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

Institut für Hygiene und Umwelt
Marckmannstraße 129 a, 20539 Hamburg

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

Field:	Medical devices meeting the requirements for independence pursuant to Directives 93/42/EEC and 90/385/EEC
Testing fields/test items:	microbiological-hygienic testing of medical devices including disinfectants, environmental monitoring

The accreditation certificate shall only apply in connection with the notice of accreditation of 15.12.2020 with the accreditation number D-PL-14095-03. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 8 pages.

Registration number of the certificate: **D-PL-14095-03-02**

Frankfurt am Main, 15.12.2020	Dipl.-Biol. Uwe Zimmermann Head of Division	Translation issued: 06.12.2021	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.

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The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products. 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 Co-operation (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-14095-03-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **15.12.2020**

Date of issue: 15.12.2020

Holder of certificate:

Institut für Hygiene und Umwelt
Marckmannstraße 129 a, 20539 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

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.
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Abbreviations used: see last page

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Disinfectants	Determination of the bacteriostatic and yeaststatic activity as well as a suitable neutraliser	VAH – Method 7 PM 314-315
		Determination of the bactericidal and yeasticidal activity in the qualitative suspension test	VAH – Method 8 PM 314-315
		Quantitative suspension test to determine the bactericidal, fungicidal or mycobactericidal effectiveness of chemical disinfectants in the medical area (phase 2, step 1)	DIN EN 13727 DIN EN 13624 DIN EN 14348 PM 314-312 PM 314-308 PM 314-307
		Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in the quantitative suspension test	VAH – Method 9 PM 314-315
		Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action in the medical area (4-field test) (phase 2, step 2)	DIN EN 16615 PM 314-302

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Disinfectants	Evaluation of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity on non-porous surfaces (practical test) - Surface disinfection without mechanical action - Surface disinfection with mechanical action – 4-field test	VAH – Method 14.1 PM 314-315 VAH – Method 14.2 PM 314-315
		Quantitative carrier test for the evaluation of bactericidal, fungicidal or yeasticidal, mycobactericidal activity in the medical area (phase 2, step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 PM 314-303 PM 314-304 PM 314-305
		Chemical/chemical-thermal instrument disinfection – quantitative carrier test	VAH – Method 15 PM 314-315
		Chemical textile disinfection – immersion method (simulated-use test)	VAH – Method 16 PM 314-315
		Chemical-thermal textile disinfection – simulated-use test (without pre-wash) At temperatures from 30 °C to < 60 °C At temperatures from ≥ 60 °C to 70 °C	VAH – Method 17.1 PM 314-315 VAH – Method 17.2 PM 314-315

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological hygienic tests	Medical devices	Test to determine the effectiveness of disinfection	ASTM E 1837 PM 314-319
		Test to determine the effectiveness of cleaning	ASTM E 2314 PM 314-313
	Antimicrobial materials	Measurement of antibacterial activity on plastics and other non-porous surfaces	ISO 22196 PM 314-310
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485:2016-08[4], section 6.4 and section 7.5			
Chemical testing	Medical devices	Determination of protein content with the BCA Protein Assay Kit	PM 314-301 (DIN ISO/TS 15883-5) Also applicable: AAMI TIR 30
		Determination of TOC content with TOC small-scale sealed tube method (expulsion method)	PM 314-302 (Ph. Eur. 2.2.44) Also applicable: AAMI TIR 30
Environment monitoring in production and testing of the cleanliness of devices in accordance with DIN EN ISO 13485:2016-08, section 6.4 and section 7.5			
Microbiological hygienic tests	Medical devices	Estimation of the population of microorganisms on products (bioburden determination)	DIN EN ISO 11737-1 Ph. Eur. 2.6.12 PM 314-318
	Condoms	Qualitative determination of cultivable microorganisms	PM 314-320 (G+P DLF)

Regulations[5]

