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Annex to the Accreditation Certificate D-PL-18398-02-02 according to DIN EN ISO/IEC 17025:2005[1] and the Directive 93/42/EEC[2] and 90/385/EEC[3]

Period of validity: 26.02.2018 to 25.02.2023 Date of issue: 26.02.2018

Holder of certificate:

SAL GmbH
Feldstraße 14, 61479 Glashütten

At the location:
Auf der Lind 10, 65529 Waldems

Field:	Medical devices
Testing fields/test items:	Microbiological-hygienic testing of medical devices, Microbiological-hygienic including physical testing of cleaning and disinfection processes as well as sterilization processes and physical testing of sterile barrier packaging and packaging systems, environmental monitoring

Abbreviations used: see last page

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Medical devices	Determining the resistance of reference germs depending on the characteristics of medical devices in sterilization processes with	PA 6.1-10-01 PA 6.1-10-02 VA 6.1-10
		- Moist heat	DIN EN ISO 11138-3 PA 6.1-02-09 PA 6.1-02-01
		- 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 Also applicable: DIN EN ISO 11138-1 DIN EN ISO 14161 DIN EN ISO 11737-1 USP <55>
		Sterility Test - Membrane filtration - Direct inoculation	DIN EN 11737-2 PA 6.1-10-06 PA 6.1-10-05

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic test including physical tests	Sterilization processes	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 Also applicable: DIN EN 13060 DIN EN 285 DIN 58951-2
	- with ethylene oxide	Installation qualification Operation qualification Performance qualification	DIN EN ISO 11135 VA 6.3-32 Also applicable: DIN EN ISO 14937 DIN EN 1422
	- with low temperature steam and Formaldehyde (LTSF)	Installation qualification Operation qualification Performance qualification	DIN EN ISO 25424 VA 6.3-33 Also applicable: DIN EN ISO 14937
	- with dry heat	Installation qualification Operation qualification Performance qualification	DIN EN ISO 20857 VA 6.3-31 Also applicable: DIN EN ISO 14937
	- with hydrogen peroxided	Installation qualification Operation qualification Performance qualification	DIN EN ISO 14937 VA 6.3-34

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic test including physical tests	Cleaning and disinfection processes	Validation	DIN EN ISO 15883-1 VA 6.3-10 PA 6.3-10-04 PA 6.3-10-05 PA 6.3-10-06
	- with thermal disinfection for surgical instruments, anesthetic devices, containers, paraphernalia, glass devices	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-2
	- with chemical or thermal disinfection for thermolabile endoscopes	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-4 AA 6.3-10-01 AA 6.3-10-02 AA 6.3-10-03 PA 6.3-10-06 PA 6.3-10-07 Also applicable: DIN ISO/TS 15883-5 KRINKO/BfArM-Empfehlung Aufbereitung MP
	Medical devices, Information for reprocessing	Tests to validate processes defined in the information for reprocessing	DIN EN ISO 17664
		Cleaning / Disinfection	VA 6.3-10 VA 6.3-02 PA 6.3-10-04 PA 6.3-10-05

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic test including physical tests	Medical devices, Information for reprocessing	Tests to validate processes defined in the information for reprocessing	DIN EN ISO 17664
		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
		- ethylene oxide	VA 6.3-32
		- formaldehyde	VA 6.3-33
		- hydrogen peroxide	VA 6.3-34
		drying	VA 6.3-02
		packaging/storage	VA 6.1-04 Also applicable: DIN EN 556-1
Physical tests	Sterile barrier and packing systems, materials	Tests to prove compliance	DIN EN ISO 11607-1
		- compatibility with sterilization with • moist heat • dry heat	DIN EN 868-5 AA 6.1-04-01
		- strength of the seal joint	DIN EN 868-5 PA 6.1-04-08 PA 6.1-04-09 VA 6.3-20
		- color change of the process indicator	DIN EN 868-5 AA 6.1-04-03
		- testing of plastic laminated films for capillary holes	DIN 58953 PA 6.1-04-05

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical tests	Sterile barrier and packing systems, materials	Tests to prove compliance - Peel characteristics of paper-plastic-laminates - suitability for storage and transport	DIN EN ISO 11607-1 DIN EN 868-5 PA 6.1-04-07 DIN EN 868-5 AA 6.1-04-02
Environmental control of the production and testing on the hygienic conditions of the products according DIN EN ISO 13485 : 2012[4] / DIN EN ISO 13485:2016[5], Para. 6.4 und Para. 7.5			
Microbiological hygienic tests	Medical devices Biological materials	Estimation of the population of microorganisms on products (Bioburden determination) - Membrane filtration method - Spread plate method - Pour plate method	DIN EN ISO 11737-1 Ph. Eur., 2.6.12 USP <61>

Regulations[6]

