Deutsche Akkreditierungsstelle

Annex to the Accreditation Certificate D-PL-12083-03-01 according to DIN EN ISO/IEC 17025:2018

Valid from: **02.12.2025**

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This annex is part of the Accreditation Certificate D-PL-12083-03-00.

Holder of the Accreditation Certificate:

Hohenstein GmbH & Co. KG
Schloss Hohenstein, 74357 Bönnigheim

with the location

Hohenstein GmbH & Co. KG
Schloss Hohenstein, 74357 Bönnigheim

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.

Biological, chemical and physical tests of medical devices and microbiological-hygienic tests of medical devices including disinfectants;
Environmental monitoring

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

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).

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices, Medical compression hosiery	tests for in vitro cytotoxicity - Cell Growth inhibition test after contact with extracts	DIN EN ISO 10993-5 3.DEC.0263 3.DEC.0265 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12 DIN EN ISO 18562-4
	Medical devices	In-vitro tests for skin sensitization - Direct Peptide Reactivity Assay (DPRA) - Reconstructed human epidermis (IL-18 RhE) - Activation of epidermal dendritic cells (U-SENS)	DIN EN ISO 10993-10 Annex C.2.2.1 3.DEC.0296 Annex C.2.2.5 3.DEC.0293 Annex C.2.2.9 3.DEC.0294 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12 DIN EN ISO 18562-4
		Tests for irritation - In vitro irritation test using reconstructed skin	DIN EN ISO 10993-23 3.DEC.0289 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12 DIN EN ISO 18562-4

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Tests for irritation - In vitro irritation test (Hen`s Egg Test on the Chorioallantoic Membrane (HET CAM)	DB-ALM Protocol N°96 3.DEC.0266 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
Chemical tests	Medical devices	Tests within the chemical characterization - Semi-quantitative determination of volatile substances by GC-MS - Determination of water-extractable elemental substances by ICP-MS - Determination of extractable substances by LC-MS	DIN EN ISO 10993-18 3.DEC.0301 3.DEC.0299 3.DEC.0859 Applicable: DIN EN ISO 10993-1
		Testing of product features - Tests for emissions of volatile organic substances	DIN EN ISO 18562-3 3.DEC.0300 Applicable: DIN EN ISO 18562-1

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Chemical tests	Medical devices	Testing of product features - Tests for leachables in condensate • GC-MS • ICP-MS • LC-MS	DIN EN ISO 18562-4 3.DEC.0298 USP 233 Ph. Eur 2.2.58 3.DEC.0299 3.DEC.0859 Applicable: DIN EN ISO 18562-1
Microbiological-hygienic tests	Disinfectants	Determination of the bactericidal and yeasticidal activity in the qualitative suspension test	VAH Method 8
		Quantitative suspension test for the evaluation of bactericidal, fungicidal, yeasticidal or mycobactericidal activity of chemical disinfectants in the medical area (phase 2, step 1)	DIN EN 13727 DIN EN 13624 DIN EN 14348
		Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in the quantitative suspension test	VAH Method 9

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Determination of the virucidal activity in the quantitative suspension test	3.DEC.0321 (VAH Method 9)
		Quantitative 4-field test for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action in the medical area (phase 2, step 2)	DIN EN 16615
		Evaluation of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity on non-porous surfaces in a practical test	
		- Surface disinfection without mechanical action	VAH Method 14.1
		- Surface disinfection with mechanical action - 4-field test	VAH Method 14.2
		Quantitative carrier test for the evaluation of bactericidal, fungicidal or yeasticidal, mycobactericidal activity in the medical area (phase 2, step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563
		Chemical/chemical-thermal instrument disinfection – quantitative carrier test	VAH Method 15
		Chemical-thermal textile disinfection (phase 2, step 2)	DIN EN 16616

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Chemical-thermal textile disinfection – simulated-use test (without pre-wash) - at temperatures between 30 °C to < 60 °C - at temperatures between ≥ 60 °C bis 70 °C	VAH Method 17 VAH Method 17.1 VAH Method 17.2
		Testing of the virucidal activity of disinfectants at the chemical-thermal textile disinfection (practical test)	3.DEC.0324 3.DEC.0325 (VAH-Method 17)
		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 (phase 2, step 2)	DIN EN 17387
	Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment	Test method to determine the resistance to wet bacterial penetration (Wet penetration)	DIN EN ISO 22610 Applicable: DIN EN 13795-1
		Test method for resistance to dry microbial penetration (Dry penetration)	DIN EN ISO 22612 Applicable: DIN EN 13795-1

