DAkkS
Deutsche
Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV
Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation

The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

Sterigenics Germany GmbH, Laboratory
Kasteler Straße 45, 65203 Wiesbaden

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following fields:

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

The accreditation certificate shall only apply in connection with the notice of accreditation of 07.09.2022 with the accreditation number D-PL-18741-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 5 pages.

Registration number of the certificate: **D-PL-18741-01-00**

Berlin,	Andrea Gabler	Translation issued:	
07.09.2022	Head of Technical Unit	07.09.2022	Head of Technical Unit

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de/en/accredited-bodies-search.html.

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

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

Standort Berlin
Spittelmarkt 10
10117 Berlin

Standort Frankfurt am Main
Europa-Allee 52
60327 Frankfurt am Main

Standort Braunschweig
Bundesallee 100
38116 Braunschweig

Es darf nicht der Anschein erweckt werden, dass sich die Akkreditierung auch auf Bereiche erstreckt, die über den durch die DAkkS bestätigten Akkreditierungsbereich hinausgehen.

Die Akkreditierung erfolgte gemäß des Gesetzes über die Akkreditierungsstelle (AkkStelleG) sowie der Verordnung (EG) Nr. 765/2008 des Europäischen Parlaments und des Rates über die Vorschriften für die Akkreditierung und Marktüberwachung im Zusammenhang mit der Vermarktung von Produkten.
Die DAkkS ist Unterzeichnerin der Multilateralen Abkommen zur gegenseitigen Anerkennung der European co-operation for Accreditation (EA), des International Accreditation Forum (IAF) und der International Laboratory Accreditation Cooperation (ILAC). Die Unterzeichner dieser Abkommen erkennen ihre Akkreditierungen gegenseitig an.

Der aktuelle Stand der Mitgliedschaft kann folgenden Webseiten entnommen werden:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18741-01-00 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 07.09.2022

Date of issue: 07.09.2022

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

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

The certificate together with the annex reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (DAkkS) at https://www.dakks.de/en/accredited-bodies-search.html

Abbreviations used: see last page

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 11135-1 DIN EN 1422 DE-G-WI-LB-MIC-003 USP <55> USP <1035> 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>
Environmental monitoring of the production and testing on the hygienic conditions of the products according to DIN EN ISO 13485: 2021[2], paragraph 6.4 and paragraph 7.5			
Microbiological-hygienic testing	Medical devices	Testing of bacterial endotoxin (LAL test) - Gel-Clotmethod - Gel-Clot	Ph. Eur., 2.6.14 Ph. Eur., 5.1.10 USP <85> USP <161> Method A WIE-WI-LB-LAL-001 Method B WIE-WI-LB-LAL-001

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing	Medical devices	- Kinetic- turbidimetric method	Method C WIE-WI-LB-LAL-002 DE-G-WI-LB-BET-001
		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

Corpus of legislation

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

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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 43, <1035>	Biological Indicators for Sterilization
JP17, <4.06>	Sterility tests
DE-G-WI-LB-BET-001 Rev. 3.0	Bacterial Endotoxins Test (BET)
DE-G-WI-LB-MIC-003 Rev. 3.0	Tests of sterilization by using bioindicators
DE-G-WI-LB-MIC-004 Rev. 3.0	Determination of bioburden
WIE-WI-LB-MIC-008 Rev. 1.0	Enumeration of Bacterial Population from Biological Indicators EZTest Steam, Smart-Read EZTest und EZTest Gas

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DE-G-WI-LB-MIC-020 Rev. 4.0	Enumeration of Bacterial Population from Biological Indicators & Inoculated Product (DE)
WIE-WI-LB-CHM-001 Rev. 10.0	Determination of ETO-, ECH- and EG-residues on medical devises
WIE-WI-LB-LAL-001 Rev. 3.0	LAL-test - Gel Clot
WIE-WI-LB-LAL-002 Rev. 6.0	LAL-test, kinetic-turbidimetric method

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

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