

Deutsche Akkreditierungsstelle GmbH

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

Valid from: 22.08.2023

Date of issue: 22.08.2023

This annex is part of the accreditation certificate D-PL-18818-02-00.

Holder of Partial Accreditation Certificate:

HygCen Germany GmbH
Bornhövedstraße 78, 19055 Schwerin

The testing laboratory shall comply with the requirements set out in DIN EN ISO/IEC 17025:2018 to perform the conformity assessment activities listed in this Annex. The testing laboratory shall, where applicable, comply with additional legal and normative requirements, including those in relevant sectoral programmes, where these are explicitly confirmed below.

The requirements for the management system in DIN EN ISO/IEC 17025 are written in a language relevant for testing laboratories and are overall in accordance with the principles of DIN EN ISO 9001.

Tests in the field of:

Health care (hospital hygiene and infection prevention), determination of the efficacy of disinfectants in the fields of medicinal products and active substances, health care (hospital hygiene and infection prevention), veterinary medicine, food, industry and consumer goods by means of cultural microbiological tests.

Within the test areas marked with **, the laboratory is permitted to modify as well as further and new develop test methods without requiring prior information and approval from the DAkkS GmbH.

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

This certificate annex is only valid together with the certificate issued in writing and reflects the status at the time of the date of issue. The current status of the valid and monitored accreditation can be found in the database of accredited bodies of the German Accreditation Body (www.dakks.de).

Abbreviations used: see last page

TRANSLATION

Annex to Accreditation Certificate D-PL-18818-02-01

Area: Health care (hospital hygiene and infection prevention)

Testing area: Hygiene and infection prevention

Test type:

Microbiological-hygienic tests**

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
DIN EN 17735: 2023-02	Commercial dishwashing machines - Hygiene requirements and testing	Bioindicators
DIN EN ISO 20743: 2021-10	Textiles - Determination of antibacterial activity of textile products	Textiles, textile products
ISO 22196: 2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces	Consumer goods, plastics, metals
ISO 27447: 2019-07	Fine ceramics (advanced ceramics, advanced technical ceramics) - Test method for antibacterial activity of semiconducting photocatalytic materials	Surfaces, ceramics
ISO 18184 : 2019-06	Textiles - Determination of antiviral activity of textile products	Textile products
ISO 21702 : 2019-05	Measurement of antiviral activity on plastics and other non-porous surfaces	Plastics, non-porous surfaces
VDI-EE 4300 Blatt 14 : 2021-09	Measurement of indoor pollution - Requirements for mobile air purifiers to reduce aerosol-borne transmission of infectious diseases	Air
ASTM E 645:2018	Standard Practice for Evaluation of Microbicides Used in Cooling Water Systems	Biocide, cooling water
In-house procedures SOP 09-016, REV001	Validation procedure for antimicrobial materials, e.g. washing gloves according to the house method. Recovery and identification of specific germs	Consumer goods
In-house procedures SOP 02-054, REV017 Chapter Reach	Practical trial to determine the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in the field of human medicine (phase 2, step 2)	Wiping system

Annex to Accreditation Certificate D-PL-18818-02-01

Test area: Determination of the activity of disinfectants in the fields of medicinal products and active substances, health care (hospital hygiene and infection prevention), veterinary medicine, foodstuffs, industry and consumer goods by means of cultural microbiological tests

Test type:

activity testing of disinfectants by means of cultural microbiological investigations**

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
VAH Method 13: 2022	Guideline for the testing and evaluation of skin disinfectants	Disinfectant solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
DIN EN 1500: 2017-10	Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2, step 2) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
DIN EN 13623: 2020-12	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)	Disinfectant solution, antiseptic solution
DIN EN 13624: 2022-08	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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution
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>	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
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>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
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>	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution
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)	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
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>	Disinfectant solution, antiseptic solution
DIN EN 16616: 2022-10	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
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) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
DIN EN 17122: 2020-02	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 2)	Disinfectant solution, antiseptic solution
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>	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
DIN EN 17272: 2020-06	Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
DIN EN 17387: 2021-10	Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution
DIN EN 17422: 2022-09	Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area - Test method and requirements (phase 2, step 2)	Disinfectant solution, antiseptic solution
DVG Guideline, Chapter IV, 21.02.2015	Methods for determining the minimum inhibitory concentration (MIC) of chemical disinfectants and for selecting suitable neutralising agents	Disinfectant solution
DVG V Column 4a/4b: 2017	Methods for testing chemical disinfectants for animal husbandry	Disinfectant solution
DVG V Column 7a/7b: 2017	Methods for testing chemical disinfectants for animal husbandry	Disinfectant solution
Guideline 3, RKI/DVV, 2012	Quantitative testing of the virucidal activity of chemical disinfectants on non-porous surfaces (application in the field of human medicine) <i>(No conformity assessment of medical devices)</i>	Disinfectant solution, antiseptic solution

Annex to Accreditation Certificate D-PL-18818-02-01

Standard / Issue date House method / Version	Title of the standard or in-house procedure (specify deviations/modifications from standard procedures, if applicable)	Test item
ASTM E2799: 2022	Standard Test Method for Testing Disinfectant activity against Pseudomonas aeruginosa Biofilm using the MBEC Assay	Disinfectant solution
ASTM E 2406: 2016	Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants for Use in High Efficiency Washing Operations	Disinfectant solution
ASTM E 2274: 2016	Standard Test Method for Evaluation of Laundry Sanitizers and Disinfectants	Disinfectant solution
In-house procedures SOP 02-063, Rev. 001	Determination of chemical parameters of disinfectants	Disinfectant solution
In-house procedures SOP 02-204 Chapter 5, Rev. 009	Quantitative testing of the virucidal activity of chemical disinfectants on surfaces (phase 2, step 2), 4-field test virucidal activity	Disinfectant solution, antiseptic solution

verwendete Abkürzungen:

ASTM	American Society for Testing and Materials
DIN	German Institute for Standardisation e.V.
DVG	German Veterinary Society e.V.
DVV	German Association for the Control of Viral Diseases e.V.
EN	European standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
RKI	Robert Koch Institute
SOP	Standard Operating Procedure
SOP-XX-XXX	In-house procedures of the CBS
VAH	Association for Applied Hygiene e.V.