DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18398-02-00 according to DIN EN ISO/IEC 17025:2005 and Council 93/42/EWG[1] und 90/385/EWG[2]

Period of validity: 17.12.2015 bis 04.03.2018 **Date of issue**: 17.12.2015

Holder of certificate:

SAL GmbH
Feldstraße 14, 61479 Glashütten

At the testing sites:
Feldstraße 14, 61479 Glashütten
Auf der Lind 10, 65529 Waldems

Testing area:	medical devices
Types of tests / test methods:	Microbiological-hygienic testing of medical devices and sterilization packaging and microbiological-hygienic testing including physical testing of washer-disinfectors as well as washing, disinfection and sterilization processes; environmental monitoring

Abbreviations used: see last page

Location Waldems

Testing categories	Device category	Test method Test type	standard method of testing
Microbiological hygienic tests	Medical devices	Testing the resistance of reference germs depending on the characteristics of medical devices and sterilization with	PA 6.1-02-09 PA 6.1-01-10 VA 6.1-10
		- Moist heat	DIN EN ISO 11138-3 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 (NTDF)	DIN EN ISO 11138-5 PA 6.1-02-04
		Testing the resistance of reference germs depending on the characteristics of medical devices and sterilization with	PA 6.1-02-09 PA 6.1-01-10
		- Hydrogen peroxide	PA 6.1-02-05 applicable: DIN EN ISO 11138-1 DIN EN ISO 14161
		Sterility test	DIN EN 11737-2
		- Membrane filtration	PA 6.1-10-05
		- Direct inoculation	PA 6.1-10-06

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests including physical tests	Sterilization processes	Validation	
	- Moist heat	Installation qualification Operational qualifcation 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 Further applicable: DIN EN 13060 DIN EN 285 DIN 58951-2
	- Ethylene oxide	Installation qualification Operational qualifcation Performance qualification	DIN EN ISO 11135 VA 6.3-32 Further applicable: DIN EN ISO 14937 DIN EN 1422
	- Low temperature steam and formaldehyde (NTDF)	Installation qualification Operational qualifcation Performance qualification	DIN EN ISO 25424 VA 6.3-33
	Sterilization processes	Validation	
	- Dry heat	Installation qualification Operational qualifcation Performance qualification	DIN EN ISO 20857 DIN EN ISO 14937 VA 6.3-31
	- Hydrogene peroxide	Installation qualification Operational qualifcation Performance qualification	DIN EN ISO 14937 VA 6.3-34

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests including physical tests	Washer disinfectors processes - Employing thermal disinfection for surgical instruments, anaesthetic devices, containers, paraphernalia, glass devices - employing chemical or thermal disinfection for thermolabile endoscopes	Validation Installation qualification Operational qualifcation Performance qualification Installation qualification Operational qualifcation Performance qualification	DIN EN ISO 15883-1 PA 6.3-10-04 PA 6.3-10-05 PA 6.3-10-06 DIN EN ISO 15883-2 DIN EN ISO 15883-4 VA 6.3-10 AA 6.3-10-01 AA 6.3-10-02 Further applicable: DIN ISO/TS 15883-5 KRINKO/BfArM-Empfehlung Aufbereitung MP
	Medical devices, information for reprocessing	Test in the context of validation on the basis of provided information Cleaning/Disinfection	DIN EN ISO 17664 VA 6.3-10 VA 6.3-02 PA 6.1-10-01
	Medical devices, information for reprocessing	Test in the context of validation on the basis of provided information Sterilization with - Moist heat - Dry heat - Ethylene oxide - Formaldehyde	DIN EN ISO 17664 VA 6.3-02 VA 6.3-30 VA 6.3-31 VA 6.3-32 VA 6.3-33

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests including physical tests	Medical devices, information for reprocessing	Test in the context of validation on the basis of provided information Sterilization with - Hydrogene peroxide Drying Packaging/Storing	 VA 6.3-34 VA 6.3-02 VA 6.1-04 applicable: DIN EN 556
Microbiologic hygienic tests	Biological indicators	Tests to prove compliance - Vitality - Population determination of spore suspensions - Population determination of spores on solid carriers - Purity	USP 38 <55> PA 6.1-01-04 PA 6.1-01-02 PA 6.1-01-03 PA 6.1-01-05 PA 6.1-01-06 applicable: DIN EN ISO 11138-1
		D-value determination and evaluation of bioindicators for sterilization processes using - Moist heat - Ethylene oxide - Low-temperature-steam- and formaldehyde - Dry heat	PA 6.1-02-06 PA 6.1-02-07 PA 6.1-02-08 PA 6.1-02-09 DIN EN ISO 11138-3 PA 6.1-02-01 DIN EN ISO 11138-2 PA 6.1-02-03 DIN EN ISO 11138-5 PA 6.1-02-05 DIN EN ISO 11138-4 PA 6.1-02-02

