

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-18398-03-01 according to DIN EN ISO/IEC 17025:2018

Valid from: 13.05.2026

Date of issue: 24.07.2026

This annex is part of the Accreditation Certificate D-PL-18398-03-00.

Holder of the Accreditation Certificate:

SAL GmbH
Auf der Lind 10, 65529 Waldems

with the location

SAL GmbH
Auf der Lind 10, 65529 Waldems

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.

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

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.

Hospital Hygiene and Infection Prevention

Microbiological-hygienic testing [Flex C]

Standard / Date of issue In-house procedure / Version	Title of the standard or in-house procedure (indicate deviations / modifications from standard methods, if applicable)	Test item
PA 6.1-01-04 / V05	Determination of the viability of biological indicators	Biological indicators
DIN EN ISO 11138-1 / 2017-07	Sterilization of health care products - Biological indicators - Part 1: General requirements • Population assay • Determination of growth inhibition by carriers and primary packaging materials • Determination of the D value using the survival curve method • Determination of the D value using the fraction-negative method • Verification of survival/kill response characteristics (no conformity assessment of medical devices)	Biological indicators
USP <55> / 49	Biological Indicators – resistance performance tests • Population assay	Biological indicators
PA 6.1-02-03 / V07	Determination of the D value under ethylene oxide conditions Determination of the resistance of biological indicators for ethylene oxide sterilization processes according to DIN EN ISO 11138-2 or Ph. Eur. 5.1.2	Biological indicators
PA 6.1-02-01 / V08	Determination of the D value under saturated steam conditions Determination of the resistance of biological indicators for moist heat sterilization processes according to DIN EN ISO 11138-3 or Ph. Eur. 5.1.2	Biological indicators

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Standard / Date of issue In-house procedure / Version	Title of the standard or in-house procedure (indicate deviations / modifications from standard methods, if applicable)	Test item
PA 6.1-02-06 V02	Determination of the z value Determination of the resistance of biological indicators for moist heat sterilization processes according to DIN EN ISO 11138-3 and dry heat sterilization processes according to DIN EN ISO 11138-4	Biological indicators
PA 6.1-02-09 / V07	Determination of the D value of microorganisms in suspensions Determination of the resistance of biological indicators for moist heat sterilization processes according to DIN EN ISO 11138-3 or Ph. Eur. 5.1.2	Biological indicators in various suspension media
PA 6.1-02-02 / V11	Determination of the D value under dry heat conditions Determination of the resistance of biological indicators for dry heat sterilization processes according to DIN EN ISO 11138-4	Biological indicators
PA 6.1-02-05 / V10	Determination of the D value under formaldehyde conditions Determination of the resistance of biological indicators for low-temperature steam and formaldehyde sterilization processes according to DIN EN ISO 11138-5	Biological indicators
PA 6.1-01-11 / V07	Population assay of spores on solid carriers Population assay of solid carriers inoculated with spore suspension (various materials) in accordance with DIN EN ISO 11138-1	Biological indicators
PA 6.1-01-13 V07	Population assay of spores on metal coupons Population assay of spores on metal coupons inoculated with spore suspension in accordance with DIN EN ISO 11138-1	Biological indicators
PA 6.1-01-06 / V08	Testing the purity of biological indicators – testing for microbiological contamination	Biological indicators

Physical and physicochemical testing [Flex C]

Standard / Date of issue In-house procedure / Version	Title of the standard or in-house procedure (indicate deviations / modifications from standard methods, if applicable)	Test item
DIN EN ISO 11140-1 / 2015-03	Sterilization of health care products - Chemical indicators - Part 1: General requirements • Color-change with steam • Color-change with dry heat • Color-change with ethylene oxide • Color-change with low temperature steam and formaldehyde • Color-change with hydrogen peroxide • Testing for Off-set (no conformity assessment of medical devices)	Chemical indicators
DIN 58921 / 2011-01	Test method to demonstrate the suitability of a medical device simulator during steam sterilization - Medical device simulator testing (no conformity assessment of medical devices)	Indicator systems Test specimen Medical device simulators
PA 6.2-01-05 V05	Testing of relative reflectance density Method for determining the color difference between the substrate and the indicator system according to DIN EN ISO 11140-3, Annex B and DIN EN ISO 11140- 4, Annex C	Chemical indicators
PA 6.2-01-06 V04	Testing the strength of an indicator Determination of the indicator's strength before and after steam sterilization according to DIN EN ISO 11140-3, Annex A und DIN EN ISO 11140-4, Annex A	Chemical indicators
PA 6.2-01-07 V04	Testing chemical indicators for transference Evaluation of the transfer of indicator substance to the standard test pack during the procedure according to DIN EN ISO 11140-3, Annex F	Chemical indicators
PA 6.2-01-08 V08	Color-change testing of chemical indicators for steam sterilization Method for testing color-change according to DIN EN ISO 11140-3, Section 6 and DIN EN ISO 11140-4, Section 6	Chemical indicators

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Standard / Date of issue In-house procedure / Version	Title of the standard or in-house procedure (indicate deviations / modifications from standard methods, if applicable)	Test item
PA 6.2-10-03 V04	Conformity testing of a Bowie-Dick simulation test according to ISO 11140-4 Method for testing performance requirements, uniform color change, equivalence to the Bowie-Dick type test, reproducibility of failure conditions and color change of the indicator when exposed to dry heat according to DIN EN ISO 11140-4, Section 6, Annexes B, D, E, F, G, J, K, L	Chemical indicators, indicator systems
PA 6.2-10-04 V04	Testing the dimensions of test specimen according to DIN EN ISO 11140-6	test specimen
PA 6.2-10-06 V04	Testing the performance of an alternative hollow indicator system according to DIN EN ISO 11140-6	Indicator systems, chemical indicators
PA 6.2-10-07 V04	Testing dimensions and materials according to EN 1422	test specimen
PA 6.2-10-09 V04	Testing the suitability of a batch monitoring system (BMS) Method for comparative testing of indicator systems for monitoring validated processes	test specimen, indicator systems, monitoring systems

Abbreviations used:

BMS	Batch Monitoring System
DIN	Deutsches Institut für Normung e.V.
EN	europäische Norm
Ph. Eur.	Pharmacopoeia Europaea
ISO	International Organization for Standardization
PA	Prüfanweisung der SAL-GmbH
USP	United States Pharmacopeia