Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-18300-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: **21.08.2023**

Date of issue: 21.08.2023

Holder of certificate:

Mikrobiologisches Testlabor GmbH
Brambacher Straße 17, 08645 Bad Elster

With the site:

Mikrobiologisches Testlabor GmbH
Brambacher Straße 17, 08645 Bad Elster

The testing laboratory meets the requirements according to DIN EN ISO/IEC 17025:2018 to perform the conformity assessment activities listed in this annex. The testing laboratory complies with additional legal and normative requirements, including those in relevant sectoral programs, if applicable, provided that these are expressly confirmed below.

The management system requirements in DIN EN ISO/IEC 17025 are written in language relevant to operations of testing laboratories and operate generally in accordance with the principles of DIN EN ISO 9001.

Microbiological-hygienic testing of medical device, washer-disinfectors and endoscopes (reprocessed) and microbiological-hygienic and physical testing of washer, disinfections- and sterilization process; environmental monitoring

outside of a recognition according to § 18 of the Medical Device Regulation (MDR)

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing	Medical devices	Testing of sterility - Membrane filtration method - Direct immersion method	DIN EN ISO 11737-2 Ph. Eur. 2.6.1 AA_L_05
		Establishing the sterilization dose	DIN EN ISO 11137-2
		Identification of microorganisms	AA_L_07 (DIN EN ISO 11737-1)
	Washer-disinfectors	Testing as part of routine monitoring	
	- Washer-disinfectors employing thermal disinfection for human waste container	- using bioindicators	AA_L_19 (Gebel, J. et. al.) Applicable: DIN ISO/TS 15883-5
	- Washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical device and healthcare equipment	- using bioindicators	AA_L_19 (Gebel, J. et. al.) Applicable: DIN ISO/TS 15883-5 DIN EN ISO 15883-6
Microbiological-hygienic testing	Washer-disinfectors	Testing as part of routine monitoring	

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	- Washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical device and healthcare equipment	- using bioindicators	AA_L_19 (Gebel, J. et. al.) Applicable: DIN ISO/TS 15883-5 DIN EN ISO 15883-7
	- Washing machines	- using bioindicators	AA_L_19 (Gebel, J. et. al.)
Microbiological-hygienic testing including physical testing	Washer-disinfectors processes - employing thermal disinfection for surgical instruments, anaesthetic equipment, receivers, utensils, glassware	Validation Installation Qualification Operational Qualification Performance Qualification	DIN EN ISO 15883-1 DIN EN ISO 15883-2 Applicable: DIN ISO/TS 15883-5 KRINKO/BfArM Recommendation Reprocessing of medical devices

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing including physical testing	Washer-disinfectors processes	Validation	DIN EN ISO 15883-1
	- employing chemical disinfection for thermolabile endoscopes	Installation Qualification Operational Qualification Performance Qualification	DIN EN ISO 15883-4 Applicable: DIN ISO/TS 15883-5 KRINKO/BfArM-Recommendation Reprocessing of medical devices
	Washer-disinfectors processes	Testing as part of validation	
	- employing thermal disinfection for surgical instruments, anaesthetic equipment, receivers, utensils, glassware	Performance Qualification	Guideline complied by DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices AA_L_23
	- employing chemical disinfection for thermolabile endoscopes	Performance Qualification	Guideline complied by DGKH, DGSV, DEGEA, DGVS and AKI for validation of automated washer-disinfection processes for reprocessing thermolabile endoscopes AA_L_24

