

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-12083-01-06 according to DIN EN ISO/IEC 17025:2018

Valid from: 02.12.2025

Date of issue: 02.12.2025

This annex is part of the Accreditation Certificate D-PL-12083-01-00.

Holder of the Accreditation Certificate:

Hohenstein Laboratories GmbH & Co. KG
Schloss Hohenstein, 74357 Bönningheim

with the location

Hohenstein Laboratories GmbH & Co. KG
Schloss Hohenstein, 74357 Bönningheim

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

Efficacy testing of disinfectants and antiseptics
Hospital hygiene and infection prevention

*This annex to the certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.
This annex to the certificate is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).*

Abbreviations used: see last page

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Flexible Scope of Accreditation:

Within the indicated test areas, the testing laboratory is permitted, without being required to prior inform and obtain approval from DAkkS

[Flex C] to modify, develop or further develop test methods.

The test methods listed are examples. The testing laboratory has an up-to-date list of all test methods within the flexible scope of accreditation. The list is publicly available on the website of the testing laboratory.

Efficacy testing of disinfectants and antiseptics [Flex C]

Qualitative suspension tests (basis tests)

Standard/Date of issue In-house method/Version	Analyt - Title of the standard Information on sample pretreatment/testing technology	Test item
VAH Standard Method 8 2015-04	Determination of the bactericidal and yeasticidal activity in the qualitative suspension test	Disinfectant

Quantitative suspension tests and practical tests

Standard/Date of issue In-house method/Version	Analyt - Title of the standard Information on sample pretreatment/testing technology	Test item
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) (EN 1040:2005) (no testing and conformity assessment of medical devices)	Disinfectant
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) (EN 1275:2005) (no testing and conformity assessment of medical devices)	Disinfectant
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) (EN 1276:2019) (no testing and conformity assessment of medical devices)	Disinfectant

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Standard/Date of issue In-house method/Version	Analyt - Title of the standard Information on sample pretreatment/testing technology	Test item
DIN EN 13697 2024-01	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas without mechanical action - Test method and requirements without mechanical action (phase 2, step 2) (EN 13697:2023) (no testing and conformity assessment of medical devices)	Disinfectant
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) (EN 14349:2012) (no testing and conformity assessment of medical devices)	Disinfectant
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) (EN 16438:2014) (no testing and conformity assessment of medical devices)	Disinfectant
DIN EN 16616 2022-10	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2) EN 16616:2022) (no testing and conformity assessment of medical devices)	Disinfectant
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) (EN 1650:2019) (no testing and conformity assessment of medical devices)	Disinfectant

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Standard/Date of issue In-house method/Version	Analyt - Title of the standard Information on sample pretreatment/testing technology	Test item
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) (EN 1656:2019) (no testing and conformity assessment of medical devices)	Disinfectant
DIN EN 1657 2025-02	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) (EN 1657: 2024) (no testing and conformity assessment of medical devices)	Disinfectant
DIN EN 17658 2022-11	Chemical disinfectants and antiseptics - Chemical textile disinfection for the domestic area - Test method and requirements (phase 2, step 2) (EN 17658:2022) (no testing and conformity assessment of medical devices)	Disinfectant
VAH Standard Method 9 2015-04	Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal activity in the quantitative suspension test (no testing and conformity assessment of medical devices)	Disinfectant
VAH Standard Method 17 2015-04	Chemical-thermal textile disinfection – simulated-use test (without pre-wash) (no testing and conformity assessment of medical devices)	Disinfectant

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Hospital hygiene and infection prevention

Microbiological-hygienic testing [Flex C]

Standard/Date of issue In-house method/Version	Analyt - Title of the standard Information on sample pretreatment/testing technology	Test item
3.DEC.0309 2025-01	Use of bioindicators for checking sterilizers and disinfection devices	Bioindicators
3.DEC.0312 2025-01	Use of bioindicators to check disinfecting washing procedures on site and subsequent evaluation in the laboratory	Bioindicators
3.DEC.0325 2025-01	Use of phage bioindicators to check disinfecting washing procedures on site and subsequent evaluation in the laboratory	Bioindicators
DIN 10113-2 2023-02	Horizontal method for the determination of surface colony count and detection of specific microorganisms on fitment and utensils along the food chain - Part 2: Method with culture media laminated taking up equipment (squeeze method) <i>(here: only in the area of hospital hygiene and infection prevention)</i>	Contact plates
3.DEC.0314 2025-01	Procedure for determining the concentration of air-born microorganisms	Sedimentation plates

Abbreviations used:

3.DEC.XXXX	Standard Operation Procedure (SOP) of the CAB
DIN	Deutsches Institut für Normung e.V. [German Institute for Standardisation]
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
VAH	Verbund für Angewandte Hygiene [German Association for Applied Hygiene]

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