

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18818-02-01 according to DIN EN ISO/IEC 17025:2018

Valid from: 16.07.2020

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Holder of certificate:

HygCen Germany GmbH
Bornhövedstraße 78, 19055 Schwerin

Tests in the fields:

Efficacy testing of disinfectants

This document is a translation by HygCen Germany GmbH. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

Within the test areas marked with ***, the testing laboratory is permitted to use the listed standardized test methods or test methods equivalent to them with different output statuses without requiring prior information and approval by DAkkS.

The listed test methods are exemplary. The testing laboratory has an up-to-date list of all test methods in the flexible accreditation area.

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/content/datenbank-akkreditierter-stellen>

Test in the field: efficacy testing of disinfectants ***

VAH Methode 13: 2015	Guideline for testing and evaluation of skin disinfectants
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 1656: 2010-03	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area - Test method and requirements (phase 2, step 1)
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 1276: 2010-01	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: 2013-08	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>

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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 13697: 2015-06	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>
DVG Richtlinie, Kapitel IV, 21.02.2015	Methods to determine the minimum inhibitory concentration (MIC) of chemical disinfectants and to select suitable neutralizing agents
DVG Richtlinie, Kapitel IV, 21.02.2015	Methods to determine the minimum inhibitory concentration (MIC) of chemical disinfectants and to select suitable neutralizing agents
DIN EN 14675: 2015-06	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1)
DIN EN 14476: 2015-12	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) <i>(No conformity assessment of medical devices)</i>
Leitlinie 3, RKI/DVV, 2012	Quantitative testing of virucidal activity chemical disinfectant on non-porous surfaces (application in the field of human medicine) <i>(No conformity assessment of medical devices)</i>

-Translation-

Annex to the accreditation certificate D-PL-18818-02-01

- DIN EN 12791: 2018-01 Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)
(No conformity assessment of medical devices)
- DIN EN 1500: 2017-10 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)
(No conformity assessment of medical devices)
- DIN EN 1499: 2017-10 Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)
(No conformity assessment of medical devices)
- DIN EN 13610: 2003-06 Chemical disinfectants - Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1)
(No conformity assessment of medical devices)
- DIN EN 16437:2014-07 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 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)
- DIN EN 16616:2015-10 Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)
(No conformity assessment of medical devices)
- DIN EN 13623:2010-12 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)

-Translation-

Annex to the accreditation certificate D-PL-18818-02-01

ASTM E2799:2017	Standard Test Method for Testing Disinfectant Efficacy against Pseudomonas aeruginosa Biofilm using the MBEC Assay
NF T72-281:2014-11-08	Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities
DVG V column 7a/7b: 2017	Methods for testing chemical disinfectants for animal husbandry
DVG V column 4a/4b: 2017	Methods for testing chemical disinfectants for animal husbandry
DIN SPEC 10534:2019	Food hygiene - Commercial dishwashing - Hygiene requirements, testing

Test in the field: efficacy testing of disinfectants

SOP 02-018, Rev. 004	Efficacy testing of skin disinfectants (VAH)
SOP 02-052, Rev. 007	Quantitative suspension test for the evaluation of bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics used in the veterinary area (phase 2, step 1)
SOP 02-053, Rev. 011	Quantitative suspension test for the evaluation of bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in food, industry, domestic and institutional areas (Phase 2, Level 1)
SOP 02-055, Rev. 007	Practical experiment to evaluate the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in the veterinary area (Phase 2, Level 2)
SOP 02-056, Rev. 006	Practical experiment to evaluate the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in in food, industrial, domestic and institutional areas (Phase 2, Level 2)
SOP 02-059, Rev. 001	Air-mediated aerosol or gas disinfection of surfaces (Airborne disinfection of surfaces)

-Translation-

Annex to the accreditation certificate D-PL-18818-02-01

SOP 02-101, Rev. 006	Evaluation of the bacteriostatic and fungistatic activity of chemical disinfection procedures and selection of suitable inactivating agents (DVG)
SOP 02-102, Rev. 003	Evaluation of the bactericidal and fungicidal activity in the qualitative suspension test (DVG)
SOP 02-200, Rev. 004	Quantitative suspension test Viruzidie for chemical disinfectants and antiseptics used in human and veterinary medicine (phase 2, step 1) according to EN 14476, EN 14675 and guideline RKI / DW
SOP 02-054, Rev. 012	Practical experiment to evaluate the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in human medicine (Phase 2, Level 2)

Abbreviations used:

DIN	German institute for standardization e.V. / Deutsches Institut für Normung e.V.
DVV	German association for combating virus diseases / Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten
DVG	German veterinary society / Deutsche Veterinärmedizinische Gesellschaft
RKI	Robert Koch Institute / Robert-Koch-Institut
SOP 00-000	In house method of the CAB
VAH	Association for applied hygiene / Verbund für angewandte Hygiene

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