What You Need to Know - AS 5369:2023 Reprocessing Reusable Medical Devices

Overview

AS 5369:2023 is the new standard for the reprocessing of reusable medical and other devices in both health and non-health-related facilities. It supersedes AS/NZS 4187:2014 and AS/NZS 4815, which have now been formally withdrawn by Standards New Zealand.

The shift reflects international best practice and provides clearer, risk-based guidance for safe and effective sterilisation, disinfection, and cleaning of medical devices.

Why the Change?

AS/NZS 4187 was introduced nearly 30 years ago, and while foundational, it has since become outdated. AS 5369:2023 introduces:

- Modernised guidance, including an improved structure and flowchart to support implementation
- Stronger emphasis on validation and performance qualification
- A clearer link to infection prevention and patient safety

Key Features of AS 5369:2023

Feature	What's new
Product Families	Devices are grouped by steam penetration resistance (SPR), with a 'master' product used for testing
Spaulding Classification	Clear categorisation of devices (Critical, Semi-critical, non-critical) informs the required level of reprocessing
Validation & Monitoring	Emphasises test loads, performance qualification (PQ), and effective sterilisation of grouped devices
Risk-Based Focus	Strong alignment to infection risk and end-user safety

Who is this Standard For?

- Hospitals and surgical facilities
- Day-stay and procedure clinics
- Dental and oral health practices
- Veterinary services
- Office-based procedure settings
- Stand-alone sterilisation services
- Any facility reprocessing reusable medical devices

Benefits of Certification to AS 5369

- Improves safety and infection control
- Demonstrates compliance with the current, contemporary national standard
- Reduces risk of infection-related incidents and supports quality assurance and risk management

- Strengthens systems for validation, documentation, and traceability
- The standard builds confidence among consumers, regulators and funders, including the Ministry of Health (Manatū Hauora), Health New Zealand (Te Whatu Ora), the Accident Compensation Corporation (ACC), and private health insurers.
- Provides sector recognition through NZSSA and certified CABs
- Aligns with global best practice

About the proposed Certification Scheme

This new national certification scheme will be finalised under the guidance of an Oversight Committee, including:

- NZ Sterile Sciences Association (NZSSA)
- Ministry of Health
- Private surgical provider representation
- Designated Audit Agency representatives

Certification is delivered by approved Conformity Assessment Bodies (CABs) authorised under the Health and Disability Services (Safety) Act 2001 and approved by the Oversight Committee.

Interested in Certification?

If your facility reprocesses reusable medical devices, we encourage you to:

- Understand how AS 5369 applies to your setting
- Review your current processes against the updated standard
- Express interest in becoming certified
- Contact Victoria Aliprantis mobile 021 783 853 or email victoria@vicconsulting.co.nz to discuss next steps or request more information.

References:

- Australian Standards:
  - Reprocessing of reusable medical devices and other devices in health and non-health related facilities
  - Spotlight On: AS 5369:2023, Reprocessing of reusable medical devices and other devices in health and non-health related facilities
- Australian Commission on Safety and Quality in Health Care:
  - Transitioning from AS/NZS 4187:2014 to AS 5369:2023 (August 2024)
  - Reprocessing reusable medical equipment gap analysis tool (2025)
- Health New Zealand Te Whatu Ora Infection prevention and control
- Te Tāhū Hauora Health Quality and Safety Commission National infection prevention and control programme