

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18411-01-01 according to DIN EN ISO/IEC 17025:2018

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:

health care (hygiene); pharmaceutical products and active agents;
efficacy testing of disinfectants, skin- and hand disinfectants and biocides;
microbiological testing for mechanic and manual cleaning and disinfection method in terms of
process validation or as routine testing in the area of food hygiene;
selected microbiological analyses of biowaste and compost;
selected microbiological analysis of feedings;
determination of germs of air and gas;
sampling and microbiological analyses of swimming and bathing pool water;
microbiological analyses according to the German Drinking Water Ordinance;
sampling of raw water and drinking water

fields of testing: hospital hygiene, biological analysis of pharmaceutical products, active agents and
excipients

Within the given testing field marked with */***, the testing laboratory is permitted

* without being required to inform and obtain prior approval from DAkKS, to freely select standards or
equivalent testing methods .

*** without being required to inform and obtain prior approval from DAkKS, to use standards or equivalent
testing methods listed here with different issue dates.

*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>*

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The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

1 Field: Health care (hygiene)

1.1 Field of testing: hospital-hygiene

1.1.1 Type of testing: cultural testing

Standard / date of issue In-house method / version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
SOP 2-65, version 03	Microbiological testing of bioindicators for the testing of cleaning and disinfection processes in cleaning and disinfection machines Washer-disinfectors — Part 1: General requirements, definitions and tests	Bioindicators

1.1.2 Test procedures of inhibitor processes

Standard / date of issue In-house method / version	Title of the Standard or the in-house method	Test item
Requirements and methods, VAH, 2019, method 7	Determination of the bacteriostatic and levurostatic activity and suitable neutralization agents	Disinfectants, Biocides

1.1.3 Test procedures of inhibitor processes

Standard / date of issue In-house method / version	Title of the Standard or the in-house method	Test item
SOP 2-25, Version 08	Germ differentiation	Microorganisms

2 Field: Drugs and active ingredients

2.1 Field of testing: Analysis of biological drugs-, active substances and excipients

2.1.1 Type of testing: Sterility testing

Standard / date of issue In-house method /version	Title of the Standard or the in-house method	Test item
European Pharmacopoeia, 9th Edition 2017 (Ph.Eur. 9.0), 2.6.1 (Supplement)	Sterility testing	Pharmaceuticals

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3 Efficacy testing of disinfectants, skin and hand disinfectants

3.1 Efficacy testing of disinfectants, skin and hand disinfectants and biocides*

Requirements and methods, VAH, 2019, method 7	Determination of the bacteriostatic and levurostatic activity and suitable neutralization agents
Requirements and methods, VAH, 2019, method 8	Determination of bactericidal and yeasticidal activity in a qualitative suspension test
Requirements and methods, VAH, 2019, method 9	Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in a quantitative suspension test (scope of application: <i>no testing of levurocidal activity</i>)
Requirements and methods, VAH, 2019, method 11	Testing of agents for hygienic hand disinfection
Requirements and methods, VAH, 2019, method 12	Testing of agents for surgical hand disinfection (<i>no conformity assessment of medical devices</i>)
Requirements and methods, VAH, 2019, method 13	Testing and evaluation of skin disinfectants
Requirements and methods, VAH, 2019, method 14.1	Determination of bactericidal, levurocidal, fungicidal, tuberculocidal or mycobactericidal efficacy on non-porous surfaces in practical experiments – Surface disinfection without mechanical action
Requirements and methods, VAH, 2019, method 14.2	Determination of bactericidal, levurocidal, fungicidal, tuberculocidal or mycobactericidal efficacy on non-porous surfaces in practical experiments – Surface disinfection with mechanical action (4-field-test)
Requirements and methods, VAH, 2019, method 15	Chemical instrument disinfection (quantitative carrier test)
Requirements and methods, VAH, 2019, method 18	Determination of sporicidal activity against spores of <i>Clostridium difficile</i> in a quantitative suspension test
Requirements and methods, VAH, 2019, method 19	Surface disinfection against spores of <i>Clostridium difficile</i> - Surface disinfection with mechanical action
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 14347 2005-08	Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)

