

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18411-01-02 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 05.11.2020

Date of issue: 05.11.2020

Holder of certificate:

Hygiene Nord GmbH
Walther-Rathenau-Straße 49 a, 17489 Greifswald

Tests in the fields:

Field: Medical devices under fulfillment of requirements according to Directives 93/42/EWG² and 90/385/EEC³ at the independence

Testing fields/test items: biological and microbiological-hygienic testing of medical devices including disinfectants; environmental monitoring

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

*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
biological testing	Medical devices	Cytotoxicity testing - Neutral-red uptake test after contact with extracts or after direct contact (NRU-Test) - Metabolic activity after contact with extracts or after direct contact <ul style="list-style-type: none"> • MTT-Test • XTT-Test - Agar diffusion test with extracts (Agarose Overlay method) - Growth-inhibition test after contact with extracts or after direct contact	DIN EN ISO 10993-5 SOP 2-09 SOP 2-56 SOP 2-48 SOP 2-57 SOP 2-53 SOP 2-54 applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
Microbiological-hygienic testing	Medical devices	Sterility testing - membrane filtration - Direct loading	DIN EN ISO 11737-2 SOP 2-29 applicable: Ph. Eur. 2.5.1
	Disinfectants	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 1040 DIN EN 1275 DIN EN 14347 SOP 2-47 SOP 2-59 SOP 2-61
		Determination of bactericidal and levurocidal activity in a qualitative suspension test	VAH method 8 SOP 2-14

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectants	Quantitative suspension test for the evaluation of bactericidal, fungicidal, levurocidal and mycobactericidal activity of chemical disinfectants in the medical area (phase 2, step1)	DIN EN 13624 DIN EN 13727 DIN EN 14348 SOP 2-32 SOP 2-33 SOP 2-41
		Determination of bactericidal, fungicidal, tuberculocidal and mycobactericidal activity in a quantitative suspension test	VAH method 9 SOP 2-15
		Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area – Test method and requirements (phase 2, step 1)	DIN EN 77726 SOP 2-79
		Surface disinfection against Clostridium difficile spores - Surface disinfection with mechanical action (4-field test)	VAH method 19 SOP 2-81
		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)	DIN EN 16615 SOP 2-75
		Determination of bactericidal, levurocidal, fungicidal, tuberculocidal or mycobactericidal efficacy on non-porous surfaces in practical experiments	
		- Surface disinfection without mechanical action	VAH method 14.1 SOP 2-81
		- Surface disinfection with mechanical action (4-field-test)	VAH method 14.2 SOP 2-75

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Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectants	Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area (phase 2, step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 SOP 2-42 SOP 2-43 SOP 2-44
		Chemical-thermal textile disinfection (phase 2, step 2)	DIN EN 16616 SOP 2-38
		Thermochemical laundry disinfection – single bath method (practice-like test) - at temperatures of 30 °C - < 60 °C - at temperatures of ≤ 60 °C – 70 °C	VAH method 17.1 SOP 2-38 VAH method 17.2 SOP 2-38
		Chemical instrument disinfection (quantitative carrier test)	VAH method 15 SOP 2-30
		Determination of sporicidal activity against <i>Clostridium difficile</i> spores in a quantitative suspension test	VAH method 18 SOP 2-30
Environmental monitoring in production and testing of cleanliness of products according to DIN EN ISO 13485 : 2016-08⁴, 6.4 and 7.5			
Microbiological- hygienic testing	Medical devices	Estimation of population of microorganisms on products (determination of bioburden)	DIN EN ISO 11737-1

Regulations

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)

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DIN EN 10993-1 2010-04	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
DIN EN 10993-5 2009-10	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
DIN EN 10993-12 2012-10	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
DIN EN 11737-1 2018-11	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN EN 11737-2 2010-04	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 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 (phase2, 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 14347 2005-08	Chemical disinfectants and antiseptics - Basic sporicidal activity -Test method and requirements (phase 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)
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
DIN EN 16616 2015-10	Chemical disinfectants and antiseptics – Chemical-thermal textile disinfection – Test method and requirements (phase 2, step 2)
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)
Ph.Eur. 9, 2.6.1	Testing for sterility

