Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-14013-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **14.08.2020**

Date of issue: 31.08.2022

Holder of certificate:

IfP Privates Institut für Produktqualität GmbH
Wagner-Régeny-Str. 8, 12489 Berlin

Field:	Medical devices
Testing fields/test items:	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 Product(category)	Type of testing Test	Regulation Test method
Microbiological-hygienic tests	Medical devices	Testing for sterility - membrane filtration - direct loading	DIN EN ISO 11737-2 Ph. Eur. 2.6.1 ifp 000507
Environmental monitoring in production and testing of product cleanliness in accordance with DIN EN ISO 13485:2016[1], par. 6.4 and par. 7.5			
Microbiological-hygienic tests	Medical devices	Determination of the population of microorganisms on a product (bioburden determination) - Membrane filtration method - Pour plate method - MPN-method - Spread plate method	DIN EN ISO 11737-1 Ph. Eur. 2.6.12 ifp 000379 ifp 000380 ifp 001346 Applicable: Ph. Eur. 5.1.4
		Detection of specified microorganisms	Ph. Eur. 2.6.13 ifp 000278 ifp 001591 ifp 001597 ifp 001599 ifp 001600 ifp 001601
		Testing for bacterial endotoxins (LAL-test)	Ph. Eur. 2.6.14 ifp 000505 ifp 001589
	Clean room technology air	Determination of the airborne germ count	DIN EN ISO 14698-1 DIN EN ISO 14698-2 ifp 002016

Testing field	Test item Product(category)	Type of testing Test	Regulation Test method
		- with air sampler (impaction method) - sedimentation method	Applicable: DIN 1946-4 VDI 2083 sheet 3 EU-Guideline, Annex 1
Environmental monitoring in production and testing of product cleanliness in accordance with DIN EN ISO 13485:2016[1], par. 6.4 and par. 7.5			
Physical testing	Clean room technology air	Determination of the air particle number - Air particle count	DIN EN ISO 14644-1, DIN EN ISO 14644-2 ifp 001345 Applicable: DIN 1946-4 VDI 2083 sheet 3 EU-Guideline, Annex 1

Regulations:

DIN 1946-4 : 2018-09	Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care
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 : 2018-07	Sterilization of health care products - 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 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
Ph. Eur. 9, 2.6.1	Sterility
Ph. Eur. 9, 2.6.12	Microbiological examination of non-sterile products: microbial enumeration tests
Ph. Eur. 9, 2.6.13	Microbiological examination of non-sterile products: test for specified micro-organisms
Ph. Eur. 9, 2.6.14	Bacterial endotoxins
Ph. Eur. 9, 5.1.4	Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use
VDI 2083 sheet 1 : 2013-01	Cleanroom technology - Particulate air cleanliness classes
ifp 002016:2020-06	Determination of the airborne germ count in food manufacturers facilities, other buildings (warehouses, apartments, schools) and enterprises for pharmaceutical products and medical devices
ifp 000278 : 2019-12	Identification of microorganisms using MALDI-TOF
ifp 000379:2020-07	Testing for microbial purity
ifp 000380:2020-07	Testing for microbial purity of herbal medicinal products for oral use
ifp 000505:2020-07	Testing for bacterial endotoxins

ifp 000507:2020-07	Testing for sterility
ifp 001345:2020-07	Determination of the air particle number
ifp 001346:2020-07	Bioburden
ifp 001589:2020-07	Testing for bacterial endotoxins using the fixed gel method
ifp 001591:2019-12	Identification of gram-positive bacteria using MALDI-TOF for microbiological isolates, food, animal feed, cosmetics, pharmaceutical products, raw materials and environmental samples
ifp 001597:2019-12	Identification of gram-negative bacteria using MALDI-TOF for microbiological isolates, food, animal feed, cosmetics, pharmaceutical products, raw materials and environmental samples
ifp 001599:2019-12	Identification of mould using MALDI-TOF for microbiological isolates, food, animal feed, cosmetics, pharmaceutical products, raw materials and environmental samples
ifp 001600:2019-12	Identification of yeast using MALDI-TOF for microbiological isolates, food, animal feed, cosmetics, pharmaceutical products, raw materials and environmental samples
ifp 001601:2019-12	Identification of spore forming bacteria using MALDI-TOF for microbiological isolates, food, animal feed, cosmetics, pharmaceutical products, raw materials and environmental samples

Abbreviations used:

DIN	Deutsches Institut für Normung e. V. (German Institute for Standardisation e. V.)
EN	Europäische Norm (European Standard)
IEC	International Electrotechnical Commission
ISO	International Organisation for Standardization
ifp …	In-house method of ifp Privates Institut für Produktqualität GmbH
VDI	Verein Deutscher Ingenieure (Association of German Engineers)

[1] DIN EN ISO 13485 : 2016-08 Medical devices - Quality management systems - Requirements for regulatory purposes