DIN EN 285 : 2016-05	Sterilization – Steam sterilizers – Large sterilizers
DIN EN 556: 2002-03 DIN EN 556 Bertg. 1 : 2006-12	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
DIN EN 868-5 : 2009-09	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
DIN EN 1422 : 2014-08	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
DIN EN ISO 11135 : 2014-10	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN EN ISO 11138-1 : 2006-09 DIN EN ISO 11138-1 Bertg. 1 : 2008-08	Sterilization of health care products - Biological indicators - Part 1: General requirements
DIN EN ISO 11138-2 : 2009-09	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
DIN EN ISO 11138-3 : 2009-09	Sterilization of health care products - Biological indicators - Part 3:

	Biological indicators for moist heat sterilization processes
DIN EN ISO 11138-4 : 2006-09	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes
DIN EN ISO 11138-5 : 2006-09	Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes
DIN EN ISO 11607-1 : 2014-11	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11737-1 : 2009-09	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2 : 2010-04	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN 13060 : 2015-03	Small steam sterilizers
DIN EN ISO 14161 : 2010-03	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results
DIN EN ISO 14937 : 2010-03	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
DIN EN ISO 15883-1 : 2014-10	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
DIN EN ISO 15883-2 : 2009-09	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.
DIN EN ISO 15883-4 : 2009-09	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
DIN ISO/TS 15883-5 : 2006-02	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
DIN EN ISO 17664 : 2004-07	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
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
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
DIN EN 25424 : 2011-09	Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices
DIN 58951-2 : 2003-07	Sterilization - Steam sterilizers for laboratory use - Part 2: Apparatus requirements, requirements on services and installation.
DIN 58953-6 : 2016-12	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
KRINKO/BfArM-Empfehlung Aufbereitung MP	Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM) Bundesgesundheitsbl. 2012, 55 : 1244–1310
Ph. Eur. 8, 2.6.12	Total viable count
USP 39 <55>	Biological Indicators: Resistance Performance Tests
USP 39 <61>	Microbiological Examination of nonsterile products: microbial enumeration tests
AA 6.1-04-01	Testing sterile barrier systems for suitability for sterilization
AA 6.1-04-02	Testing sterile barrier systems for suitability for storage and transport
AA 6.1-04-03	Sterile barrier systems, testing of the process indicator
AA 6.3-10-01	Making a test piece for WD
AA 6.3-10-02	Making a test soil with E. faecium
AA 6.3- 10-03	Making a tubular test piece for WD
PA 6.1-01-10	Testing for a growth inhibition by solid samples
PA 6.1-02-01	Resistance determination – moist heat
PA 6.1-02-02	Resistance determination – dry heat
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	D-value determination for germs in suspensions
PA 6.1-04-05	sterile barrier systems, integrity testing
PA 6.1-04-07	sterile barrier systems, assessment of peel characteristics
PA 6.1-04-08	sterile barrier systems, determining the strength of the dry heat

	sealed joint
PA 6.1-04-09	sterile barrier systems, determining the strength of the wet heat sealed joint
PA 6.1-10-01	Inoculation and validation of the recovery
PA 6.1-10-02	Influence of substances from the product on the germination of spores
PA 6.1-10-04	Population determination on a product
PA 6.1-10-05	Sterility test by direct inoculation
PA 6.1-10-06	Sterility test by membrane filtration
PA 6.3-10-04	Determining the protein amount of blood contaminations
PA 6.3-10-05	Evaluation of test pieces with E. faecium
PA 6.3-10-06	Determination of the bioburden of process water
PA 6.3-30-01	steam quality test for non-condensable gases
PA 6.3-30-02	steam quality test for dryness
PA 6.3-30-03	steam quality test for superheating
VA 6.1-04	Testing of sterile barrier systems (SBS)
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 6.3-20	Validation of heat-sealing processes
VA 6.3-30	Validation of sterilization processes with steam
VA 6.3-31	Validation of sterilization processes with dry heat
VA 6.3-32	Validation of sterilization processes with ethylene oxide
VA 6.3-33	Validation of sterilization processes with formaldehyde
VA 6.3-34	Validation of sterilization processes with hydrogen peroxide

Abbreviations

AA	Arbeitsanweisung of SAL-GmbH (standard operation procedure of SAL-GmbH)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal institute for pharmaceutical products and medical devices)
DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization, registered Society)

EN	Europäische Norm (European standard)
ISO	International Organization for Standardization
KRINKO	Kommission für Krankenhaushygiene und Infektionsprävention (Commission for Hospital Hygiene and Infection Prevention)
Ph. Eur.	Pharmacopoeia Europaea
PA	Prüfanweisung der SAL-GmbH (testing instruction of SAL-GmbH)
TS	Technical Standard
USP	United States Pharmacopeia
VA	Verfahrensanweisung der SAL GmbH (Process instruction of SAL-GmbH)

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[1] DIN EN ISO/IEC 17025 : 2005-08 General requirements for the competence of testing and calibration laboratories

[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices

[3] Council Directive 90/385/EWG of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[4] DIN EN ISO 13485 : 2012-11 Medizinprodukte – Qualitätsmanagementsysteme – Anforderungen für regulatorische Zwecke

5 DIN EN ISO 13485 : 2016-08 Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke

[6] For the transition periods, see the list of harmonized standards on the homepage of the EU.