

Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-19422-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: 16.04.2025

Date of issue: 16.04.2025

This annex is a part of the accreditation certificate D-PL-19422-01-00.

Holder of partial accreditation certificate:

SAS hagmann GmbH & Co. KG
Weberstraße 3, 72160 Horb am Neckar

With the location:

SAS hagmann GmbH & Co. KG
Weberstraße 3, 72160 Horb am Neckar

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 confirm generally with the principles of DIN EN ISO 9001.

Chemical Testing of medical devices

outside of a recognition according to § 18 Medical Device Law Implementation Act.

This certificate annex 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 given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://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.

Testarea	Test item category of product	Type of test Test	Rules test methods
Chemical Testing	Medical devices	Determination of Ethylene oxide-Sterilisation Residuals	DIN EN ISO 10993-7 SOP F6 SOP F7 SOP F8 SOP F14
		Testing for chemical characterisation <ul style="list-style-type: none"> - Gas chromatography <ul style="list-style-type: none"> Ph. Eur. 2.2.28 SOP F22 SOP F23 SOP F24 - Infrared spectroscopy <ul style="list-style-type: none"> ASTM E 1252 Ph. Eur. 2.2.24 SOP F1 SOP F3 SOP F4 - Liquid chromatography <ul style="list-style-type: none"> Ph. Eur. 2.2.29 o IC <ul style="list-style-type: none"> SOP F18 SOP F19 o HPLC <ul style="list-style-type: none"> SOP F20 SOP F20.1 SOP F21 SOP F 25 - Mass spectrometry with inductively coupled plasma <ul style="list-style-type: none"> Ph. Eur. 2.2.58 SOP F16 SOP F17 - Microbeam analysis <ul style="list-style-type: none"> DIN ISO 22309 SOP F12 	DIN EN ISO 10993-18 Ph. Eur. 2.2.28 SOP F22 SOP F23 SOP F24 ASTM E 1252 Ph. Eur. 2.2.24 SOP F1 SOP F3 SOP F4 Ph. Eur. 2.2.29 SOP F18 SOP F19 SOP F20 SOP F20.1 SOP F21 SOP F 25 Ph. Eur. 2.2.58 SOP F16 SOP F17 DIN ISO 22309 SOP F12 <u>referenced document:</u> DIN EN ISO 10993-12

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List of sources for the rules/test methods:

DIN EN ISO 10993-7 : 2022-09	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
DIN EN ISO 10993-12 : 2021-08	Biological evaluation of medical devices - Part12: Sample preparation and Reference materials
DIN EN ISO 10993-18 : 2023-11	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
DIN ISO 22309 : 2015-11	Microbeam analysis — Quantitative analysis using energy-dispersive spectrometry (EDS) for elements with an atomic number of 11 (Na) or above
ASTM E1252 - 98(2013)e1	Standard Practice for General Techniques for Obtaining Infrared Spectra for Qualitative Analysis
Ph. Eur. 11, 2.2.24	Infrared spectroscopy
Ph. Eur. 11, 2.2.28	Gas Chromatography
Ph. Eur. 11, 2.2.29	Liquid Chromatography
Ph. Eur. 11, 2.2.58	Mass spectrometry with inductively coupled plasma
SOP F1 06.08.2024	SOP for sample preparation of various substances for FT-IR
SOP F3 06.08.2024	SOP for the determination of organic substances and lubricants with FT-IR ATR
SOP F4 06.08.2024	SOP for determination of organic substances and lubricants with FT- IR Transmission
SOP F6 24.09.2024	Determination of ethylene oxide residuals in plastic and metal by exhaustive extraction and GC-FID
SOP F7 24.09.2024	Determination of ethylene oxide residuals in plastic and metal by simulated extraction and GC-FID
SOP F8 24.09.2024	Determination of ethylene chlorohydrin residuals in plastic and metal by exhaustive extraction and GC-FID

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SOP F12 29.11.2023	SOP to obtain X-ray spectra with energy dispersive Microbeam analysis
SOP F14 24.09.2024	SOP for the determination of ethylene chlorohydrin residuals in plastic and metal by simulated extraction and GC-FID
SOP F16 06.07.2023	SOP for the determination of elements in water samples and eluates of metal materials, ceramic products und plastics with ICP-MS
SOP F17 06.07.2023	SOP for the determination of metals in water samples with ICP-MS
SOP F18 24.07.2023	SOP for the determination of cations in water samples and eluates of metal materials with IC
SOP F19 24.07.2023	SOP for the determination of anions in water samples and eluates of metal materials with IC
SOP F20 28.07.2023	SOP for the determination of oil residue and lubricants in solvent extracts of metal materials, ceramic products und plastics with HPLC – ELSD
SOP F20.1 28.07.2023	SOP for the determination of residue in solvent extracts of metal materials, ceramic products und plastics with HPLC - DAD
SOP F21 26.11.2021	SOP for the determination of additives in granulates and a master batch with HPLC UV/DAD
SOP F22 27.07.2023	SOP for identification and semi-quantitative determination of organic compounds in solvent and eluates of metal materials, ceramic products und plastics with GC-MS
SOP F23 31.08.2023	SOP for the quantitative and semi-quantitative determination of organic compounds in solvent and eluates with GC-FID
SOP F24 08.10.2024	SOP for the quantitative and semi-quantitative determination of Total Organic Carbon [TOC] und major gas components with GC-WLD
SOP F25 08.03.2024	SOP for screening for NVOC in various matrices with HPLC-MS and UPLC-MS

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Abbreviations used

ASTM	American Society for Testing and Materials
DIN	German institute for standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
SOP	Standard Operating Procedure