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests	Biological indicators	D-value determination and evaluation of bioindicators for sterilization processes using	Applicable: DIN EN ISO 14161 DIN EN ISO 11138-1 DIN EN ISO 18472
	Test systems Chemical indicators	Tests to prove compliance in sterilization processes using	DIN EN ISO 11140-1 DIN EN ISO 11140-3 DIN EN ISO 11140-4 ISO 11140-5 PA 6.2-01-01 PA 6.2-01-02 PA 6.2-01-04 PA 6.2-01-05 PA 6.2-01-06 PA 6.2-01-07 VA 6.2-01
		- Moist heat	PA 6.2-01-08
		- Dry heat	PA 6.2-01-09
		- Ethylene oxide	PA 6.2-01-10
		- Low-temperature-steam- and formaldehyde	PA 6.2-01-11
		- Hydrogene peroxide	PA 6.2-01-12 applicable: DIN EN 20187 DIN EN ISO 18472
	Simulators and monitoring systems (MDS, BMS)	Testing to prove applicability of	
		- Bowie-Dick-Simulation-Tests	DIN EN ISO 11140-4 PA 6.2-10-03
		- Test devices according EN 867-5	DIN EN 867-5 PA 6.2-10-04 PA 6.2-10-05 PA 6.2-10-06
		- Test devices according DIN EN 1422	DIN EN 1422 PA 6.2-10-07
		- Medical Device Simulators (MDS)	DIN 58921 PA 6.2-10-08

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests	Simulators and monitoring systems (MDS, BMS)	Testing to prove applicability of - Batch Monitoring Systems (BMS)	PA 6.2-10-09
	Sterile barrier and packaging systems Materials	Tests in the context of proving compliance	DIN EN ISO 11607-1
		- Compatibility to sterilisation with • Moist heat • Dry heat	DIN EN 868-5 AA 6.1-04-01
		Tests to prove compliance	DIN EN ISO 11607-1
		- Stability of the heat sealed joint	DIN EN 868-5 PA 6.1-04-08 PA 6.1-04-09 VA 6.3-20
		- Colour change of the process indicator	DIN EN 868-5 DIN EN ISO 11140-1 AA 6.1-04-03
		- of plastic laminated film for capillary holes	DIN EN 868-5 PA 6.1-04-05
		- Peel characteristics of paper-plastic-laminates	DIN EN 868-5 PA 6.1-04-07
		- Suitability for storage and transport	DIN EN 868-5 AA 6.1-04-02
	Environmental investigation of the production and testing on the hygienic conditions of the products according EN ISO 13485:2012[4], Para. 6.4 and Para. 7.5		

Testing categories	Device category	Test method Test type	standard method of testing
Microbiologic hygienic tests	Medical devices Biologic 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. 8, 2.6.12 USP 38 <61>

Set of Rules[5]

DIN EN 285 : 2009-08	terilization - Steam sterilizers - Large sterilizers
DIN EN 556 : 2002-03 DIN EN 556 Bertg. 1 : 2006-12	Sterilisation von Medizinprodukten - Anforderungen an Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
DIN EN 867-5 : 2001-11	on-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S
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	terilizers 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 11140-1 : 2015-03	Sterilization of health care products - Chemical indicators - Part 1: General requirements
DIN EN ISO 11140-3 : 2009-09	Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test
DIN EN ISO 11140-4 : 2007-07	Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration
ISO 11140-5 : 2007-03	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests
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 18472 : 2006-10	Sterilization of health care products - Biological and chemical indicators - Test equipment
DIN EN 20187 : 1993-11	Paper, board and pulps; standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples
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 58921 : 2011-01	Test method to demonstrate the suitability of a medical device simulator during steam sterilisation - Medical device simulator testing
DIN 58951-2 : 2003-07	Sterilization - Steam sterilizers for laboratory use - Part 2: Apparatus requirements, requirements on services and installation
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 38 <55>	Biological Indicators: Resistance Performance Tests
USP 38 <61>	Microbiological Examination of nonsterile products: microbial enumeration tests
AA 6.1-04-01	Testing sterile barrier systems for sterilizability
AA 6.1-04-02	Testing sterile barrier systems for storability and transportability
AA 6.1-04-03	sterile barrier systems, testing of the process indicator
AA 6.3-10 -01	manufacturing a PCD for WD
AA 6.3-10 -02	manufacturing a test soil with E. faecium
PA 6.1-01-02	Population determination in spore suspensions
PA 6.1-01-03	Population determination on spore strips
PA 6.1-01-04	Vitality determination of biological indicators