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing including physical testing	Sterilization processes	Validation	
	- Moist heat	Installation Qualification Operational Qualification Performance Qualification	DIN EN ISO 17665-1 AA_L_28 Applicable: ISO/TS 17665-2 DGKH-Recommendation moist heat
	- Low temperature steam and formaldehyde	Installation Qualification Operational Qualification Performance Qualification	DIN EN 14180 AA_L_30 Applicable: DIN EN ISO 25424 DGKH- Recommendation Low temperature steam and formaldehyde
Microbiological-hygienic testing	Endoscopes (reprocessed)	Control of reprocessing - Microbiological testing of endoscope rinsing fluid	KRINKO/BfArM-Recommendation Reprocessing of medical devices
	Sterilization processes	Testing as part of routine monitoring	
	- Moist heat	- using bioindicators	DIN EN ISO 17665-1 Ph. Eur. 5.1.2 Ph. Eur. 5.1.5 AA_L_18 Applicable: DIN EN 285 DIN EN ISO 11138-1 DIN EN ISO 11138-3 DIN EN ISO 11138-7
Microbiological-hygienic testing	Sterilization processes	Testing as part of routine monitoring	

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
	- Ethylene oxide	- using bioindicators	DIN EN ISO 11135-1 AA_L_18 Applicable: DIN EN ISO 11138-1 DIN EN ISO 11138-2 DIN EN ISO 11138-7
	- Dry heat	- using bioindicators	AA_L_18 (DIN EN ISO 20857) Applicable: DIN EN ISO 11138-1 DIN EN ISO 11138-4 DIN EN ISO 11138-7
	- Low temperature steam and formaldehyde	- using bioindicators	DIN EN 14180 AA_L_18 Applicable: DIN EN ISO 11138-1 DIN EN ISO 11138-5 DIN EN ISO 11138-7
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485: 2021[1], 6.4 and 7.5			
Microbiological-hygienic testing	Medical devices	Bacterial endotoxins test (BET) - Quantitative detection of bacterial endotoxin using Limulus Amoebozyten-Lysat (LAL-test)	Ph. Eur. 2.6.14 Ph. Eur. 5.1.10 USP <85>, <161> ANSI/AAMI ST72 AA_L_06
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485 : 2021[5], 6.4 and 7.5			

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing	Medical devices	Determination of a population of microorganisms on products (Bioburden) - by membran filtration method - by pour plate method and by streak plate procedure - by MPN-method	DIN EN ISO 11737-1 Ph. Eur. 2.6.12 AA_L_04 AA_L_10 AA_L_04 Applicable: DIN EN ISO 11137-2 DIN EN ISO 17665-1 Ph. Eur. 5.1.4
		Detection of specified microorganisms	Ph. Eur. 2.6.13 AA_L_12
	Clean rooms Air	Determination of biocontamination - by air sampler (impaction method) - by settle plates	DIN EN 17141 AA_L_14 Applicable: EU-Guideline, Annex 1
	Surfaces	Determination of biocontamination by contact plates - semi-quantitative contact method	DIN EN 17141 AA_L_14 Applicable: KRINKO/BfArM-Recommendation Cleaning and Disinfecting Surfaces EU-Guideline, Annex 1
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485 : 2021[5], 6.4 and 7.5			

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing	Water and aqueous solutions - Dialysis fluids	Testing for microbial contamination - Total germ count - Bacterial endotoxins test	DIN EN ISO 8199 Ph. Eur. 5.1.4 AA_L_11 Ph. Eur. 2.6.14 AA_L_06
Physical testing	Medical devices	Determination of released-particle count - Microscopical method	DIN EN ISO 8871-3 DIN EN ISO 8536-4 AA_L_08 Applicable: DIN EN ISO 8536-8 DIN EN 45502-1
	Clean rooms Air	Determination of airborne particle concentration - Airborne particle count	DIN EN ISO 14644 -1, -2, AA_L_13 Applicable: EU-Guideline, Annex 1

Regulations/Methods:

