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Evaluation of Reusables for their intended Reprocessing Procedure

Following DIN EN ISO 17664 manufacturers are obliged to indicate one validated procedure of manual and automatic cleaning, disinfection and sterilization.

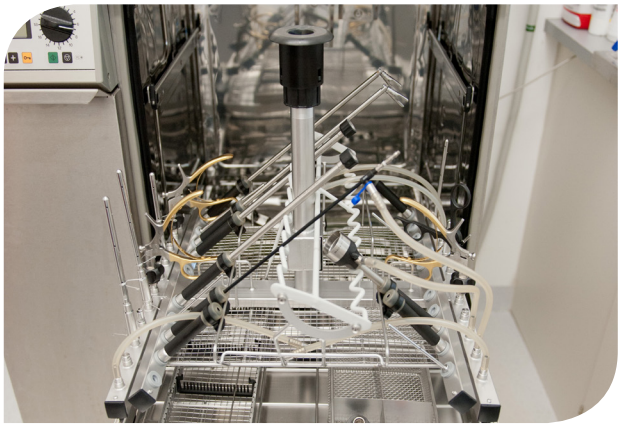
With more than 20 years of experience in this field **Eurofins BioPharma Product Testing Munich** offers a broad range of microbiological, bio-/chemical and toxicological test systems to examine the clients' products for the intended reprocessing procedures.

Depending on the aim of the study and the regulatory requirements the tests are individually designed for each product.

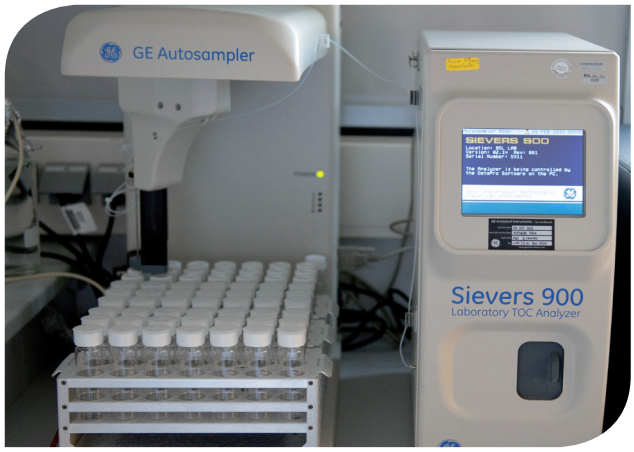
Eurofins BioPharma Product Testing Munich works closely together with its clients in order to make the most suitable choice regarding the contamination/inoculation of the products, the performance of the reprocessing and the process parameters etc.

Whatever cleaning or disinfection procedure is needed within the individual study (either manual cleaning and manual/chemical cleaning and/or automatic cleaning and disinfection) all products are contaminated with a test soil simulating the practical use and/or are inoculated with the appropriate test organism.

Contaminated and/or inoculated products are cleaned, disinfected or sterilized. Residuals are determined by different methods, e.g. protein determination, determination of TOC (total organic carbon) and/or counting of surviving organisms. The results are afterwards evaluated by a defined set of evaluation criteria.



Detailed reports help clients with the world-wide registration of their products, with the optimization of their instructions for use and with fulfilling marketing needs.



Equipment

- Cleaning Equipment
  (All sizes of brushes, syringes, cleaning pistols etc.)
- Big sized ultrasound bath
- TOC Analyzer
  (TOC determination)
- TECAN Reader
  (Protein determination)
- MIELE Washer-Disinfector
  (Processes validated according to DIN EN ISO 15883)
- Vario TD Program
  - Alkaline Cleaning
    (Slight or high)
  - Enzymatic Cleaning
  - Thermal Disinfection
  - Other programs possible
- MMM Hospital Sterilizer
  (middle-sized)
  (Processes validated according to DIN EN 285)

  In cooperation with MMM
  - Moist heat sterilization
  - Fractional prevacuum
  - Other programs possible

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Test Systems 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*) for standard (low level acc. to US requirements) chemical disinfection
- 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!

Global Services:

Biocompatibility according to ISO 10993
Hemocompatibility Testing
Microbiology
Extractable and Leachable Testing
Evaluation of Reusables
Professional Scientific Services

Our Sites in Germany:

Eurofins BioPharma Product Testing Munich GmbH
Behringstraße 6-8
D-82152 Planegg near Munich

Eurofins Fintelmann & Meyer GMP GmbH
Großmoorbogen 25
D-21079 Hamburg

Phone: +49 89 899 650 0
Email: info-munich@eurofins.com
www.eurofins.com/medical-devices