

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

Dr. Brill + Partner GmbH
Institut für Hygiene und Mikrobiologie

at the sites:

Stiegstück 34, 22339 Hamburg

Norderoog 2, 28259 Bremen

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

Medical devices

Testing fields/test items: microbiological-hygienic testing of medical devices including disinfectants, endoscopes (reprocessed), sterilization methods; environmental monitoring

The accreditation certificate shall only apply in connection with the notice of accreditation of 03.01.2022 with the accreditation number D-PL-13412-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 13 pages.

Registration number of the certificate: **D-PL-13412-01-02**

Frankfurt am Main,
03.01.2022

Dipl.-Biol. Uwe Zimmermann
Head of Division

Translation issued:
02.05.2022



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 can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de/en/accredited-bodies-search.html>.

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13412-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: 03.01.2022

Date of issue: 03.01.2022

Holder of certificate:

Dr. Brill + Partner GmbH
Institut für Hygiene und Mikrobiologie
at the sites:
Stiegstück 34, 22339 Hamburg
Norderoog 2, 28259 Bremen

Field: Medical devices

Testing fields/test items: microbiological-hygienic testing of medical devices including disinfectants, endoscopes (reprocessed), sterilization methods; 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>

Site Stiegstück 34, 22339 Hamburg

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Medical devices	Enumeration of total viable aerobic microorganisms	Ph. Eur. 2.6.12 SOP AA-00119
		Detection of specific microorganisms	Ph. Eur. 2.6.13 SOP AA-00120
		Microbial challenge test	Ph. Eur. 5.1.3 SOP AA-00131 SOP AA-00139
		Testing of antimicrobial effect	ASTM E2149 ASTM E2180 SOP AA-00143 SOP AA-00287 ISO 22196 JIS Z 2801 DIN EN ISO 20743
		Efficacy testing of cleaning-devices	ASTM E2314
		Efficacy testing of disinfectants	ASTM E1837
	Disinfectant	Quantitative suspension test for the evaluation of bactericidal, fungicidal or levurocidal or sporicidal activity of chemical disinfectants and antiseptics (basis test – phase 1)	DIN EN 1040 DIN EN 1275 DIN EN 14347 SOP AA-00068 SOP AA-00069 SOP AA-00090
		Determination of bacterio-static and leuvrostatic efficacy as well as suitable neutralization agents	VAH - Method 7 SOP AA-00040
		Determination of bactericidal and levurocidal efficacy in a qualitative suspension test	VAH - method 8 SOP AA-00041

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectant	Quantitative suspension test for the evaluation of bactericidal, fungicidal or mycobactericidal or sporicidal activity of chemical disinfectants in the medical area (phase 2, step 1)	DIN EN 13624 DIN EN 13727 DIN EN 14348 SOP AA-00087 SOP AA-00082 SOP AA-00091
		Determination of bactericidal, leuvcidal, fungicidal, tuberculocidal or mycobactericidal efficacy in a quantitative suspension test	VAH - method 9 SOP AA-00042
		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 17126 SOP AA-00230
		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 - practice-related quantitative 4-field test with mechanics	DIN EN 16615 GuidelineBGA SOP AA-00108
		Determination of bactericidal, leuvcidal, fungicidal, tuberculocidal or mycobactericidal efficacy on non-porous - surfaces in practical experiments - surface disinfection with mechanics - 4-fields test	VAH - method 14.1 Guideline BGA SOP AA-00043 VAH - method 14.1 Guideline BGA SOP AA-00051

Annex to the accreditation certificate D-PL-13412-01-02

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectant	Quantitative suspension test for the evaluation of bactericidal, fungicidal or mycobactericidal or sporicidal activity of chemical disinfectants in the medical area (phase 2, step 1)	DIN EN 13624 DIN EN 13727 DIN EN 14348 SOP AA-00087 SOP AA-00082 SOP AA-00091
		Determination of bactericidal, leuvcidal, fungicidal, tuberculocidal or mycobactericidal efficacy in a quantitative suspension test	VAH - method 9 SOP AA-00042
		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 17126 SOP AA-00230
		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 - practice-related quantitative 4-field test with mechanics	DIN EN 16615 Guideline BGA SOP AA-00108
		Determination of bactericidal, leuvcidal, fungicidal, tuberculocidal or mycobactericidal efficacy on non-porous - surfaces in practical experiments - surface disinfection with mechanics - 4-fields test	VAH - method 14.1 Guideline BGA SOP AA-00043 VAH - method 14.1 Guideline BGA SOP AA-00051