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Sterile barrier and packaging systems, materials	Test to Verification verify compliance - Microbial barrier	DIN EN ISO 11607-1 ASTM F 1608-21 3.DEC.0358
	Medical devices, information for the processing	Testing within the scope of validation - Cleaning, desinfection and drying	DIN EN ISO 17664-1 DIN EN ISO 17664-2 3.DEC.0864
Physical tests	Compression hosiery	Testing of product features	RAL-GZ 387/1 3.DEC.0506 DIN 58133
	Compression armsleeves	Testing of product features	RAL-GZ 387/2 3.DEC.0508
	Stocking systems for Ulcus Cruris	Testing of product features	RAL-GZ 387/3 3.DEC.0507
	Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment	Testing for particle release in the dry state	DIN EN ISO 9073-10 Applicable: DIN EN 13795-1
	Medical face masks	Test method for resistance against penetration by synthetic blood	ISO 22609 Applicable: DIN EN 14683
		In vitro testing of bacterial filtration efficiency (BFE)	DIN EN 14683 Annex B

Testing area	Test item	Testing area	Test item
Physical tests	Medical face masks	Test to determine breathability (differential pressure)	DIN EN 14683 Annex C
	Medical devices	Testing of product features - Tests for emissions of particulate matter	DIN EN ISO 18562-2 3.DEC.0295 Applicable: DIN EN ISO 18562-1
Environmental monitoring in manufacturing and testing of the cleanliness of the products according to DIN EN ISO 13485 : 2021, Para. 6.4 and Para. 7.5			
Microbiological-hygienic tests	Medical devices	Determination of a population of microorganisms on products (Bioburden)	DIN EN ISO 11737-1
		Bacterial endotoxin testing (LAL test)	ISO 11737-3 Ph. Eur. 2.6.14 USP 85 ANSI/AAMI ST72 3.DEC.0304
		Cleanliness, risk orientated validation	DIN/TS 5343 3.DEC.0864

Bibliography Regulation/Testing method:

DIN/TS 5343 : 2022-04	Cleanliness of medical devices - Risk orientated validation of cleanliness, development of acceptance criteria and selection of test methods
DIN EN ISO 9073-10 : 2005-03	Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)
DIN EN ISO 10993-1 : 2021-05	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)

DIN EN ISO 10993-5 : 2009-10	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
DIN EN ISO 10993-10 : 2023-04	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
DIN EN ISO 10993-12 : 2021-03	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
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 (ISO 10993-18:2020 + Amd 1:2022)
DIN EN ISO 10993-23 : 2021-10	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
DIN EN ISO 11607-1 : 2024-02	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019 + Amd 1:2023)
DIN EN ISO 11737-1 : 2021-10	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)
ISO 11737-3:2023-06	Sterilization of health care products – Microbiological methods – Part 3: Bacterial endotoxin testing
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)
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)
DIN EN 13795-1 : 2025-03	Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
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)

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)
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)
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)
DIN EN 14683 : 2019-10	Medical face masks - Requirements and test methods
DIN EN 14683 : 2019-10 Annex B	Medical face masks - Requirements and test methods Annex B – Method for in vitro determination of bacterial filtration efficiency (BFE)
DIN EN 14683 : 2019-10 Annex C	Medical face masks - Requirements and test methods Annex C – Breathability - Method for determination of the differential pressure
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)
DIN EN 16616 : 2022-10	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)
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)
DIN EN ISO 17664-1 : 2021-11	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)

DIN EN ISO 17664-2 : 2024-04	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices (ISO 17664-2:2021)
DIN EN ISO 18562-1 : 2025-02	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2024)
DIN EN ISO 18562-2 : 2025-02	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter (ISO 18562-2:2024)
DIN EN ISO 18562-3 :2025-02	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances (ISO 18562-3:2024)
DIN EN ISO 18562-4 : 2025-02	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate (ISO 18562-4:2024)
ISO 22609 : 2004-12	Clothing for protection against infectious agents- Medical face masks- Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
DIN EN ISO 22610 : 2006-10	Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)
DIN EN ISO 22612 : 2005-05	Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration (ISO 22612:2005)
DIN 58133 : 2008-07	Medical compression hosiery
ANSI/AAMI ST72 : 2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
ASTM F 1608-21 : 2021	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
DB-ALM-Protocol n° 96 : 2010-02	Hen`s Egg Test on the Chorioallantoic Membrane (HET-CAM)
Ph. Eur. 2.2.58 Edition 10 : 2020	Inductively coupled plasma-mass spectrometry
Ph. Eur. 2.6.14 Edition 10 : 2020	Bacterial endotoxins
RAL-GZ 387/1 : 2008-01	Medical Compression Hosiery - Quality Assurance
RAL-GZ 387/2 : 2008-01	Medical Compression Armsleeves - Quality Assurance
RAL-GZ 387/3 : 2020-02	Stocking systems for the therapy of Ulcus cruris patients