DIN EN 285 2021-12	Sterilization – Steam sterilizers – Large sterilizers
DIN EN ISO 8199 : 2008-01	Water quality – General guidance on the enumeration of microorganisms by culture (ISO 8199 : 2005)
DIN EN ISO 8536-4 : 2020-05	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4 : 2019)
DIN EN ISO 8536-8 : 2015-11	Infusion equipment for medical use - Part 8: Infusion sets for single use with pressure infusion apparatus (ISO 8536-8 : 2015)
DIN EN ISO 8871-3 : 2019-08	Elastomeric parts for parenterals and for medical devices for pharmaceutical use - Part 3: Determination of released-particle count (ISO 8871-3 : 2003 + Amd 1 : 2018)
DIN EN ISO 11137-2 : 2015-11	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2 : 2013)
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 and 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 : 2021-10	Sterilization of health care products – Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1 : 2018 + Amd 1 : 2021)
DIN EN ISO 11737-2 : 2020-07	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in definition, validation and maintenance of a sterilization process (ISO 11737-2 : 2019)
DIN EN 14180 : 2014-09	Sterilizer for medical purposes – Low temperature steam and formaldehyde sterilizers – Requirements and testing
DIN EN ISO 14644-1 : 2016-06	Cleanrooms and associated controlled environments - Part 1: Classification for air cleanliness by particle concentration (ISO 14644-1 : 2015)
DIN EN ISO 14644-2 : 2016-05	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2 : 2015)
DIN EN ISO 15883-1 : 2014-10	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1 : 2006 + Amd 1 : 2014)
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. (ISO 15883-2 : 2009)
DIN EN ISO 15883-4 : 2019-06	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4 : 2018)

DIN ISO/TS 15883-5 : 2006-02	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
DIN EN ISO 15883-6 : 2016-04	Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical device and healthcare equipment (ISO 15883-6 : 2011)
DIN EN ISO 15883-7 : 2016-10	Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical medical device and healthcare equipment (ISO 15883-7 : 2016)
DIN EN ISO 17665-1 : 2006-11	Sterilization of health care products – Moist heat - Teil 1: Requirements for development, validation and routine control of a sterilization process for medical device (ISO 17665-1 : 2006)
ISO/TS 17665-2 : 2009-07	Sterilization of health care products – Moist heat - Part 2: Guidance on the application of ISO 17665-1
DIN EN 17141 : 2021-02	Cleanrooms and associated controlled environments – Biocontamination control
DIN EN 20857 : 2013-08	Sterilization of health care products – Dry heat- Requirements for development, validation and routine control of a sterilization process for medical device
DIN EN 25424 : 2020-05	Sterilization of health care products – Low-temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical device
DIN EN 45502-1 : 2016-02	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer
DGKH-Recommendation: 2004 Moist heat	Recommendation for validation and routine monitoring of sterilization processes employing moist heat for medical devices
DGKH-Recommendation: 2004 Low temperature steam and formaldehyde	Recommendation for validation and routine monitoring of sterilization processes employing steam containing formaldehyde for medical devices
Guideline complied by DGKH, DGSV und AKI : 5. Edition 2017	Guideline complied by DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices
Guideline complied by DGKH, DGSV, DEGEA, DGVS and AKI : 2011-10	Guideline complied by DGKH, DGSV, DEGEA, DGVS and AKI for validation of automated washer-disinfection processes for reprocessing thermolabile endoscopes
KRINKO/BfArM-Recommendation	Hygiene Requirements for Cleaning and Disinfecting Surfaces, Recommendation of the Commission for Hospital Hygiene and