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Ph.Eur. 9, 2.6.12	Microbiological testing of non-sterile products: Counting the total number of germs capable of reproduction
VAH method 8 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Determination of bactericidal and levurocidal activity in a qualitative suspension test
VAH method 9 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in a quantitative suspension test
VAH method 14.1 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Testing of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidaleffectiveness on non-porous surfaces (practical test) without mechanical action
VAH method 14.2 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Testing of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal effectiveness on non-porous surfaces - Practical test with mechanical action
VAH method 15 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Chemical/chemothermal instrument disinfection –Practical quantitative germ carrier test
VAH method 17 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Thermochemical laundry disinfection – single bath method (practice-like test)
VAH method 18 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Determination of sporicidal activity against spores of <i>Clostridium difficile</i> in a quantitative suspension test
VAH method 19 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: Surface disinfection against spores of <i>Clostridium difficile</i> - Surface disinfection with mechanical action
SOP 2-09, Version 4	DIN 10993-5: Cytotoxicity (NR-Test)
SOP 2-14, Version 6	Determination of the bactericidal and fungicidal effect in a qualitative suspension test
SOP 2-15, Version 7	Determination of bactericidal, fungicidal, tuberculocidal and mycobactericidal activity in a quantitative suspension test
SOP 2-29, Version 8	Testing for sterility
SOP 2-30, Version 5	Testing of agents for instrument disinfection
SOP 2-32, Version 6	Quantitative suspension test bactericidal activity according to EN 13727
SOP 2-33, Version 4	Quantitative suspension test fungicidal and levurocidal activity according to EN 13624

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SOP 2-38, Version 5	Chemothermal laundry disinfection
SOP 2-41, Version 2	Quantitative suspension test for the evaluation of mycobactericidal activity according to EN 14348
SOP 2-42, Version 3	Quantitative carrier test for the evaluation of mycobactericidal activity for instruments according to EN 14563
SOP 2-43, Version 3	Quantitative carrier test for the evaluation of fungicidal activity for instruments according to EN 14562
SOP 2-44, Version 5	Quantitative carrier test for the evaluation of bactericidal activity for instruments according to EN 14561
SOP 2-47, Version 3	DIN 14347 Sporicidy
SOP 2-48, Version 4	DIN 10993-5: Cytotoxicity (MTT Test)
SOP 2-53, Version 4	DIN 10993-5: Cytotoxicity (Agarose-Overlay test)
SOP 2-54, Version 4	DIN 10993-5: Cytotoxicity (Growth-inhibition test)
SOP 2-56, Version 4	DIN 10993-5: Cytotoxicity (3T3-NRU test)
SOP 2-57, Version 4	DIN 10993-5: Cytotoxicity (L929-XTT test)
SOP 2-59, Version 3	Quantitative suspension test for the evaluation of fungicidal or levurocidal activity according to EN 1275
SOP 2-61, Version 3	Quantitative suspension test for the evaluation of bactericidal activity according to EN 1040
SOP 2-69, Version 2	Testing of agents for surface disinfection without mechanical action according to VAH
SOP 2-75, Version 1	4-field test
SOP 2-76, Version 2	Determination of bioburden (biopsy needles)
SOP 2-79, Version 1	Quantitative suspension test for the evaluation of sporicidal activity according to EN 17726
SOP 2-80, Version 1	Determination of sporicidal activity against spores of <i>Clostridium difficile</i> in a quantitative suspension test
SOP 2-81, Version 1	VAH / 4-field test - Surface disinfection with mechanical action against spores of <i>Clostridium difficile</i> -

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Abbreviations

DIN	German Institute for Standards (Deutsches Institut für Normung)
EN	European Standards (Europäische Norm)
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
SOP	Standard Operating Procedure (In house method of Hygiene Nord GmbH)
VAH	Association for applied hygiene / Verbund für angewandte Hygiene e.V.

¹ DIN EN ISO/IEC 17025 : 2018-08 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 systems —. Requirements for regulatory purposes