Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL18398-02-01 according to DIN EN ISO/IEC 17025:2005

Period of validity: 26.02.2018 to 25.02.2023 Date of issue: 26.02.2018

Holder of certificate:

SAL GmbH

At the location:
Auf der Lind 10, 65529 Waldems

Tests in the fields:

Health Care (Hygiene)

Testing area:
Hospital Hygiene / Microbial hygienic tests

Within the given testing field marked with *), the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standard or equivalent testing methods.
The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.
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Abbreviations used: see last page

Hospital Hygiene / Microbial hygienic tests

Type of testing: Cultural methods*

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
PA 6.1-01-04 / V02	Determination of vitality of biological indicators	Biological indicators
DIN EN ISO 11138-1 / 2006-09 and corrigendum 2008-08	Sterilization of health care products – Biological indicators – Part 1: General requirements • Determination of viable count • Determination of growth inhibition by carriers and primary packaging materials • D value determination by the survivor curve method • D value determination by the fraction negative method • Testing of Survival-kill response characteristics (no conformity assessment of medical devices)	Biological indicators
USP <55> / 39	Biological Indicators – resistance performance tests • viable spore count	Biological indicators
PA 6.1-02-03 / V04	Determination of D-values under ethylene oxide conditions Determination of the resistance of biological indicators for sterilization processes with ethylene oxide in compliance with DIN EN ISO 11138-2 or Ph. Eur. 5.1.2	Biological indicators
PA 6.1-02-01 / V05	Determination of D-values under saturated steam conditions Determination of the resistance of biological indicators for sterilization processes with moist heat in compliance with DIN EN ISO 11138-3 or Ph. Eur. 5.1.2	Biological indicators
PA 6.1-02-06 V01	Determination of z-values Determination of the resistance of biological indicators for sterilization processes with moist heat in compliance with DIN EN ISO 11138-3 and dry heat in compliance with DIN EN ISO 11138-4	Biological indicators

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
PA 6.1-02-09 / V03	Determination of D-values for germs in suspensions Determination of the resistance of biological indicators for sterilization processes with moist heat in compliance with DIN EN ISO 11138-3 or Ph. Eur. 5.1.2	Biological indicators in different suspension media
PA 6.1-02-02 / V07	Determination of D-values under dry heat conditions Determination of the resistance of biological indicators for sterilization processes with dry heat in compliance with DIN EN ISO 11138-4	Biological indicators
PA 6.1-02-05 / V05	Determination of D-values under formaldehyde conditions Determination of the resistance of biological indicators for sterilization processes with low temperature steam formaldehyde in compliance with DIN EN ISO 11138-5	Biological indicators
PA 6.1-01-11 / V04	Determination of the spore population on solid carriers Determination of viable count in compliance with DIN EN ISO 11138-1 of solid carriers (various materials) inoculated with spore suspension	Biological indicators
PA 6.1-01-06 / V02	Purity testing of biological indicators – testing for microbiological contamination	Biological indicators

Type of testing: Chemical tests*

Testing field	Test item Device(category)	Type of testing Test
DIN EN ISO 11140-1 / 2015-03	Sterilization of health care products – Chemical indicators – Part 1: General requirements • Color change performance in moist heat • Color change performance in dry heat • Color change performance in ethylene oxide • Color change performance in low temperature steam formaldehyde • Color change performance in hydrogen peroxide vapor • Testing for indicator color bleeding (no conformity assessment of medical devices)	Chemical indicators

Testing field	Test item Device(category)	Type of testing Test
DIN 58921 / 2011	Suitability test of a medical device simulator for steam sterilization – Medical device simulator testing (no conformity assessment of medical devices)	Indicator systems, process challenge devices, medical device simulators
PA 6.2-01-05 V02	Determination of the relative reflectance density Method to determine the color difference between substrate and indicator, in compliance with DIN EN ISO 11140-3, annex A and DIN EN ISO 11140-4, annex C	Chemical indicators
PA 6.2-01-06 V02	Determination of the strength of the indicator Determination of the strength of the indicator before and after steam sterilization, in compliance with DIN EN ISO 11140-3, annex A and DIN EN ISO 11140-4, annex A	Chemical indicators
PA 6.2-01-07 V02	Testing of chemical indicators for color transfer Determination of transfer of indicator to standard test pack on processing, in compliance with DIN EN ISO 11140-3, annex F	Chemical indicators
PA 6.2-01-08 V04	Color change test of chemical indicators for steam sterilization Method to determine color change performance in compliance with DIN EN ISO 11140-3, section 6 and DIN EN ISO 11140-4, section 6	Chemical indicators
PA 6.2-10-03 V02	Conformity test of a Bowie-Dick simulation test according to DIN EN ISO 11140-4 Process for assessing performance requirements, uniform color change, equivalence to the Bowie-Dick test, the reproducibility of fail conditions and the indicator color change on exposure 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 V02	Probing the dimensions of process challenge devices according to EN 867-5	Process challenge devices
PA 6.2-10-05 V02	Testing the compatibility of the Process challenge device's materials according to EN 867-5	Process challenge devices
PA 6.2-10-06 V02	Performance test of Process challenge devices according to EN 867-5 Performance test of process challenge devices for hollow body loads according to EN 867-5	Indicator systems, Chemical indicators

Testing field	Test item Device(category)	Type of testing Test
PA 6.2-10-07 V02	Checking the dimensions and materials of process challenge devices according to EN 1422 In compliance with EN 1422 and DIN EN 867-5, section 4.5	Process challenge devices
PA 6.2-10-09 V02	Suitability test of a BMS comparative assessment of indicators systems intended for monitoring validated processes.	Process challenge devices, Indicator systems, monitoring systems

Abbreviations used:

BMS	Batch Monitoring System
DIN	Deutsches Institut für Normung e.V. (German Institute for Standardization, registered Society)
EN	europäische Norm (european standard)
Ph. Eur.	Pharmacopoeia Europaea
ISO	International Organization for Standardization
PA	Prüfanweisung der SAL-GmbH (testing instruction of SAL-GmbH)
USP	United States Pharmacopeia