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 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)
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 ISO/TS 15883-5 : 2006-02	Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy
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)
AAMI TIR 30 : 2011	A Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ISO 22196 : 2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces
ASTM E1837 – 96 (2014)	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)

ASTM E 2314 - 03 (2014)	Standard Test Method for Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)
G+P DLF : 2009-03	"Quality and test specifications for condoms made of natural rubber latex" of Deutsche Latex Forschungsgemeinschaft Kondome e.V. (German Latex Research Association for Condoms).
Ph. Eur. 9, 2.2.44	Total organic carbon in water for pharmaceutical use
Ph. Eur. 9, 2.6.12	Microbiological examination of non-sterile products: microbial enumeration tests
VAH – Method 7: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Determination of the bacteriostatic and yeaststatic activity as well as a suitable neutraliser"
VAH – Method 8: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Determination of the bactericidal and yeasticidal activity in the qualitative suspension test"
VAH – Method 9: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in the quantitative suspension test"
VAH – Method 14.1: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Surface disinfection without mechanical action – simulated-use test"
VAH – Method 14.2: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Surface disinfection with mechanical action – simulated-use test (4-field test)"
VAH – Method 15: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Chemical/chemical-thermal instrument disinfection – quantitative carrier test"
VAH – Method 16: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Chemical textile disinfection – immersion method (simulated-use test)"
VAH – Method 17.1: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Test for textile disinfection procedures at temperatures between 30 °C to < 60 °C"
VAH – Method 17.2: 2019-06	Requirements and methods for VAH certification of chemical disinfection procedures: "Test for textile disinfection procedures at temperatures between ≥ 60 °C to 70 °C"
PM 314-301 2019-06-01	Experimental investigation of the treatment of medical devices and other test items

PM 314-302 2019-08-01	Quantitative test method for 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) in accordance with DIN EN 16615
PM 314-303 2019-08-01	Quantitative carrier test for evaluation of the mycobactericidal effect of chemical disinfectants for instruments in the medical area – Test method and requirements (phase 2, step 2) in accordance with DIN EN 14563
PM 314-304 2019-08-01	Quantitative carrier test for evaluation of the fungicidal or yeasticidal effect of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 2) in accordance with DIN EN 14562
PM 314-305 2019-08-15	Quantitative carrier test for evaluation of the bactericidal effect of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 2) in accordance with DIN EN 14561
PM 314-307 2019-08-15	Quantitative suspension test for evaluation of the fungicidal effect of chemical disinfectants for instruments in the medical area – Test method and requirements (phase 2, step 1) in accordance with DIN EN 13624
PM 314-308 2019-08-15	Quantitative suspension test for evaluation of the bactericidal effect of chemical disinfectants for instruments in the medical area – Test method and requirements (phase 2, step 1) in accordance with DIN EN 13727
PM 314-310 2019-09-01	Measurement of antibacterial activity on plastics and other non-porous surfaces in accordance with ISO 22196
PM 314-312 2019-08-15	Quantitative suspension test for the evaluation of the mycobactericidal effect of chemical disinfectants in the medical area including instrument disinfectants in accordance with DIN EN 14348 (2005)
PM 314-313 2019-08-15	Standard test method for determination of the effectiveness of cleaning methods for reusable medical instruments using a microbiological method (simulated application test) in accordance with ASTM E2314-03 (2014)
PM 314-315 2019-08-01	Analysis for testing of chemical disinfection methods in accordance with the standard VAH methods
PM 314-318 2019-08-01	Testing of non-sterile products for total germs

PM 314-319 2019-08-01	Standard test method for determining the effectiveness of disinfection methods for reusable medical devices (simulated application test) in accordance with ASTM E1837-96 (2014)
PM 314-320 2019-08-15	Preparation of condoms

Abbreviations used:

AAMI	Association for the Advancement of Medical Instrumentation
ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
PM 314-3xx	Work instructions of Hamburg Institut für Hygiene und Umwelt (Institute for Hygiene and Environment)
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: 2016-08 Medical devices – Quality management systems – Requirements for regulatory purposes

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