Annex to the accreditation certificate D-PL-13412-01-02

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectant	Quantitative germ carrier test for testing the bactericidal, fungicidal or levurocidal, mycobactericidal effect in human medicine (Phase 2, Step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 Guideline RKI SOP AA-00094 SOP AA-00095 SOP AA-00096
		Chemothermic laundry disinfection (phase 2, step 2)	DIN EN 16616 SOP AA-00107
		Chemical/Chemo-Thermal Instrument Disinfection - Practical Quantitative Germ Carrier Test	VAH - method 15 Guideline RKI SOP AA-00044
		Chemical laundry disinfection – inlay procedure (practice-like test)	VAH - method 16 SOP AA-00292
		Chemical-thermal textile disinfection – single-bath process (practice-like test) - at temperatures from 30 °C bis < 60 °C - at temperatures from ≥ 60 °C bis 70 °C	VAH - method 17.1 SOP AA-00045 VAH - method 17.2 SOP AA-00045
Microbiological- hygienic testing	Endoscopes (reprocessed)	Control of endoscope reprocessing	Gebel et al., 2.4 SOP AA-00132 Recommendation DGKH
	Sterilization method - with moist heat - with dry heat	Examination within routine monitoring - using bioindicators - using bioindicators	Ph. Eur. 5.1.2 SOP AA-00124 Also applicable: DIN EN ISO 11138-3 DIN EN ISO 11138-4

Annex to the accreditation certificate D-PL-13412-01-02

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Environmental monitoring in production and testing of cleanliness of products according to DIN EN ISO 13485 : 20162, 6.4 and 7.5			
Chemical testing	Medical devices	Detection of the cleaning performance Determination of protein concentration with the modified OPA method	DIN ISO/TS 15883-5 SOP AA-00130 SOP AA-00133
Microbiological-hygienic testing	Medical devices	Estimation of population of microorganisms on products (determination of bioburden)	DIN EN ISO 11737-1 SOP AA-00118

Site Norderoog 2, 28259 Bremen

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic testing	Medical devices	Carrier test on treated surface of disposable gloves	SOP AA-00031 (ASTM D7907)
		Carrier test on treated surfaces	SOP AA-00032 (JIS Z 2801) (ISO 22196)
	Disinfectant	Quantitative suspension test to determine the virucidal effectiveness of chemical disinfectants (Phase 2, Stage 1)	DIN EN 14476 Guideline DVV/RKI ASTM E1052 SOP AA-00016 SOP AA-00028
		Testing the virucidal effectiveness of chemical disinfectants with practical test models (Phase 2, Level 2)	Guideline DVV SOP AA-00019 SOP AA-00021 SOP AA-00025

Annex to the accreditation certificate D-PL-13412-01-02

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological- hygienic testing	Disinfectant	Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2)	DIN EN 16777 SOP AA-00018
		Carrier test for testing instrument disinfectants on frosted glass (Phase 2, step 2)	DIN EN 17111 SOP AA-00027
		Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate Nonporous Environmental Surfaces	ASTM E1053 SOP AA-00029
Environmental monitoring in production and testing of cleanliness of products according to DIN EN ISO 13485 : 201652, 6.4 and 7.5			
Chemical testing	Water and aqueous solutions	Testing for microbial contamination - Determination of TOC (Total Organic Carbon)	SOP AA-00263 (DIN EN 1484)

Regulations

DIN EN 1040 : 2006-03	Bactericidal effect (basic test) - phase 1
DIN EN 1275 : 2006-03	Fungicidal effect (basic test) - phase 1
DIN EN 1484 : 2019-04	Water analysis - Guidelines for the determination of total organic carbon (TOC) and dissolved organic carbon (DOC).
DIN EN ISO 11138-3 : 2017-07	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)
DIN EN ISO 11138-4 : 2017-07	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes (ISO 11138-3:2017)
DIN EN ISO 11737-1 : 2018-11	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)
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 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 14476 : 2019-10	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method 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)

Annex to the accreditation certificate D-PL-13412-01-02

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 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)
DIN EN 16616 : 2015-10	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection – test method and requirements (phase 2, step 2)
DIN EN 16777 : 2019-03	Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2)
DIN EN 17111: 2018-12	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
DIN EN 17126 : 2019-02	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 ISO 20743 : 2013-12	Textiles - Determination of antibacterial activity of textile products (ISO 20743:2013)
ISO 22196 : 2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces
ASTM D7907 -14	Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves
ASTM E1052-20	Standard Test Method to Assess the Activity of Microbiocides against Viruses in Suspension
ASTM E1053-20	Standard Test Method to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces

