Deutsche Akkreditierungsstelle GmbH

Annex to the accreditation certificate D-PL-18398-02-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **01.11.2021**

Date of issue: 26.09.2022

Certificate holdrer:

SAL GmbH
Feldstraße 14, 61479 Glashütten

At the location:

Auf der Lind 10, 65529 Waldems

Field:	Medical Devices
Testing areas:	Microbiological-hygienic testing of medical devices and microbiological-hygienic including physical testing of cleaning and disinfection procedures as well as sterilization procedures; environmental monitoring

The requirements for the management system in DIN EN ISO/IEC 17025 are written in a language relevant for testing laboratories and are overall in accordance with the principles of DIN EN ISO 9001. The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation is available in the database of accredited bodies of the Deutsche Akkreditierungsstelle GmbH.
https://www.dakks.de/content/accredited-bodies-dakks

Abbreviations used: see last page

Location Waldems

Testing area	**Test item** **Device (category)**	**Type of testing** **Test**	**Regulation** **Testing method**
Microbiological hygienic tests	Medical devices	Testing the resistance of reference germs as a function of medical device properties and sterilization	PA 6.1-10-01 PA 6.1-10-02 VA 6.1-10
		- with moist heat	DIN EN ISO 11138-3 PA 6.1-02-09 PA 6.1-02-01
		testing the resistance of reference germs as a function of medical device properties and sterilization	PA 6.1-02-09 PA 6.1-01-10 VA 6.1-10
		- Dry heat	DIN EN ISO 11138-4 PA 6.1-02-02
		- Ethylene oxide	DIN EN ISO 11138-2 PA 6.1-02-03
		- Low temperature steam and formaldehyde (LTSF)	DIN EN ISO 11138-5 PA 6.1-02-05
		- Hydrogen peroxide	PA 6.1-02-04 Applicable: DIN EN ISO 11138-1 DIN EN ISO 11138-7 DIN EN ISO 11737-1 USP <55>
		Testing the inactivation of bacterial endospores on inoculated products.	
		- Direct inoculation	PA 6.1-10-05 (DIN EN ISO 11737-2)
		- Membrane filtration	PA 6.1-10-06 (DIN EN ISO 11737-2)

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Sterilization process	Validation	
	- with moist heat	Installation qualification Operation qualification Performance qualification	DIN EN ISO 17665-1 VA 6.3-30 PA 6.3-30-01 PA 6.3-30-02 PA 6.3-30-03 Applicable: DIN EN 13060 DIN EN 285 DIN 58951-2
	- with dry heat	Installation qualification Operation qualification Performance qualification	DIN EN ISO 20857 VA 6.3-31 Applicable: DIN EN ISO 14937
	Cleaning and disinfection procedures	Validation	DIN EN ISO 15883-1 VA 6.3-10 PA 6.3-10-04 PA 6.3-10-08
	- with thermal disinfection for chir. instruments, anesthesia equipment, vessels, utensils, glassware	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-2 Applicable: DIN ISO/TS 15883-5 KRINKO/BfArM-Recommendation Preparation MD

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Medical devices, information for reprocessing	Checks as part of the validation of information provided	DIN EN ISO 17664
		Cleaning / Disinfection	VA 6.3-10 VA 6.3-02 PA 6.3-10-04
		Sterilization with	VA 6.3-02 PA 6.1-10-01 PA 6.1-10-04
		- moist heat	VA 6.3-30
		- Dry Heat	VA 6.3-31
		Drying	VA 6.3-02
Environmental monitoring in manufacturing and testing of cleanliness of products according to DIN EN ISO 13485:2016, para. 6.4 and para. 7.5			
Microbiological-hygienic tests	Medical devices Biomaterials	Estimation of the population of microorganisms on products (Bioburden determination) - Membrane filter method - Spatula method - Plate casting process	DIN EN ISO 11737-1 Ph. Eur. 2.6.12 USP <61>

