



## Reprocessing Validations

The importance of ensuring your products and instruments are clean and sterile every time they come into contact with a patient or end user cannot be overstated. The burden of responsibility falls on the manufacturers of finished medical devices to provide clear, understandable and reproducible cleaning and sterilization protocols that have been validated to be effective.

With more than 30 years of experience in this field, Eurofins Medical Device Testing offers a broad range of microbiological, bio-/chemical and toxicological testing to examine products for the intended reprocessing procedures according to ISO 17664 to validate procedures for manual and automatic cleaning, disinfection and sterilization.

### Choose Eurofins Medical Device Testing to help you:

- Evaluate the effectiveness of your cleaning, disinfecting and sterilization protocols
- Select the most appropriate test soil or organism to simulate practical use
- Identify inoculation sites on your instruments which represent worst case challenges
- Optimize your Instructions for Use
- Complete your regulatory dossiers with proven validation reports

### Testing Available

- Manual and Automatic Cleaning\*
  - Quantitative determination of protein by BCA test
  - Quantitative determination of TOC (total organic carbon)
- Chemical and Thermal Disinfection
  - Vegetative test organisms (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella-Enterobacter*) for chemical disinfection requirements according to regional regulations
  - Vegetative test organism (*Enterococcus faecium*) for thermal disinfection



- Mycobacterium terrae for high level disinfection
- Sterilization
  - Half and full cycle method as well as alternative methods using bioindicators
- Chemical Residuals
  - Test for Cytotoxicity

\* For the evaluation of the cleaning procedures one parameter is sufficient in Europe. For the registration by the FDA, two parameters have to be examined.

### Instrumentation

- Cleaning Equipment (all sizes of brushes, syringes, cleaning pistols, etc.)
- Large ultrasound bath
- TOC Analyzer (TOC determination)
- TECAN Reader (protein determination)
- MIELE Washer-Disinfector (processes validated according to ISO 15883)
- Vario TD Program Alkaline Cleaning (low or high)
- Enzymatic Cleaning
- Thermal Disinfection
- MMM Hospital Sterilizer (medium-sized) (Processes validated according to EN 285)
  - Moist heat sterilization
  - Fractional prevacuum
  - Other programs possible