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DIN EN 12791 2018-01	Chemical disinfectants and antiseptics – Surgical hand disinfection – Test method and requirements (phase 2, step 2) <i>(no conformity assessment of medical devices)</i>
DIN EN 1499 2017-10	Chemical disinfectants and antiseptics – Hygienic handwash – Test method and requirements (phase 2/step 2) <i>(no conformity assessment of medical devices)</i>
Requirements and methods, VAH, 2019, method 10	Hygienic hand washing - practical test with subjects (volunteers) <i>(no conformity assessment of medical devices)</i>
DIN EN 1500 2017-05	Chemical disinfectants and antiseptics – Hygienic handrub – Test method and requirements (phase 2/step 1) <i>(no conformity assessment of medical devices)</i>
DIN EN 16616 2015-10	Chemical disinfectants and antiseptics – Chemical-thermal textile disinfection – Test method and requirements (phase 2, step 2)
Requirements and methods, VAH, 2019, method 17	Thermochemical laundry disinfection – single bath method (practice-like test)
DIN EN 1276 2019-11	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1) <i>(no conformity assessment of medical devices)</i>
DIN EN 1650 2019-10	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1) <i>(no conformity assessment of medical devices)</i>
DIN EN 13704 2018-09	Chemical disinfectants – Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements (phase 2, step 1) <i>(no conformity assessment of medical devices)</i>
DIN EN 13697 2019-10	Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (phase 2, step 2) <i>(no conformity assessment of medical devices)</i>
Requirements and methods, VAH, 2019, Annex P	Surface disinfection – Carrier test with untreated wood for the determination of fungicidal activity

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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) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
DIN EN 14347 2005-08	Chemical disinfectants and antiseptics - Basic sporicidal activity -Test method and requirements (phase 1) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
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) <i>(no conformity assessment of medical devices)</i>
DIN EN 1656 2019-12	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area – Test method and requirements (phase 2, step 1)

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DIN EN 1657 2016-11.	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)
DIN EN 14204 2013-02	Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area – Test method and requirements (phase 2, step 1);
DIN EN 16437 2019-12	Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)
DIN EN 14349 2013-02	Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)
DIN EN 16438 2014-07	Chemical disinfectants and antiseptics – Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action – Test method and requirements (phase 2, step 2)

4 Microbiological testing for mechanic and manual cleaning and disinfection method in terms of process validation or as routine testing in the area of food hygiene

DIN 10510 2013-10	Food hygiene – Commercial dishwashing with multitank-transportdishwashers – Hygiene requirements, procedure testing
SOP 2-65, Version 03	Microbiological examination of bioindicators for the testing of cleaning and disinfection processes in cleansing devices and disinfectors Cleansing devices/disinfectors - Part 1- : General requirements, Definitions and tests <i>(no conformity assessment of medical devices)</i>
DIN 10113-1 1997-07	Determination of surface colony count on fitment and utensils in foodareas - Part 1: Quantitative swab method
DIN 10113-2 1997-07	Determination of surface colony count on fitment and utensils in foodareas - Part 2: Semiquantitative swab method

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DIN 10113-3
1997-07

Determination of surface colony count on fitment and utensils in foodareas - Part 3: Semiquantitative method with culture media laminated taking up equipment (squeeze method)
Selective determination of individual microorganisms on a defined surface

5 Selected microbiological analyses of biowaste and compost

Bioabfallverordnung -
BioAbfV, 2013-04

Detection of *Salmonella* spp.

6 Selected microbiological analysis of feedings

DIN EN ISO 6579-1
2017-07

Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* – Part 1: Detection of *Salmonella* spp.

7 Determination of germs of air and gas

SOP 2-26, Version 05

Determination of airborne germ content in non-medical areas

SOP 2-27, Version 04

Air sampling of airborne microorganisms and sedimentation

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8 Analysis of swim- and bath water ***

8.1 Sampling

DIN EN ISO 19458 (K 19)
2006-12 Water quality – Sampling for microbiological analysis

DIN EN ISO 5667-3 (A 21)
2013-03 Water quality – Sampling –
Part 3: Preservation and handling of water samples

DIN 19643-1
2012-11 Treatment of water of swimming pools and baths –
Part 1: General requirements (*here: for sampling*)

UBA recommendation
2014 Hygiene requirements for baths and their monitoring
(*here: for sampling*)

8.2 Microbiological analysis

DIN EN ISO 16266 (K 11)
2008-05 Water quality – Detection and enumeration of *Pseudomonas*
aeruginosa – Method by membrane filtration

DIN EN ISO 9308 (K 6-1)
2014-06 Water quality — Enumeration of *Escherichia coli* and coliform
bacteria — Part 2: Most probable number method