PA 6.1-01-05	Population determination in test tubes
PA 6.1-01-06	Purity determination of biological indicators
PA 6.1-01-10	Determination of the growth inhibition on solid samples
PA 6.1-02-01	Resistance determination – Steam
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 6.1-02-06	z-value determination
PA 6.1-02-07	D-value determination according to the Fraction Negative Method
PA 6.1-02-08	Determination of the survival window
PA 6.1-02-09	D-value determination for germs in suspensions
PA 6.1-04-05	Testing sterile barrier integrity of sterile barrier systems
PA 6.1-04-07	Determination of the Peel characteristics of sterile barrier systems
PA 6.1-04-08	Determination of the stability of the stability of the dry heat-sealed joint of sterile barrier systems
PA 6.1-04-09	Determination of the stability of the moist heat-sealed joint of sterile barrier systems
PA 6.1-10-01	Inoculation and validation of the recovery
PA 6.1-10-04	Population determination on a product
PA 6.1-10-05	Sterility test with membrane filter test
PA 6.1-10-06	Sterility test by direct inoculation
PA 6.2-01-01	Testing of completeness of the manufactur's instructions
PA 6.2-01-02	Testing of readability of the indicator labeling before and after sterilization
PA 6.2-01-04	Testing of size, form and indicator print
PA 6.2-01-05	Testing of the relative refexion density
PA 6.2-01-06	Stability test of an indicator
PA 6.2-01-07	Testing of chemical indicators for bleeding
PA 6.2-01-08	Colour change test of chemical indicators for steam sterilization
PA 6.2-01-09	Colour change test of chemical indicators for dry heat sterilization
PA 6.2-01-10	Colour change test of chemical indicators for ethylene oxide sterilization

PA 6.2-01-11	Colour change test of chemical indicators for formaldehyde sterilization
PA 6.2-01-12	Colour change test of chemical indicators for H_2O_2-/ plasma sterilization
PA 6.2-10-03	Testing of standard conformity of a Bowie-Dick-Simulation-Test according ISO 11140-4
PA 6.2-10-04	Testing the PCD dimensions according EN 867-5
PA 6.2-10-05	Compatibility test of the PCD materials according EN 867-5
PA 6.2-10-06	Performance test of PCDs according EN 867-5
PA 6.2-10-07	Testing of the dimensions and materials of the norm test device according DIN EN 1422
PA 6.2-10-08	Conformity test of a medical device simulator (MDS)
PA 6.2-10-09	Conformity test of a batch monitoring system (BMS)
PA 6.3-10-04	Determination of the protein amounts of blood contaminations
PA 6.3-10-05	Vitality tests of PCDs with E. faecium test contamination
PA 6.3-10-06	Determination of the bioburden of a process water
PA 6.3-30-01	Testing steam quality for non condensable gases
PA 6.3-30-02	Testing steam quality for dryness
PA 6.3-30-03	Testing steam quality for superheation
VA 6.1-04	Testing sterile barrier systems (SBS)
VA 6.1-10	Qualification of medical devices: Determination of the bioburden
VA 6.2-01	Testing of chemical indiators
VA 6.3-02	Validation of reprocessing medical devices according ISO 17664
VA 6.3-10	Validation of washing, disinfection and drying processes
VA 6.3-20	Validation of heat-sealed joint processes
VA 6.3-30	Validation of steam sterilization processes
VA 6.3-31	Validation of dry heat sterilization processes
VA 6.3-32	Validation of ethylene oxide sterilization processes
VA 6.3-33	Validation of formaldehyde sterilization processes
VA 6.3-34	Validation of hydrogen peroxide sterilization processes

Abbreviations

AA	Arbeitsanweisung der SAL GmbH (Standard operating procedure)
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	Europäische Norm (European standard)
ISO	International Organization for Standardardization
Ph. Eur	Pharmacopoeia European
PA	Prüfanweisung der SAL GmbH (Test instruction)
TS	Technical Standard
USP	United States Pharmacopeia
VA	Verfahrensanweisung der SAL GmbH (Process instruction)

[1] Guidance 93/42/EEC of the council of June 14, 1993 about medical devices, ABI No. L 169 dated 1993-07-12, p. 1; last modified by guidance 2007/47/EG dated 2007-09-05, ABI No. L 247/21 dated 2007-09-21, p. 21

[2] Guidance 90/385/EWG of the council of June 20, 1990 to adapt the regulations of the member states about medical devices for active implantation. ABI No. L 189 dated 1990-07-20, p. 17, last modified by guidance 2007/47/EG of September 5, 2007, ABI No. L 247/21 dated 2007-09-21, p. 21

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

[4] For the transition period please refer to the list of harmonized standards on the homepage of the EU.