Cleaning and Disinfecting Surfaces	Infection Prevention (KRINKO) at the Robert Koch Institut (RKI) Bundesgesundheitsbl. 2004, 47 : 51–61
KRINKO/BfArM-Recommendation Reprocessing of medical devices	Hygiene requirements for the reprocessing of medical devices. Recommendations by 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
Gebel, J. et al.	Quality assurance for cleaning, disinfection and sterilization. Validated test methods for hygiene. Part 2, Behr´s Verlag (09-2020)
EU Guideline	EUROPEAN COMMISSION Guidelines to Good Manufacturing Practice: Medicinal Products for Human and Veterinary Use. Vol. 4, Brussels, 01 March 2009, Annex 1: Manufacture of Sterile Medicinal Products
Ph. Eur. 10, 2.6.1	Testing for sterility
Ph. Eur. 10, 2.6.12	Microbiological examination of non-sterile products: Microbial enumeration tests
Ph. Eur. 10, 2.6.13	Microbiological examination of non-sterile products: Tests for specified microorganisms
Ph. Eur. 10, 2.6.14	Bacterial Endotoxins
Ph. Eur. 10, 5.1.1	Methods of preparation of sterile products
Ph. Eur. 10, 5.1.2	Biological indicators and related microbial preparations use in the manufacturing of sterile products
Ph. Eur. 10, 5.1.4	Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
Ph. Eur. 10, 5.1.5	Application of the F_0 concept to steam sterilization
Ph. Eur. 10, 5.1.10	Guidelines for using the test for bacterial endotoxins
ANSI AAMI ST72 : 2019	Bacterial endotoxins - Test methods, routine monitoring and alternatives to batch testing
USP 41, <85>	Bacterial Endotoxins Test
USP 41, <161>	Medical Devices – Bacterial endotoxin and pyrogen tests
AA_L_04 : 2021-12-21	Determination of bioburden
AA_L_05 : 2021-06-08	Test of sterility
AA_L_06 : 2021-06-08	Bacterial Endotoxins Test (BET): turbidimetric-kinetic method
AA_L_07 : 2021-06-08	Identification of microorganisms
AA_L_08 : 2021-06-08	Determination of particulate contamination – test method for solid, water-insoluble products

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AA_L_10 : 2021-06-08	Determination of total colony count by pour plate method and by streak plate procedure
AA_L_11 : 2021-06-08	Analysis of water
AA_L_12 : 2021-06-08	Microbiological examination of non-sterile products: Enumeration of viable microorganisms and tests for specified microorganisms
AA_L_13 : 2021-06-08	Determination of particle concentration
AA_L_14 : 2021-06-08	Biocontamination control - Determination of airborne viable particle count, settle plates and surface contamination
AA_L_16 : 2021-06-08	Bioindicators for steam sterilization
AA_L_17 : 2021-06-08	Bioindicators sterilization with dry heat
AA_L_18 : 2021-06-08	Evaluation of bioindicators for testing of sterilization processes
AA_L_19 : 2021-06-08	Production and evaluation of bioindicators for testing cleaning and disinfection processes employing thermal or chemical-thermal disinfection
AA_L_23 : 2022-07-11	Performance qualification of automated cleaning and thermal disinfection processes
AA_L_24 : 2022-07-11	Performance qualification of automated washer-disinfection processes employing chemical disinfection for reprocessing thermolabile endoscopes
AA_L_28 : 2021-06-08	Validation of steam sterilization processes: Part – Performance Qualification
AA_L_29 : 2021-06-08	Validation of sterilization processes employing dry heat
AA_L_30 : 2022-07-11	Validation of sterilization processes employing low temperature steam and formaldehyde

Abbreviations

AA_L_Nr.	Arbeitsanweisung_Labor_Nr. (Standard operation procedure_Laboratory_No. of the Mikrobiologische Testlabor GmbH Bad Elster)
AAMI	Association for the Advancement of Medical Instrumentation
AKI	Arbeitskreis Instrumentenaufbereitung
ANSI	American National Standard Institute
BET	Bacterial Endotoxins Test
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
DEGEA	Deutsche Gesellschaft für Endoskopie - Assistenzpersonal e.V.
DGKH	Deutsche Gesellschaft für Krankenhaushygiene e.V.
DGSV	Deutsche Gesellschaft für Sterilgutversorgung e.V.
DGVS	Deutschen Gesellschaft für Verdauungs- und Stoffwechselkrankheiten e.V.
DIN	Deutsches Institut für Normung
EU	Europäische Union
EN	Europäische Norm
FDA	Food and Drug Administration
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardization
KRINKO	Kommission für Krankenhaushygiene und Infektionsprävention
LAL	Limulus-Amöbozyten-Lysat
MPN	Most Probable Number
Ph. Eur.	Pharmacopoeia European
RKI	Robert Koch-Institut
TS	Technical Standard
USP	United States Pharmacopoeia
VDI	Verband Deutscher Ingenieure

[1] DIN EN ISO 13485 : 2021-12 Medical devices – Quality management system – Requirements for regulatory purposes