Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-18741-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: **06.12.2023**

Date of issue: 06.12.2023

Holder of accreditation certificate:

Sterigenics Germany GmbH, Laboratory
Kasteler Straße 45, 65203 Wiesbaden

with the location

Sterigenics Germany GmbH, Laboratory
Kasteler Straße 45, 65203 Wiesbaden

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

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

Chemical and microbiological-hygienic testing of medical devices; environmental monitoring

outside of a recognition according to § 18 Medical Devices Implementation Act.

Kasteler Straße 45, 65203 Wiesbaden

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Chemical testing	Medical devices	Determination of ethylene oxide-residues after sterilization	DIN EN ISO 10993-7 ISO 10993-7 AMD 1 WIE-WI-LB-CHM-001
Microbiological-hygienic testing	Sterilization methods - with ethylene oxide	Testing in the context of routine monitoring - by using bioindicators	DIN EN ISO 11135 DIN EN 1422 DE-G-WI-LB-MIC-003 USP <55> USP <1229.5> Referred document: DIN EN ISO 11138-2
	Medical devices	Testing for sterility	DIN EN ISO 11737-2 USP <71> Ph. Eur. 2.6.1 JP <4.06> DE-G-WI-LB-MIC-027 DE-G-WI-LB-MIC-036
Environmental monitoring of the production and testing on the hygienic conditions of the products according to DIN EN ISO 13485: 2021[1], paragraph 6.4 and paragraph 7.5			
Microbiological-hygienic testing	Medical devices	Testing of bacterial endotoxin (LAL test) - Gel-Clot: Marginal Test - Gel-Clot: Semi-quantitative test	Ph. Eur., 2.6.14 Ph. Eur., 5.1.10 USP <85> USP <161> Method A DE-G-WI-LB-BET-002 Method B DE-G-WI-LB-BET-002

Testing field	**Test item** **Device(category)**	**Type of testing** **Test**	**Regulation** **Testing method**
Microbiological-hygienic testing	Medical devices	- Kinetic- turbidimetric method - Chromogen-kinetic method	Method C DE-G-WI-LB-BET-001 Method D DE-G-WI-LB-BET-001
		Estimation of the population of micro-organisms of products (Determination of Bioburden)	DIN EN ISO 11737-1 Ph. Eur., 2.6.12
		- Membrane filtration method	DE-G-WI-LB-MIC-004
		- Pour plating	DE-G-WI-LB-MIC-020 WIE-WI-LB-MIC-008 Referred document: DIN EN ISO 11137-2

Rules and Regulations:

DIN EN 1422 : 2014-08	Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
DIN EN ISO 10993-7 : 2009-02	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-7 AMD 1 : 2019-12	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals - Amendment 1: Applicability of allowable limits for neonates and infants
DIN EN ISO 11135-1 : 2020-04	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 11137-2 : 2015-11	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
DIN EN ISO 11737-1 : 2018-11	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2 : 2020-07	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN ISO 11138-2 : 2017-07	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
Ph. Eur. 10, 2.6.1	Sterility tests
Ph. Eur. 10, 2.6.12	Microbiological examination of non-sterile products: microbial enumeration tests
Ph. Eur. 10, 2.6.14	Bacterial endotoxins test
Ph. Eur. 10, 5.1.10	Recommendation for procedure of bacterial endotoxins test
USP 43, <55>	Biological Indicators – Resistance Performance Tests
USP 43, <71>	Sterility tests

USP 43, <85>	Bacterial Endotoxins Test
USP 43, <161>	Transfusion and Infusion Assemblies and Similar Medical Devices
USP 41-NF 36. 2019 , <1229.5>	Biological Indicators for Sterilization
JP17, <4.06>	Sterility tests
DE-G-WI-LB-BET-001 Rev. 4.0	Bacterial Endotoxins Test (BET)
DE-G-WI-LB-BET-002 Rev. 3.0	Bacterial Endotoxins Test (Gel Clot)
DE-G-WI-LB-MIC-003 Rev. 3.0	Tests of sterilization by using bioindicators
DE-G-WI-LB-MIC-004 Rev. 9.0	Determination of bioburden
WIE-WI-LB-MIC-008 Rev. 2.0	Enumeration of Bacterial Population from Biological Indicators EZTest Steam, Smart-Read EZTest und EZTest Gas
DE-G-WI-LB-MIC-020 Rev. 4.0	Enumeration of Bacterial Population from Biological Indicators & Inoculated Product (DE)
DE-G-WI-LB-MIC-027 Rev. 4.0	Method Suitability Test for Sterility Testing
DE-G-WI-LB-MIC-036 Rev. 6.0	Product Sterility Testing
WIE-WI-LB-CHM-001 Rev. 10.0	Determination of ETO-, ECH- and EG-residues on medical devises

Abbreviations used:

DIN	German institute for standardization
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JP	Japanese Pharmacopoeia
Ph. Eur.	European Pharmacopoeia
USP	United States Pharmacopeia
DE-G-WI-LB- XXX-XXX / WIE-WI-LB-XXX-XXX	Work instruction of STERIGENICS Germany GmbH (old/new nomenclature)