
- FDA guidance document: Reprocessing Medical Devices in Health Care Settings:Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff

### At STERIS, our Reusable Device Testing Services Include Validation of:

- Automated, manual, and mechanical (manual with sonication) processes
- Moist heat (steam), vaporized hydrogen peroxide (VHP), and dry heat sterilization processes
- Processing fatigue simulation, which includes repeated cleaning, disinfection, and/or sterilization designed to artificially age the device for end-of-life and functionality testing

### Benefits of Reusable Device Testing

Testing reusable or single-use medical devices through an independent laboratory supports conformance to domestic and international testing standards, guidance, and industry best practices.

STERIS's reusable device testing services include:

- Compliance to applicable standards and guidance
- Customized process validation services (tailoring standardized testing to specific device requirements)
- Identification of device design or process limitations, which could affect the efficacy of the recommended processing instructions

To assure efficient and effective validation testing, the STERIS reusable device testing team prepares highly customized protocols and final reports to outline proposed test plans and to summarize testing results demonstrating compliance to industry standards and guidance.

## FOR MORE INFORMATION

**STERIS Applied Sterilization Technologies**
Web: steris-ast.com
Email: ast_info@steris.com
(EMEA-APAC) +44 330 236 8344
(Americas) 877.783.7479

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