Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-20966-02-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 16.07.2020

Date of issue: 17.09.2020

Holder of certificate:

ap-qualifizierung GmbH
Lembergstraße 17, 72766 Reutlingen

Field:	Medical devices and the Directive 93/42/EEC[2] and 90/385/EEC[3]
Testing fields/test items:	Microbiological-hygienic testing of medical devices as well as sterile barrier and packaging systems and physical testing of sterile and packaging systems; 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

Testing area	**Test subject** **Product(category)**	**Type of testing** **Test**	**Regulatory requirement** **Test method**
Microbiological-hygienic tests	Medical devices	Test for Sterility - Membrane filtration - Direct inoculation	DIN EN ISO 11737-2 T-301-SOP In addition: Ph. Eur. 2.6.1
	Sterile barrier and packaging systems, materials	Examinations as part of proof of compliance - Microbiological barrier using „Exposure chamber method“	DIN EN ISO 11607-1 ASTM F1608 T-303-SOP
Physical tests	Sterile barrier and packaging systems, materials	Examinations as part of proof of compliance	DIN EN ISO 11607-1
		- Rip-off	DIN EN 868-5 T-304-SOP
		- Seal strength	DIN EN 868-5 T-304-SOP
		- Integrity of sterile barrier system	ASTM F1929 ASTM F3039 ASTM F1886/F1886M T-302-SOP
Environmental monitoring in the manufacture and testing of the cleanliness of the products in accordance with DIN EN ISO 13485:2012[4] / DIN EN ISO 13485:2016[5], paragraph 6.4 and paragraph 7.5			
Microbiological-hygienic tests	Medical devices	Determination of a population of microorganisms on products (Bioburden)	DIN EN ISO 11737-1 Ph. Eur. 2.6.12 T-400-SOP
		Bacterial Endotoxins	Ph. Eur. 2.6.14 Ph. Eur. 5.1.10 T-410-SOP

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Microbiological-hygienic tests	air	Microbiological count of air - Air sampling - Sedimentation	DIN EN ISO 14698-1 DIN EN ISO 14698-2 DIN 1946-4 T-110-SOP T-210-SOP T-211-SOP In addition: VDI 2083 Blatt 3
	surface	Counting of viable aerobic germs (on surface)	DIN EN ISO 14698-1 DIN EN ISO 14698-2 DIN 1946-4 T-211-SOP In addition: VDI 2083 Blatt 3
Physical tests	air	Testing of compressed air - Contamination and cleanroom class - Oil aerosol content - Test methods for measurement of humidity	 ISO 8573-1 T-110-SOP ISO 8573-2 T-110-SOP ISO 8573-3 T-110-SOP
		Cleanroom monitoring	DIN EN ISO 14644-1 DIN EN ISO 14644-2 DIN EN ISO 14644-3 DIN EN ISO 14644-4 T-110-SOP T-111-SOP In addition: DIN 1946-4 VDI 2083 Blatt 3 VDI 6022 Blatt 1 EU- GMP guideline, Annex 1

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Environmental monitoring in the manufacture and testing of the cleanliness of the products in accordance with DIN EN ISO 13485:2012[4] / DIN EN ISO 13485:2016[5], paragraph 6.4 and paragraph 7.5			
Physical tests	Microbiological safety cabinets	Performance criteria for microbiological safety cabinets	DIN EN 12469 T-120-SOP

Regulations

DIN EN 868-5 : 2009-09	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
DIN 1946-4:2016-04	Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care
ISO 8573-1:2010-04	Compressed air - Part 1: Contaminants and purity classes
ISO 8573-2:2018-02	Compressed air - Contaminant measurement - Part 2: Oil aerosol content
ISO 8573-3:1999-06	Compressed air - Part 3: Test methods for measurement of humidity
DIN EN ISO 11607-1:2017-10	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11737-1:2009-11	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 12469:2000-09	Biotechnology - Performance criteria for microbiological safety cabinets
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

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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
ASTM F1608 - 16	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
ASTM F1929 - 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F3039 - 15	Standard Test Method for Detecting Seal Leaks in Nonporous Medical Packaging by Dye Penetration
ASTM F1886 / F1886M - 16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
EG-Leitfaden GMP, Anhang 1	EU GMP Annex 1: Manufacture of Sterile Medicinal Products - revision November 2008
Ph. Eur. 9, 2.6.1	Test for Sterility
Ph. Eur. 9, 2.6.12	Microbiological examination of non-sterile products (total viable aerobic count)
Ph. Eur. 9, 2.6.14	Bacterial Endotoxins
Ph. Eur. 9, 5.1.10	Guidelines for using the test for bacterial endotoxins
VDI 2083 Blatt 3:2004-01	Cleanroom technology – Metrology and test methods
VDI 6022 Blatt 1	Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)
T-110-SOP_2018-05-07	Clean Room Monitoring
T-111-SOP_2018-05-07	Counting airborne particles for classification
T-120-SOP_2018-05-07	Testing of safety workbenches
T-210-SOP_2018-05-07	Microbiological testing of air
T-211-SOP_2018-05-07	Microbiological testing of surfaces
T-301-SOP_2018-04-17	Test for Sterility of medical devices

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T-302-SOP_2018-05-07	Checking of sealings
T-303-SOP_2018-05-07	Microbiological Dusting
T-304-SOP_2018-05-07	Checking for peelability
T-400-SOP_2018-04-17	Bioburden
T-410-SOP_2018-05-07	Bacterial Endotoxins (Gel clot method)

Abbreviations used

ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization)
EN	Europäische Norm (European standard)
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
T-xxx-SOP	SOP from ap-qualifizierung GmbH
VDI	Verein Deutscher Ingenieure (Association of German Engineers)

[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 device
[3] COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
[4] DIN EN ISO 13485:2012-11 Medical devices - Quality management systems - Requirements for regulatory purposes
[5] DIN EN ISO 13485:2016-08 Medical devices - Quality management systems - Requirements for regulatory purposes

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[1] DIN EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories
[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices
[3] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
[4] DIN EN ISO 13485 : 2016-08 Medical devices - Quality management system

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