Annex to the accreditation certificate D-PL-13412-01-02

ASTM E1837-96	Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test)
ASTM E2149-10	Standard Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions
ASTM E2180-18	Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials
ASTM E2314-03	Determination of Effectiveness of Cleaning Processes for Reusable Medical Instruments Using a Microbiologic Method (Simulated Use Test)
Recommendation DGKH	Deutsche Gesellschaft für Krankenhaushygiene (DGKH), Hyg Med, 35 [3] 2010
Gebel, Hornei, Lerner	Quality assurance for cleaning, disinfection and sterilisation, Accepted test methods for hygiene, Behr's Verlag; February 2020
JIS Z 2801:2010	Antimicrobial products – Test for antimicrobial activity and efficacy
Guideline DVV	Guideline of Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. Quantitative test of virucidal activity of chemical disinfectants on non-porous surfaces (application i the medical area) (phase 2, step 2), Hyg & Med, 37 3, 78-85
Guideline DVV/RKI	Guideline of Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. and Robert Koch-Institute (RKI) for testing chemical disinfectants on efficacy of viruses in the medical area, Bundesgesundheitsblatt 58 (2015) 493-504
Guideline BGA	Guideline of the Federal Health Office for testing the efficacy of surface disinfectants for the disinfection of tuberculosis, Bundesgesundheitsblatt 37 (1994): 274-278
Guideline RKI	Guideline of the Robert Koch-Institute (RKI) for testing the efficacy of disinfectants for chemical instrument disinfection at tuberculosis, Bundesgesundheitsblatt 37 (1994) 474-477
Ph. Eur. 10, 2.6.1	Sterility testing
Ph. Eur. 10, 2.6.12	Microbiological testing of non-sterile products: Total viable count

Annex to the accreditation certificate D-PL-13412-01-02

Ph. Eur. 10, 2.6.13	Microbiological testing of non-sterile products: Detection of specific microorganisms
Ph. Eur. 10, 5.1.3	Testing on sufficient preservation
VAH - method 7 : 2019-06	Determination of bacteriostatic and leuurostatic efficacy as well as suitable neutralizing agents
VAH - method 8 : 2019-06	Determination of bactericidal and levurocidal activity in the qualitative suspension test
VAH - method 9 : 2019-06	Determination of bactericidal, levurocidal, fungicidal, tuberculocidal and mycobactericidal respectively activity in the quantitative suspension test
VAH - method 14.1 : 2019-06	Surface disinfection without mechanics
VAH - method 14.2 : 2019-06	Surface disinfection -practice-related quantitative 4-field test with mechanics
VAH - method 15 : 2019-06	Chemical / chemo-thermal instrument disinfection – practice-like quantitative carrier test
VAH - method 16 : 2019-06	Chemical laundry disinfection – inlay procedure (practice-like test)
VAH - method 17.1 : 2019-06	Thermochemical laundry disinfection – single bath method (practice-like test) at temperatures from 30 °C to < 60 °C
VAH - method 17.2 : 2019-06	Thermochemical laundry disinfection – single bath method (practice-like test) at temperatures from ≥60 °C to 70°C
SOP AA-00016, 30.12.2018	Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants in the veterinary area according to DIN EN 14675 : 2015 (phase 2, step 1)
SOP AA-00018, 15.02.2019	Quantitative virucidal efficacy testing of chemical disinfectants on non-porous surfaces (prEN 16777)
SOP AA-00019, 20.02.2019	Quantitative virucidal efficacy testing of chemical disinfectants on non-porous surfaces (carrier test according to OECD draft 2010)
SOP AA-00021, 12.02.2019	Efficacy testing of chemical disinfectants on inanimate germ carriers according to ASTM E 2197-11 (phase 2, step 2)
SOP AA-00025, 29.06.2017	Virucidal testing of chemical disinfectants with mechanical action in the 4-field-test (phase 2, step 2)
SOP AA-00027, 19.09.2019	Carrier test for testing the virucidal effect of ID agents on frosted glass according to EN 17111
SOP AA-00028, 21.12.2020	Virucidal testing according to ASTM E1052
SOP AA-00029, 21.12.2020	Virucidal testing according to ASTM E1053