Regulations

DIN EN 285: 2016-05	Sterilization - Steam sterilizers - Large sterilizers
DIN EN ISO 11138-1: 2017-07	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
DIN EN ISO 11138-2: 2017-07	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)
DIN EN ISO 11138-3: 2017-07	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)
DIN EN ISO 11138-4: 2017-07	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-4:2017)
DIN EN ISO 11138-5: 2017-07	Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam formaldehyde sterilization processes (ISO 11138-5:2017)
DIN EN ISO 11138-7: 2019-11	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results (ISO 11138-7:2019)
DIN EN ISO 11737-1: 2018-11	Sterilization of medical devices - Microbiological methods - Part 1: Determination of the population of microorganisms on devices (ISO 11737-1:2018)
DIN EN ISO 11737-2: 2020-07	Sterilization of medical devices - Microbiological methods - Part 2: Tests for sterility in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
DIN EN 13060: 2019-02	Small steam sterilizers
DIN EN ISO 14937: 2010-03	Sterilization of health care products - General requirements for the characterization of a sterilizing agent and for the development, validation and control of the application of a sterilization process for medical devices (ISO 14937:2009)
DIN EN ISO 15883-1: 2014-10	Washer-disinfectors - Part 1: General requirements, terminology and test methods (ISO 15883-1:2006 + Amd 1:2014)
DIN EN ISO 15883-2: 2009-09	Washer-disinfectors - Part 2: Requirements and test methods for washer-disinfectors with thermal disinfection for surgical instruments, anaesthetic equipment, vessels, utensils, glassware, etc. (ISO 15883-2:2006)

DIN ISO/TS 15883-5: 2006-02	Washer-disinfectors - Part 5: Test soils and methods to demonstrate cleaning efficacy (ISO/TS 15883-5:2005)
DIN EN ISO 17664: 2018-04	Reprocessing of health care products - Information to be provided by the medical device manufacturer for the reprocessing of medical devices (ISO 17664:2017)
DIN EN ISO 17665-1: 2006-11	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
DIN EN ISO 20857: 2013-08	Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)
DIN 58951-2: 2018-01	Sterilization - Steam sterilizers for laboratory sterilization processing - Part 2: Equipment requirements, constructional requirements and requirements for the operating equipment
KRINKO/BfArM-Recommendation Preparation MD	Medical devices, recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) Bundesgesundheitsbl. 2012, 55: 1244-1310.
Ph. Eur. 9, 2.6.12	Counting the total number of reproducible germs
USP 42 <55>	Biological indicators: resistance performance tests
USP 42 <61>	Microbiological Examination of nonsterile products: microbial enumeration tests
AA 6.3-10-01	Production test specimen RDG
PA 6.1-01-10	Determination of growth inhibition by solid samples
PA 6.1-02-01	Resistance determination - moist heat
PA 6.1-02-02	Resistance determination - Dry air
PA 6.1-02-03	Resistance determination - ethylene oxide
PA 6.1-02-04	Resistance determination - hydrogen peroxide
PA 6.1-02-05	Resistance determination - Formaldehyde
PA 6.1-02-09	Determination of the D-value for germs in suspensions
PA 6.1-10-01	Inoculation and validation of the recovery
PA 6.1-10-02	Influence of the germination by substances of the product
PA 6.1-10-04	Determination of the population on a product
PA 6.1-10-05	Testing the inactivation of bacterial endospores on inoculated products by direct loading.

PA 6.1-10-06	Testing the inactivation of bacterial endospores on inoculated products by membrane filter test.
PA 6.3-10-04	Determination of the protein content of blood smears
PA 6.3-10-08	Quantification hemoglobin
PA 6.3-30-01	Steam quality test for non-condensable gas
PA 6.3-30-02	Steam quality test for dryness
PA 6.3-30-03	Checking the steam quality for overheating
VA 6.1-10	Qualification of medical devices for reprocessing
VA 6.3-02	Validation of processes for reprocessing medical devices according to ISO 17664
VA 6.3-10	Validation of cleaning, disinfection and drying processes
VA 6.3-30	Validation of sterilization processes with steam
VA 6.3-31	Validation of sterilization processes with hot air

Abbreviations

AA	Work instruction of SAL GmbH
BfArM	Federal Institute for Drugs and Medical Devices
DIN	German Institute for Standardization
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardardization
KRINKO	Commission for Hospital Hygiene and Infection Prevention
Ph. Eur.	Pharmacopoeia European
PA	Test instruction of SAL GmbH
TS	Technical Standard
USP	United States Pharmacopeia
VA	Process instruction of SAL GmbH

[1] DIN EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories