Hygienic reprocessing of medical devices is of high importance for manufacturers, operators and patients. Therefore detailed user manuals containing reprocessing instructions need to be provided to those who use these devices. The requirements for these instructions are described in the new MDR (Medical Device Regulation) and international standards, such as EN ISO 17664, and they are more rigorously monitored by certification bodies. The validation of reprocessing instructions guarantees that the reprocessing procedures are effective and yield reproducible results.

Laboratories carrying out the validation effort must be experienced in setting up a suitable validation concept. Depending on the reprocessing procedures they need to be familiar with a variety of national and international regulations and standards, describing procedures and laboratory methods. Of fundamental importance here are among others:

- National and international standards
- FDA guidelines
- National guidelines
- Laws and Regulations

In order to plan the validation and the documentation, the laboratory works closely with the manufacturer of the medical devices. It has shown to be beneficial to follow a risk-based approach in order to avoid examining every single aspect with each instrument.

Based on the following characteristics, instruments are classified and a ‘worst-case’ scenario based on representative instruments is developed.

- reprocessing methods
- applicable standards and regulations
- specific product properties, e.g. materials and geometry
- field of application and potential test soils
- chemical and microbiological examination methods

The validation plan describes the exact steps of the classification, the ‘worst case’ definition and the type of necessary documentation. For analysis, chemical or microbiological methods are typically applied.

- residual protein analysis using the oPA or BCA method
- microbiological analysis using Bacillus atrophaeus, Enterococcus faecium and Geobacillus staerothermophilus

The examination report summarizes the overall procedure and the results based on the validation plan.