Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

## From the Blog

# Validating Cleaning & Disinfection of Reusable Medical Devices

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At Medistri, we help healthcare manufacturer ensure that their reusable medical devices are not only safe to use — but also scientifically validated to be cleaned, disinfected, and reprocessed effectively between uses. With the increasing scrutiny from international regulators such as the European Commission and the U.S. FDA, manufacturers must go beyond intuitive instructions and provide robust, validated reprocessing procedures. These procedures must comply with strict standards such as ISO 17664, AAMI ST98, and the ISO 15883 series.

**Reprocessing: A Critical Phase in Device Safety**
Reusable devices — from surgical forceps to flexible endoscopes — must undergo validated reprocessing between uses to ensure they remain safe, functional, and compliant.

Reprocessing validation includes the demonstration that:
- The device can be effectively cleaned and disinfected
- It can be reprocessed multiple times without compromising function or safety
- The instructions for each reprocessing step are clear, testable, and repeatable

In many cases, functional integrity testing is conducted in parallel with or following cleaning validation to ensure that repeated cycles do not degrade performance or introduce risks.

**Cleaning & Disinfection Validation at Medistri**
Medistri's ISO 17025-accredited laboratory designs and executes tailored studies to demonstrate that your reprocessing instructions are safe, effective, and reproducible.

**Cleaning Validation:**
We assess the removal of organic, chemical, and particulate residues using validated methods including:
- Total Organic Carbon (TOC)
- Protein & Hemoglobin Assays
- Hydrocarbon Testing (HCT)
- Particle Testing
- Visual Inspection

**Disinfection Validation:**
Confirms the microbiological efficacy of high-level or low-level disinfection processes:
- Bioburden Reduction Studies
- Endotoxin Testing (LAL / rFC)
- Neutralizer Validation

**Integrated Reprocessing Validation: Beyond Cleanliness**
For many reusable devices, it is essential to verify that repeated reprocessing cycles — including soiling, cleaning, and disinfection — do not compromise device integrity.

At Medistri, we support manufacturers by integrating cycle-based reprocessing simulations (e.g. 10, 20, or 50 cycles) into our validation studies. Alongside chemical and microbiological assessments, we can perform:
- Visual inspections to detect changes in surface appearance or material degradation
- Mechanical observations such as flexibility or structural response
- Surface characterization to identify residual buildup or wear across reprocessing cycles

These evaluations are conducted within the scope of cleaning and disinfection validation and can provide early indicators of potential device impact. For more advanced or performance-specific testing, manufacturers typically apply their internal qualification protocols.

**Applicable Standards: ISO 17664, ST98, and ISO 15883**
Medistri's validation services are based on the most widely recognized international standards:

- **ISO 17664:2017 –** Specifies the content manufacturers must include in reprocessing instructions (cleaning, disinfection, inspection, packaging, sterilization)
- **AAMI ST98:2022 –** Defines how to develop and validate Instructions for Use (IFUs) for reusable devices, including performance validation after reprocessing
- **ISO 15883 series –** Governs automated cleaning and disinfection systems such as washer-disinfectors:
  - Part 1: General Requirements
  - Part 2: Instruments and accessories
  - Part 4: Thermolabile endoscopes
- **ISO 14937 –** Applies where disinfection achieves sterilization-level microbial inactivation
- **ISO 11737-1 –** Used to define pre-disinfection bioburden levels in validation (not as a cleanliness indicator)

**Partnering with Medistri**
Medistri provides an end-to-end service that aligns your reprocessing instructions with international regulations and delivers traceable, reproducible evidence for notified bodies and regulatory agencies.

By choosing Medistri, you benefit from:
- ISO 17025-accredited methods
- Support for both functional and analytical validation
- Fast turnaround times and personalized consultation
- Full protocol development and reporting

Contact our team at contact@medistri.com to learn how we can support your cleaning, disinfection, and reprocessing validation strategy.

— The Medistri Team

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