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

GfPS Gesellschaft für Produktionshygiene und Sterilitätssicherung mbH
Talbotstraße 21, 52068 Aachen

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

Field:	Medical devices in compliance with the requirements according to Directives 93/42/EEC on independence
Testing fields/test items:	Microbiological-hygienic tests of Medical devices, cleaning devices, Sterilization processes as well as microbiological-hygienic and physical tests of sterile barrier and packaging systems; Environmental monitoring

The accreditation certificate shall only apply in connection with the notice of accreditation of 12.05.2021 with the accreditation number D-PL-13422-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 7 pages.

Registration number of the certificate: **D-PL-13422-01-00**

Frankfurt am Main, 12.05.2021	Dipl.-Biol. Uwe Zimmermann Head of Division	Translation issued: 12.05.2021	Head of Division

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 may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

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

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13422-01-00 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **12.05.2021**

Date of issue: 12.05.2021

Holder of certificate:

GfPS Gesellschaft für Produktionshygiene und Sterilitätssicherung mbH
Talbotstraße 21, 52068 Aachen

Field:	Medical devices and the Directive 93/42/EEC[23] on independence
Testing fields/test items:	Microbiological-hygienic tests of Medical devices, cleaning devices, Sterilization processes as well as microbiological-hygienic and physical tests of sterile barrier and packaging systems; 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 may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

Abbreviations used: see last page

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

Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Microbiological hygienic testing	Medical devices	Sterility test	DIN EN ISO 11737-2 Ph. Eur. 2.6.1 USP <71>
		Total aerobic microbial count	Ph. Eur. 2.6.12 USP <61>
		Test for particular microorganisms - Enterobacteriaceae - Salmonellae - Pseudomonas aeruginosa - Staphylococcus aureus - Eschericha coli Test for adequate antimicrobial preservation	Ph. Eur. 2.6.13 USP <62> SOP 120 Ph. Eur. 5.1.3 USP <51>
	Sterilization processes - by moist heat	Tests within the context of routine monitoring - by means of biological indicators	DIN EN ISO 17665-1 SOP 109 other applicable documents: DIN EN 285
	- by dry heat	- by means of biological indicators	SOP 109
	- by ethylene oxide	- by means of biological indicators	DIN EN ISO 11135 SOP 109

Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Microbiological hygienic testing	Cleaning devices	Tests within the context of routine monitoring	
	- decontamination systems for mechanically decontaminable mattresses	- by means of biological indicators	SOP 147 Directive of BGA thermal disinfection processes and cleaning machines AK-BWA, Part 8
	- decontamination systems for bed frames and bedside tables	- by means of biological indicators	SOP 147 Directive of BGA thermal disinfection processes and cleaning machines AK-BWA, Part 8
	- decontamination systems for circulation containers	- by means of biological indicators	SOP 147 Directive of BGA thermal disinfection processes and cleaning machines AK-BWA, Part 8
	Sterile barrier- and packaging systems, packaging materials	Test for conformity	DIN EN ISO 11607-1
		- Micobiological barrier	DIN 58953-6 ASTM F 1608 SOP 169
Physical testing	Sterile barrier- and packaging systems, packaging materials	Test for conformity	DIN EN ISO 11607-1
		- Accelerated aging	ASTM F 1980
		- Seal strength	N EN 868-5 ASTM F 88/ F 88M
		- Integrity of the sterile barrier seal	ASTM F 1886 / F 1886M ASTM F 1929 ASTM F 3039
		- Integrity of the sterile barrier system	ASTM F 2096

Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Physical testing	Sterile barrier- and packaging systems, packaging materials	Real time aging	SOP 160 (ASTM F 1980)
Environmental Monitoring by Production and Testing of Product Cleanliness according to DIN EN ISO 13485:2016-08[4], Par. 6.4 und Par. 7.5			
Microbiological hygienic testing	Medical devices	Test for bacterial endotoxins (LAL –Test)	Ph. Eur. 2.6.14 USP <85>
		Determination of a population of microorganisms on products	DIN EN ISO 11737-1
	Air conditioning systems	Clean-room monitoring	DIN EN ISO 14644-1 DIN EN ISO 14644-2 DIN EN ISO 14644-3 DIN EN ISO 14644-4 VDI 6022 Blatt 1 VDI 2083 Blatt 3
		Microbiological examination of air	DIN EN ISO 14698-1 DIN EN ISO 14698-2 DIN 1946-4 VDI 2083 Blatt 3
		Microbiological examination of surfaces	DIN EN ISO 14698-1 DIN EN ISO 14698-2
		Semi-quantitative microbial enumeration in compressed air	SOP 119 SOP 120
	Water and aqueous solutions	Counting the total viable aerobic microorganisms capable of reproduction	Ph. Eur. 2.6.12 USP <61> SOP 120

