Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-11020-04-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 15.05.2020

Date of issue: 15.05.2020

Holder of certificate:

SGS Germany GmbH
Rödingsmarkt 16, 20459 Hamburg

With its testing laboratory at the location

Weidenbaumsweg 137, 21035 Hamburg

Field:	Medical devices meeting the requirements for independence pursuant to Directives 93/42/EEC[2] and 90/385/EEC[3]
Testing fields/test items:	Microbiological-hygienic testing of medical devices including disinfectants, 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 field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Medical devices	Testing for sterility	DIN EN ISO 11737-2 SOP 1682
		Testing for adequate antimicrobial preservation	Ph. Eur. 5.1.3 SOP M 1685
	Disinfectants	Determination of bactericidal, fungicidal or yeasticidal effectiveness in a qualitative suspension test (phase 1 / step 1)	DIN EN 1040 DIN EN 1275
		Determination of bactericidal and yeasticidal effectiveness in a qualitative suspension test	VAH Method 8
		Determination of bactericidal, yeasticidal, fungicidal and mycobactericidal effectiveness in a quantitative suspension test (phase 2 / step 1)	DIN EN 13727 DIN EN 13624 DIN EN 14348
		Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in a quantitative suspension test	VAH Method 9
		Determination of bactericidal, fungicidal, yeasticidal and mycobactericidal activity in a quantitative germ carrier test (phase 2 / step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 Also applicable:: DIN EN 14885
		Chemical/chemothermal instrument disinfection – Practical quantitative germ carrier test	VAH Method 15

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Disinfectants	Determination of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action using cloths in the human medical field (phase 2 / stage 2)	DIN EN 16615
		Testing of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal effectiveness on non-porous surfaces (practical test) - Without mechanics - With mechanics	 VAH Method 14.1 VAH Method 14.2
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485: 2016 [4], section 6.4 and section 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 SOP M 943 SOP M 1704
	Water and aqueous solutions	Testing for microbial contamination - Count of germs capable of reproduction	Ph. Eur. 2.6.13 SOP M 1302 Ph. Eur. 2.6.12 SOP M 1680 SOP M 1694
		Test for bacterial endotoxins	Ph. Eur. 2.6.14 SOP M 945
	Environmental samples, production line samples, personnel swab samples	Hygienic environmental testing	SOP M 1679
		Determination of airborne germ content	SOP M 1677
Physical tests	Air	Measurement of air particle concentration	SOP M 1695

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Regulations[5]

DIN EN 1040 : 2006-03	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)
DIN EN 1275 : 2006-03	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics – Test method and requirements (phase 1)
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	Sterilisation of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN 13624 : 2013-12	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1)
DIN EN 13727 : 2015-12	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)
DIN EN 14348 : 2005-04	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants – Test methods and requirements (phase 2, step 1)
DIN EN 14561 : 2006-08	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)
DIN EN 14562 : 2006-08	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2)

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DIN EN 14563 : 2009-02	Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test method and requirements (phase 2, step 2)
DIN EN 14885 : 2015-11	Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics
DIN EN 16615 : 2015-06	Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) – Test method and requirements (phase 2, step 2)
VAH Method 8: 2015-04	Requirements and methods for VAH certification of chemical disinfection processes – Determination of bactericidal and yeasticidal effectiveness in a qualitative suspension test
VAH Method 9: 2015-04	Requirements and methods for VAH certification of chemical disinfection processes – Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal effectiveness in a quantitative suspension test
VAH Method 14.1: 2015-04	Requirements and methods for VAH certification of chemical disinfection processes – Surface disinfection without mechanics – Practical test
VAH Method 14.2: 2015-04	Requirements and methods for VAH certification of chemical disinfection processes – Surface disinfection with mechanics – Practical test (4-field test)
VAH Method 15: 2015-04	Requirements and methods for VAH certification of chemical disinfection processes – Chemical instrument disinfection – Practical quantitative germ carrier test
Ph. Eur. 9, 2.6.12	Microbiological testing of non-sterile products: Counting of microorganisms capable of reproduction
Ph. Eur. 9, 2.6.13	Microbiological testing of non-sterile products: Detection of specified microorganisms
Ph. Eur. 9, 2.6.14	Test for bacterial endotoxins
Ph. Eur. 9, 5.1.3	Testing for adequate antimicrobial preservation
SOP M 943	Bioburden test – Analysis of the basic microbiological load
SOP M 945	Detection of endotoxins of gram-negative bacteria with the Limulus test
SOP M 1302	Testing for microbial contamination of non-sterile pharmaceutical products

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SOP M 1677	Microbiological determination of airborne germ content
SOP M 1679	Methods for hygienic control of production lines, environment and personnel
SOP M 1680	Microbiological analysis of water
SOP M 1682	Testing of pharmaceutical and medical products for sterility
SOP M 1685	Testing of cosmetics for sufficient antimicrobial preservation
SOP M 1694	Sampling of water
SOP M 1695	Measurement of airborne particle concentration in clean rooms using the APC ErgoTouch Pro2 particle collector from Merck
SOP M 1704	Identification of microorganisms with the MALDI Biotyper System

Abbreviations used:

DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardardization
Ph. Eur	Pharmacopoeia European
SOP	Standard operating procedure of SGS Germany GmbH
VAH	Verbund für Angewandte Hygiene e.V. (Association for Applied Hygiene)

[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

[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 Medical devices – Quality management systems – Requirements for regulatory purposes

[5] For the transition periods, see the list of harmonized standards on the homepage of the EU.

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