

SAL-GmbH • Feldstr. 14 • D-61479 Glashütten

HM 4.4-01-01-11 V02 Rückfragen Validierung 17664.docx

# Questionnaire for validation projects according to ISO 17664

Dear Sir or Madam,

Thank you for your interest in a validation of your cleaning, disinfection or sterilization processes according to ISO 17664.

In order to offer a custom-fit validation service we require a sample of your medical device at our site. For a fist estimate you can assist us by answering the questions listed below as far as applicable.

If you require assistance answering the questionnaire we will gladly support you!

Your validation team

SAL-GmbH

GF: Dr. Danja Kühn Reg. Ger.: 61462 Königstein

USt-Ident-Nr.: DE 114127819



### **Technical product information:**

- Manufacturer and product name
- Design drawing and photos
- Possibly details about special features as gaskets etc.

#### Information about the cleaning process:

•	Which type of cleaning process is used?  ○ □ manual ○ □ automated (WD)
•	Which cleaning program is used (specify parameters time, temperature, and dosage in all process steps)?
•	Which type of cleansing agent (alkaline, enzymatic) is used?
•	How is he device placed inside the washer disinfector? Are special adapters used?



### Information about the disinfection process:

•	0	e of disinfection process is used? □ manual □ automated (WD)
•	Which dis	infecting mechanism is used? □ thermo-disinfection □ chemical
•	Which dis	infection program is used (specify parameters time, temperature, and dosage in steps)?



# Information about the sterilization process:

•	Which sterilization method is used?
	○ □ steam
	○ □ dry heat
	○ □ ethylene oxide
	○ ☐ formaldehyde
	○ □ hydrogen peroxide
	o □ other:
•	Which sterilization program is used (specify parameters time, pressure, temperature, and possibly dosage in all process steps)?
•	How are medical devices packaged for sterilization?
	How is the medical device to be sterilized (assembled or disassembled, valves opened or closed, etc.)?