

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18741-01-00 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 31.08.2020

Date of issue: 31.08.2020

Holder of certificate:

**Sterigenics Germany GmbH, Laboratory
Kasteler Straße 45, 65203 Wiesbaden**

Field: Medical devices

Testing fields/test items: Chemical and microbiological-hygienic testing of medical devices;
environmental monitoring

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

*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 can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>*

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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 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 11135-1 DIN EN 1422 DE-G-WI-LB-MIC-003 USP <55> USP <1035> Referred document: DIN EN ISO 11138-2
Microbiological-hygienic testing	Environmental monitoring of the production and testing on the hygienic conditions of the products according to DIN EN ISO 13485: 2016³, paragraph 6.4 and paragraph 7.5		
	Medical devices	Testing of bacterial endotoxin (LAL test)	Ph. Eur., 2.6.14 Ph. Eur., 5.1.10 USP <85> USP <161> DE-G-WI-LB-BET-001 WIE-WI-LB-LAL-001 WIE-WI-LB-LAL-002
		Estimation of the population of micro-organisms of products (Determination of Bioburden) - Membrane filtration method - Pour plating	DIN EN ISO 11737-1 Ph. Eur., 2.6.12 DE-G-WI-LB-MIC-004 DE-G-WI-LB-MIC-020 WIE-WI-LB-MIC-008 Referred document: DIN EN ISO 11137-2

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Corpus of legislation²

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
DIN EN ISO 11135-1 : 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 11137-2 : 2015-11	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
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 ISO 11138-2 : 2017-07	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
Ph. Eur. 9, 2.6.12	Microbiological examination of non-sterile products: microbial enumeration tests
Ph. Eur. 9, 2.6.14	Bacterial endotoxins test
Ph. Eur. 9, 5.1.10	Recommendation for procedure of bacterial endotoxins test
USP 40, <55>	Biological Indicators – Resistance Performance Tests
USP 40, <85>	Bacterial Endotoxins Test
USP 40, <161>	Transfusion and Infusion Assemblies and Similar Medical Devices
USP 40, <1035>	Biological Indicators for Sterilization

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DE-G-WI-LB-BET-001	Bacterial Endotoxins Test (BET)
DE-G-WI-LB-MIC-003	Tests of sterilization by using bioindicators
DE-G-WI-LB-MIC-004	Determination of bioburden
DE-G-WI-LB-MIC-020	Enumeration of Bacterial Population from Biological Indicators & Inoculated Product (DE)
WIE-WI-LB-CHM-001	Determination of ETO-, ECH- and EG-residues on medical devices
WIE-WI-LB-LAL-001	LAL-test - Gel Clot
WIE-WI-LB-LAL-002	LAL-test, kinetic-turbidimetric method
WIE-WI-LB-MIC-008	Enumeration of Bacterial Population from Biological Indicators EZTest Steam, Smart-Read EZTest und EZTest Gas

Abbreviations used:

DIN	German institute for standardization
EN	European standard
ISO	International Organization for Standardization
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)

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

² Regarding the transition periods see the list of harmonized standards on the homepage of the EU

³ DIN EN ISO 13485 : 2016-08 Medical devices – Quality management systems - Requirements for regulatory purposes

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