Valid from: 03.01.2022
Date of issue: 03.01.2022

Annex to the accreditation certificate D-PL-13412-01-02

SOP AA-00031, 08.01.2018	Determination of Virucidal Efficacy on the Surface of Medical Examination Gloves based on ASTM D7907-14
SOP AA-00032, 09.07.2020	Measurement of antiviral activity on non-porous surfaces based on JIS Z 2801/ISO 22196
SOP AA-00040, 19.03.2021	Determination of MIC and suitable neutralizer, VAH 2015 (method 7)
SOP AA-00041, 19.03.2021	Qualitative suspension test VAH 2015 (method 8)
SOP AA-00042, 19.03.2021	Quantitative suspension test with bacteria and fungi according to VAH 2015 (method 9)
SOP AA-00043, 14.05.2021	Surface disinfection – non-porous surfaces without mechanical action (practice-like test) VAH 2015 (method 14.1)
SOP AA-00044, 19.03.2021	Quantitative carrier test instruments (frosted glass) VAH 2015 (method 15)
SOP AA-00045, 19.03.2021	Thermochemical laundry disinfection (inlay procedure) VAH 2015 (method 17)
SOP AA-00051, 19.03.2021	Surface disinfection – (practice-like 4-field-test) VAH 2015 (method 14.2)
SOP AA-00068, 21.10.2020	Quantitative suspension test for bactericidal activity according to DIN EN 1040:2005
SOP AA-00069, 13.01.2020	Quantitative suspension test for fungicidal activity according to DIN EN 1275:2005
SOP AA-00082, 27.03.2020	Quantitative suspension test for fungicidal activity according to DIN EN 13624:2013
SOP AA-00087, 28.02.2019	Quantitative suspension test for bactericidal activity according to DIN EN 13727:2012
SOP AA-00090, 27.11.2020	Basic sporicidal activity according to DIN EN 14347:2005
SOP AA-00091, 10.11.2020	Quantitative suspension test for mycobactericidal activity according to DIN EN 14348:2005
SOP AA-00094, 21.10.2020	Quantitative carrier test for bactericidal activity according to DIN EN 14561:2006
SOP AA-00095, 21.10.2020	Quantitative carrier test for fungicidal activity according to DIN EN 14562:2006
SOP AA-00096, 21.10.2020	Quantitative carrier test for mycobactericidal activity according to DIN EN 14563:2008
SOP AA-00108, 27.04.2018	4-field test according to DIN EN 16615
SOP AA-00107, 13.02.2018	Chemo-thermal laundry disinfection DIN EN 16616-2015

Valid from: 03.01.2022
Date of issue: 03.01.2022

Annex to the accreditation certificate D-PL-13412-01-02

SOP AA-00118, 20.07.2020	Determination of bioburden of instruments
SOP AA-00119, 20.07.2020	Enumeration of viable microorganisms according to Ph. Eur. 2.6.12
SOP AA-00120, 18.08.2020	Detection of specific microorganisms according to Ph. Eur. 2.6.13
SOP AA-00124, 20.05.2021	Sterility testing of medical devices and pharmaceuticals according to Ph. Eur.
SOP AA-00130, 18.08.2020	Detection of the cleaning performance of reprocessing processes according to DIN EN ISO 15883
SOP AA-00131, 18.08.2020	Detection of the disinfection performance of reprocessing processes according to DIN EN ISO 15883
SOP AA-00132, 19.02.2019	Microbiological control of endoscope reprocessing
SOP AA-00133, 25.04.2018	Determination of protein concentration with the modified OPA method
SOP AA-00139, 28.02.2019	Preservation test according to EuAB
SOP AA-00143, 03.11.2020	Agar diffusion test
SOP AA-00230, 20.09.2018	Quantitative suspension test Sporicidie according to EN 17126:2018
SOP AA-00263, 16.03.2021	Determination of total organic carbon (TOC) and dissolved organic carbon (DOC)
SOP AA-00287, 16.03.2021	Antimicrobial wound dressings according to Brill/Braunwarth
SOP AA-00292, 19.03.2021	Chemical-thermal textile disinfection – immersion-bath process (VAH method 16)

Annex to the accreditation certificate D-PL-13412-01-02

Abbreviations:

DIN	German Institute for Standards (Deutsches Institut für Normung)
EN	European Standards (Europäische Norm)
ISO	International Organization for Standardization
ASTM	American Society for Testing and Materials
BGA	Federal Public Health Office (Bundesgesundheitsamt)
DGHM	Germany Society for Hygiene and Microbiology (Deutsche Gesellschaft für Krankenhaushygiene)
DVV	German Association for the Control of Virus Diseases (Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V.)
JIS	Japanese Standards Association
Ph. Eur.	European Pharmacopoeia
RKI	Robert Koch-Institute
VAH	Standard Methods of the Association for Applied Hygiene e.V. (Verbund für Angewandte Hygiene e.V.)
SOP AA- ...	Standard operating procedures of Dr. Brill + Partner GmbH

¹ DIN EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories

² DIN EN ISO 13485 : 2016-08 Medical devices - Quality management systems - Requirements for regulatory purposes