DIN EN ISO 7899 (K 15)
2000-11 Water quality – Detection and enumeration of intestinal enterococci –
Part 2 Membrane filtration method

German Drinking Water Ordinance
TrinkwV §15 par. (1c) Quantitative determination of culturable microorganisms –Colony
count at 20 °C and 36 °C (pour plate method)

DIN EN ISO 11731
2019-03 Water quality - Enumeration of *Legionella*

UBA recommendation
December 18, 2018 Systemic analysis of drinking water installations for *Legionella*
according to the Drinking Water Ordinance- sampling, examination and
indication of the result

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9 Testing according to Drinking Water Ordinance-TrinkwV -***

Sampling

Method	Title
DIN ISO 5667-5 (A 14) 2011-02	Water quality -Sampling -Part 5: Guidance on sampling of drinking water from treatment works and piped distribution
DIN EN ISO 5667-3 (A 21) 2013-03	Water quality -Sampling -Part 3: Preservation and handling of water samples
DIN EN ISO 19458 (K 19) 2006-12	Water quality -Sampling for microbiological analysis
UBA recommendation December 18, 2018	Evaluation of drinking water quality with regard to the parameters lead, copper and nickel

ANNEX 1: MICROBIOLOGICAL PARAMETER

Part I: General requirements for drinking water

No.	Parameter	Method
1	Escherichia coli (E. coli)	DIN EN ISO 9308-2 (K 6-1) 2014-06
2	Enterococci	DIN EN ISO 7899-2 (K 15) 2000-11

Part II: Requirements for drinking water in closed bins

No.	Parameter	Method
1	Escherichia coli (E. coli)	DIN EN ISO 9308-2 (K 6-1) 2014-06
2	Enterococci	DIN EN ISO 7899-2 (K 15) 2000-11
3	Pseudomonas aeruginosa	DIN EN ISO 16266 (K 11)2008-05

ANNEX 2: CHEMICAL PARAMETER

Part I: Chemical parameters, whose concentration in the distribution network, including the drinking water installation, usually no longer increases

not determined

Part II: Chemical parameters, whose concentration in the distribution network, including the drinking water installation, may increase

not determined

ANNEX 3: INDICATOR PARAMETERS

Part I: General indicator parameters

No.	Parameter	Method
1	Aluminium	not determined
2	Ammonium	not determined
3	Chloride	not determined

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No.	Parameter	Method
4	Clostridium perfringens (including spores)	DIN EN ISO 14189 (K24) 2016-11
5	Coliform Bacteria	DIN EN ISO 9308-2 (K 6-1) 2014-06
6	Iron	not determined
7	Colour (spectral absorption coefficient Hg 436 nm)	not determined
8	Odour	not determined
9	Taste	not determined
10	Colony count at 22 °C	TrinkwV §15 Absatz (1c)
11	Colony count at 36 °C	TrinkwV §15 Absatz (1c)
12	Electric conductivity	DIN EN 27888 (C 8) 1993-11
13	Manganese	not determined
14	Sodium	not determined
15	Totally organically bound carbon (TOC)	not determined
16	Oxidisability	not determined
17	Sulphate	not determined
18	Turbidity	not determined
19	Hydrogen ion concentration	DIN EN ISO 10523 (C 5) 2012-04
20	Calcit saturation	not determined

Part II: Special requirements for drinking water in systems of drinking water installation

Parameter	Method
Legionella spec.	ISO 11731 2017-05 UBA recommendation Dezember 18, 2018

ANNEX 3a: Requirements for drinking water in relation to radioactive substances

not determined

Parameters not included in Annex 1 to 3 of the Drinking Water Ordinance

Additional periodic testing

not determined

The accreditation does not replace the recognition or approval procedure of the competent pursuant to §15 (4) TrinkwV.

Abbreviations used:

DGHM	German Society For Hygiene And Microbiology
VAH	Association for applied hygiene / Verbund für angewandte Hygiene e.V.
DIN	German institute for standardization e.V. / Deutsches Institut für Normung e.V.
EN	European Standard
ISO	International Organization for Standardization

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UBA	Umweltbundesamt (German Federal Environmental Agency)
BioAbfV	Ordinance on Biowastes (Bioabfallverordnung)
SOP	Standard Operating Procedure (In house method of Hygiene Nord GmbH)
TrinkwV	German Drinking Water Ordinance (Trinkwasserverordnung)

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