USP 233 : 2015	Elemental Impurities - Procedures
USP 85 : 2012	Bacterial endotoxins test
VAH Method 8 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Determination of the bactericidal and yeasticidal activity in the qualitative suspension test”
VAH Method 9 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal activity in the quantitative suspension test”
VAH Method 14.1 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Surface disinfection without mechanical action – simulated-use test”
VAH Method 14.2 : 2018-05	Requirements and methods for VAH certification of chemical disinfection procedures: “Surface disinfection with mechanical action – simulated-use test (4-field test)”
VAH Method 15 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Chemical/Chemical-thermal instrument disinfection – quantitative carrier test”
VAH Method 17.1 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Chemical-thermal textile disinfection – simulated-use test (without pre-wash) – Test for textile disinfection procedures at temperatures between 30 °C to < 60 °C”
VAH Method 17.2 : 2015-04	Requirements and methods for VAH certification of chemical disinfection procedures: “Chemical-thermal textile disinfection – simulated-use test (without pre-wash) – Test for textile disinfection procedures at temperatures between ≥ 60 °C to 70 °C”
3.DEC.0506 : 2025-01	Testing of medical compression hosiery according to RAL-GZ 387/1
3.DEC.0507 : 2025-01	Testing of stocking systems for the treatment of Ulcus Cruris patients according to RAL-GZ 387/3
3.DEC.0508 : 2025-01	Testing of medical compression armsleeves according to RAL-GZ 387/2
3.DEC.0263 : 2025-02	Cytotoxicity test

3.DEC.0265 : 2025-01	Cytotoxicity testing on elastane-containing materials for medical devices
3.DEC.0266 : 2025-02	Tests for irritation: The Hens´s Egg Test on the Chorioallantoic Membrane (Het-CAM)
3.DEC.0289 : 2025-02	Tests for irritation in the skin model according to DIN EN ISO 10993-23
3.DEC.0293 : 2025-03	Testing for skin sensitization (IL-18 RhE) of medical devices according to DIN EN ISO 10993-10
3.DEC.0294 : 2025-03	Testing for skin sensitization (U-SENS) of medical devices according to DIN EN ISO 10993-10
3.DEC.0295 : 2025-02	Tests for particle emissions in medical applications according to DIN EN ISO 18562-2
3.DEC.0296 : 2025-03	Testing for skin sensitization of medical devices (DPRA) according to DIN EN ISO 10993-10
3.DEC.0298 : 2025-03	Chemical testing of organic extractable substances from medical devices according to DIN EN ISO 18562-4
3.DEC.0299 : 2025-03	Determination of water-extractable elemental substances in medical devices by ICP-MS
3.DEC.0300 : 2025-03	Tests for emissions of volatile organic compounds (VOCs) in medical applications according to DIN EN ISO 18562-3
3.DEC.0301 : 2025-03	Chemical characterization of medical devices by semi-quantitative screening using GC-MS according to DIN EN ISO 10993-18
3.DEC.0304 : 2025-03	Testing of bacterial endotoxins in health care products
3.DEC.0321 : 2025-01	Testing of disinfectant washing procedures for their effectiveness against viruses in the quantitative suspension test
3.DEC.0324 : 2025-01	Testing of disinfectant washing procedures for their effectiveness against phages in a practical test (washing test)
3.DEC.0325 : 2025-01	Use of phage bioindicators to verify disinfecting washing procedures on site and subsequent evaluation in the laboratory
3.DEC.0358 : 2025-01	Microbiological assessment of porous packaging materials according to ASTM F 1608
3.DEC.0859 : 2025-03	Chemical characterization of medical devices by screening using HPLC-qTOF
3.DEC.0864 : 2025-03	Validation of reprocessing procedures for medical devices

Abbreviations used

3.DEC.XXXX	Standard Operating Procedure (SOP) of the CAB
AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
DB-ALM	DataBase service on Alternative Methods by the European Union Reference Laboratory on Alternatives to Animal Testing
DIN	Deutsches Institut für Normung [German Institute for Standardisation]
DIN/TS	DIN technical specification
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
Ph. Eur.	European Pharmacopoeia
RAL-GZ	Quality and testing specifications of the RAL Deutsches Institut für Gütesicherung und Kennzeichnung e.V. [RAL German Institute for Quality Assurance and Certification]
USP	United States Pharmacopeia
VAH	Verbund für Angewandte Hygiene e.V. [The Association for Applied Hygiene]