Regulations:

DIN EN 285 : 2016-05	Sterilization – Steam sterilizers – Large-sterilizers
DIN EN 11135 : 2014-10	Sterilization of health care products - Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical device
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 868-5 : 2019-03	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
ISO 8573-7: 2003-05	Compressed air – Part 7: Test method for viable microbiological
DIN 1946-4: 2018-09	Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care
DIN EN ISO 11607-1: 2020-05	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11737-1: 2018-11	Sterilization of health care products - 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 14644-1 : 2016-06	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
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
DIN EN ISO 14644-3 : 2006–03	Cleanrooms and associated controlled environments - Part 3: Test methods
DIN EN ISO 14644-4 : 2003–06	Cleanrooms and associated controlled environments - Part 4: Design, construction and start up
DIN EN ISO 14698-1 : 2004-04	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
DIN EN ISO 14698-2 : 2004-02	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data

DIN EN ISO 14698-2 : 2010-07 Corrigendum 1	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
DIN 58953-6 : 2016-12	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
AK-BWA	Working Committee for Bedframe and Trolley Decontamination: mechanical cleaning and disinfection of bedframes, bedside tables, mattresses, trollies and circulatory containers *Bundesgesundheitsblatt*, **23**, 1980, pp. 364-367
ASTM F 1608 - 16	Standard Test Method for Microbial Ranking of Porous Packaging
ASTM F 1886/F1886M-16	Standard Test Method for Determining Integrity of Seals for
ASTM F 88/F 88M - 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F 1929 - 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F 1980 - 16	Standard Guide for Accelerated Aging of Sterile Barrier Systems
ASTM F 2096 - 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F 3039 - 15	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration
Ph. Eur. 10.0, 2.6.1	Testing for sterility
Ph. Eur. 10.0, 2.6.12	Microbiological testing of non-sterile products: Counting the total number of germs capable of reproduction
Ph. Eur. 10.0, 2.6.13	Microbiological testing of non-sterile products: Detection of specified microorganisms
Ph. Eur. 10.0, 2.6.14	Testing for bacterial endotoxins
Ph. Eur. 10.0, 5.1.3	Testing for sufficient preservation
Directive of BGA thermal disinfection processes and cleaning machines	Guidelines from the Federal Ministry for Health for the testing of thermal disinfection processes and cleaning machinery (Complied from the comments on the guidelines of the BGA for the testing of thermal disinfection processes and cleaning machinery *Bundesgesundheitsblatt*, **23**, 1980, pp. 364-367
SOP 109 REV T	Microbiological in - process control of EO-/steam-/heat-/ plasma- sterilization

SOP 119 REV H	Semi-quantitative determination of the microbial count in compressed air
SOP 120 REV K	Microbiological Differentiation
SOP 147 REV I	Testing of dishwashers, disinfection machine and disinfection facilities for trollies and bedframes using bioindicators
SOP 160 REV L	Packaging tests
SOP 169 REV G	Testing of microbial barrier behaviour by microbiological dusting
USP 42, <51> : 2018	Antimicrobial Effectiveness Test
USP 42, <61> : 2018	Microbiological Examination of Non-Sterile Products: Microbial
USP 42, <62> : 2018	Microbiological Examination of Non-Sterile Products: Tests for Specified Microorganisms
USP 42, <71> : 2018	Sterility Tests
USP 42, <85> : 2018	Bacterial Endotoxins Test
VDI 2083 Blatt 3: 2005-07	Cleanroom technology - Metrology and test methods
VDI 6022 Blatt 1: 2018-01	Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units

Abbreviations used:

AK-BWA	Arbeitskreis Bettgestell- und Wagendekontamination
DIN	Deutsches Institut für Normung
EN	Europäische Norm
ISO	International Organization for Standardardization
Ph. Eur.	Pharmacopoeia European
SOP	Standard Operating Procedure (Standardarbeitsanweisung der GfPS)
USP	United States Pharmacopeia
VDI	Verein Deutscher Ingenieure

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

[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices