Deutsche Akkreditierungsstelle GmbH

Annex to the Partial Accreditation Certificate D-PL-18818-02-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **22.08.2023**

Date of issue: 07.12.2023

This annex is part of the accreditation certificate D-PL-18818-02-00.

Holder of the Partial Accreditation Certificate:

HygCen Germany GmbH
Bornhövedstraße 78, 19055 Schwerin

with the location:
HygCen Germany GmbH
Bornhövedstraße 78, 19055 Schwerin

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 general with the principles of DIN EN ISO 9001.

Biological and chemical tests of medical devices, microbiological-hygienic tests of medical devices including disinfectants, microbiological-hygienic including physical tests of cleaning and disinfection devices (WDG), cleaning and disinfection procedures as well as sterilisers and sterilisation procedures and physical tests of medical devices; environmental surveillance

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

Bornhövedstraße 78, 19055 Schwerin

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Testing for genotoxicity, carcinogenicity and reproductive toxicity *in vitro*- genotoxicity tests Bacterial reverse mutation test (Ames-Test) Mouse Lymphoma tk-Test (MLA)	DIN EN ISO 10993-3 SOP 09-003 OECD-Guidelines 471 OECD-Guidelines 490 Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Testing in the context of interaction with blood Haemolysis test • Cyanhämoglobin-Method Coagulation • Determination of PTT Thrombocyte activation • Thrombocyte count Complement system • SC5b-9 Haematology • PMN • Leukocyte count	DIN EN ISO 10993-4 SOP 09-004 Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Cytotoxicity test	DIN EN ISO 10993-5 SOP 09-001
		Cell vitality test after contact with extracts (Colorimetric measurement of vitality (neutral red, MTT and XTT)	
		Test for membrane integrity after contact with extracts (LDHe release)	
		Agar diffusion test / Agar overlay Direct cell contact	DIN EN ISO 7405 USP <87> SOP 09-015
		Cell proliferation assay after contact with extracts (BCA assay)	
		Cell vitality test after contact with extracts (ATP assay)	Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Testing for skin sensitisation	DIN EN ISO 10993-10 SOP 09-013
		IL-18 Assay	
		In vitro irritation test using KeratinoSens™	OECD 442D
		h-CLAT (human Cell Line Activation Test)	OECD 442E

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Irritation test In vivo irritation test on human skin (Primary Skin Irritation test)	DIN EN ISO 10993-23 SOP 09-013
		In vitro irritation testing using reconstructed 3D skin models	SOP 09-013 (OECD TG 439) Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Quantitative detection of pyrogenic impurities in the human whole blood model by ELISA (MAT)	Ph. Eur. 2.6.30 SOP 09-006 Also applicable: DIN EN ISO 10993-11
Chemical tests	Medical devices	Testing within the framework of chemical characterisation Qualitative and semiquantitative data	DIN EN ISO 10993-18 SOP 17-020 SOP 17-021 SOP 17-022
	Polymer	Chemical structure Additives, process residues, trace substances or impurities Monomer residues	
	Metals & Alloys	Additives, process residues, trace substances or impurities	
	Ceramics	Characterisation of the extractability of soluble substances	
	Natural macromolecules	Impurities Chemical structure	Also applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Medical devices	Sterility testing	DIN EN ISO 11737-2 Ph. Eur. 2.6.1 SOP 09-012
		Counting of the total reproducible aerobic germs	Ph. Eur. 2.6.12 USP <61> SOP 09-011
		Testing for antimicrobial activity	ISO 22196 JIS Z 2801 JIS L 1902 SOP 02-058
		Testing for antiviral activity	ISO 18184 ISO 21702 SOP 02-206
		Testing for sufficient preservation	Ph. Eur. 5.1.3 SOP 02-303
	Disinfectants	Quantitative suspension test for the determination of the bactericidal, fungicidal, yeasticidal or sporicidal activity of chemical disinfectants and antiseptics (Basic test - phase 1)	DIN EN 1040 DIN EN 1275 DIN EN 14347 SOP 02-050 Also applicable: DIN EN 14885
		Determination of bacteriostatic and levurostatic activity and suitable neutralising agents	VAH – Method 7 SOP 02-001 SOP 02-101
		Determination of bactericidal and yeasticidal activity in the qualitative suspension test	VAH – Method 8 SOP 02-002 SOP 02-102

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Quantitative suspension test to determine the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants in the field of human medicine (phase 2, step 1)	DIN EN 13727 DIN EN 13624 DIN EN 14348 SOP 02-051 Also applicable: DIN EN 14885
		Quantitative suspension test to determine the virucidal activity of chemical disinfectants (phase 2, step 1)	DIN EN 14476 Guideline DVV/RKI, chemical disinfectants against viruses SOP 02-204 SOP 02-200
		Quantitative suspension test to determine the sporicidal activity of chemical disinfectants (phase 2, step 1)	DIN EN 17126 SOP 02-057
		Determination of sporicidal activity on non-porous surfaces in a practical test against Clostridioides difficile spores. Surface disinfection with mechanics - 4-field test	VAH-Method 19 SOP 02-302
		Determination of bactericidal, fungicidal, tuberculocidal and mycobactericidal activity in quantitative suspension tests	VAH – Method 9 SOP 02-003 SOP 02-103 SOP 02-010

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity on non-porous surfaces in a practical test - Surface disinfection without mechanics - Surface disinfection with mechanics -4-field test	 VAH - Method 14.1 SOP 02-006 SOP 02-007 VAH - Method 14.2 SOP 02-054
		Quantitative germ carrier test for testing the bactericidal, fungicidal or yeasticidal, mycobactericidal activity in the field of human medicine (phase 2, step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 SOP 02-054 Also applicable: DIN EN 14885
		Chemo-thermal laundry disinfection (phase 2, step 2)	DIN EN 16616 SOP 02-014
		Chemical disinfectants and antiseptics - Quantitative test on non-porous surfaces without mechanical action to determine virucidal activity in human medicine - Test method and requirements (phase 2, step 2)	DIN EN 16777 SOP 02-204

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Chemical disinfectants and antiseptics - Quantitative test for the determination of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the field of human medicine on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)	DIN EN 17387 SOP 02-054
		Carrier test for testing instrument disinfectants on frosted glass (phase 2, step 2)	DIN EN 17111 SOP 02-204
		Chemical/chemotherapeutic instrument disinfection - practical quantitative germ carrier test	VAH - Method 15 SOP 02-054
		Chemical laundry disinfection - insertion process (practical experiment)	VAH - Method 16 SOP 02-014
		Determination of the bactericidal and yeasticidal activity of chemical disinfectants on non-porous surfaces by means of a Practical quantitative 4-field test with mechanics	DIN EN 16615 SOP 02-054 SOP 02-302

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Chemo-thermal laundry disinfection - single bath method (practical test) - at temperatures from 30°C to < 60°C - at temperatures from ≥ 60°C to 70°C	 VAH - Method 17.1 SOP 02-014 VAH - Method 17.2 SOP 02-014
		Chemical disinfectants and antiseptics - Quantitative suspension test to determine the sporicidal activity	VAH – Method 18 SOP 02-051 SOP 02-053
		Testing the activity of disinfectants for chemical instrument disinfection for tuberculosis	German Federal Health Gazette 11/94 SOP 02-011
		Testing the activity of surface disinfectants for the disinfection of tuberculosis	German Federal Health Gazette 04/94 SOP 02-012
	Disinfectant dosing devices	Testing of decentralised disinfectant dispensers	German Federal Health Gazette 1/2004 SOP 07-010
	Sterile barrier and packaging systems, materials	Tests within the framework of the proof of conformity - Microbial barrier	DIN EN ISO 11607-1 ASTM F 1608 SOP 07-012
Physical tests	Sterile barrier and packaging systems, materials	Testing as part of the proof of compliance - Accelerated ageing	DIN EN ISO 11607-1 ASTM F 1980 SOP 19-008

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Cleaning and disinfection equipment (RDG)	Equipment testing	DIN EN ISO 15883-1
	- with thermal disinfection for surgical instruments, anaesthesia equipment, vessels, utensils, glassware	Type testing	DIN EN ISO 15883-2 SOP 16-001 SOP 16-002
	- with thermal or chemo-thermal disinfection for containers for human excreta	Type testing	DIN EN ISO 15883-3 SOP 16-001 SOP 16-003
	- with chemical or thermal disinfection for thermolabile endoscopes	Type testing	DIN EN ISO 15883-4 SOP 16-001 SOP 16-004
	- Thermal disinfection for non-invasive, non-critical medical devices and accessories in the healthcare sector	Type testing	DIN EN ISO 15883-6 SOP 16-001 SOP 16-011

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Cleaning and disinfection equipment (RDG)	Equipment testing	DIN EN ISO 15883-1
	- Chemical disinfection for non-invasive, non-critical thermolabile medical devices and accessories in the healthcare sector	Type testing	DIN EN ISO 15883-7 SOP 16-001 SOP 16-012 Also applicable: DIN EN ISO 15883-5 KRINKO/BfArM, Recommendation Reprocessing MP
	Cleaning and disinfection procedures	Validation	DIN EN ISO 15883-1
	- with thermal disinfection for surgical instruments, anaesthesia equipment, vessels, utensils, glassware	Installation qualification Operational qualification Performance qualification	DIN EN ISO 15883-2 SOP 16-001 SOP 16-002 SOP 16-008
	- with thermal or chemo-thermal disinfection for containers for human excreta	Installation qualification Operational qualification Performance qualification	DIN EN ISO 15883-3 SOP 16-001 SOP 16-003 SOP 16-008

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Cleaning and disinfection procedures	Validation	DIN EN ISO 15883-1
	- with chemical or thermal disinfection for thermolabile endoscopes	Installation qualification Operational qualification Performance qualification	DIN EN ISO 15883-4 SOP 16-001 SOP 16-004 SOP 16-008
	- with thermal disinfection for non-invasive, non-critical medical devices and accessories in the healthcare sector	Installation qualification Operational qualification Performance qualification	DIN EN ISO 15883-6 SOP 16-001 SOP 16-011
	- with chemical disinfection for non-invasive, non-critical thermolabile medical devices and accessories in the healthcare sector	Installation qualification Operational qualification Performance qualification	DIN EN ISO 15883-7 SOP 16-001 SOP 16-012 Also applicable: DIN EN ISO 15883-5 KRINKO/BfArM, Recommendation Reprocessing MP

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Cleaning and disinfection procedures	Testings within the scope of validation	
	- with thermal disinfection for surgical instruments, anaesthesia equipment, vessels, utensils, glassware	Performance qualification	Guideline DGKH, DGSV and AKI, mechanical cleaning and thermal disinfection processes for medical devices SOP 16-009
	- with chemical or thermal disinfection for thermolabile endoscopes	Performance qualification	Guideline DGKH, DEGEA, DGSV, DGVS and AKI, Reprocessing of thermolabile endoscopes SOP 16-008
	Disinfection procedures Airborne room disinfection through automated processes	Performance qualification	DIN EN 17272 SOP 02-059
	Disinfection procedures Indoor air pollution - mobile air purifiers	Performance qualification	VDI-EE 4300 Blatt 14 SOP 16-014
	Disinfection procedures Evaporated hydrogen peroxide at low temperature	Performance qualification	ISO 22441 SOP 07-016
	Steam sterilisers	Type testing Factory inspection Acceptance inspection	DIN EN 285 SOP 07-015
	Small steam sterilisers	Type testing Factory inspection Acceptance inspection	DIN EN 13060 SOP 07-015

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Sterilisation procedures	Validation	
	- with damp heat	Installation qualification Operational qualification Performance qualification	DIN EN ISO 17665-1 SOP 07-016 Also applicable: DIN EN 13060 DIN EN 285
	- with ethylene oxide	Installation qualification Operational qualification Performance qualification	DIN EN ISO 11135 DIN EN 1422 SOP 07-016
	- with low-temperature steam formaldehyde (NTDF)	Installation qualification Operational qualification Performance qualification	DIN EN 14180 DIN EN ISO 25424 SOP 07-016
	- with hydrogen peroxide (H_2O_2)	Installation qualification Operational qualification Performance qualification	DIN EN ISO 14937 SOP 07-016
	Storage cabinet with controlled environmental conditions for reprocessed, thermolabile endoscopes	Type testing Factory inspection Acceptance inspection	DIN EN 16442 SOP 16-013
	Maintaining the condition of the endoscopes	Installation qualification Operational qualification Performance qualification	DIN EN 16442 SOP 16-013

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic including physical tests	Information for the reprocessing of medical devices	Testings within the scope of validation	DIN EN ISO 17664-1 ISO 17664-2 FDA Guideline Validation Methods AAMI TIR 30 AAMI TIR 12 ANSI/AAMI ST79 SOP 19-001
		Cleaning	SOP 19-002
		Disinfection	SOP 19-002
		Drying	SOP 19-002
		Sterilisation	SOP 19-003
		with moist heat	
		Ethylene oxide	
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			
Chemical tests	Medical devices	Organic contaminants	ISO 19227, Kap. 5.5 SOP 17-019
	Water and aqueous solutions	Quantitative determination of free NH_2 groups of proteins by the OPA method	SOP 17-008 (DIN EN ISO 15883-5)
		Determination of the protein content of liquids with the BCA Protein Assay Kit	SOP 17-015 (DIN EN ISO 15883-5)
		Testing for microbial contamination - Determination of TOC (Total Organic Carbon)	USP <643> SOP 17-019 Also applicable: AAMI TIR12 AAMI TIR30

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
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			
Chemical tests	Medical devices	Testing of product properties Testing for leachable substances in condensates	DIN EN ISO 18562-4 SOP 17-020 SOP 17-021 SOP 17-022 Also applicable: DIN EN ISO 18562-1
Microbiological-hygienic tests	Medical devices	Estimation of the population of microorganisms on products (Bioburden determination)	DIN EN ISO 11737-1 ISO 19227, Kap. 5.3 SOP 07-014
		Testing for bacterial endotoxins (LAL test)	DIN EN ISO 10993-11 ISO 19227, chap. 5.4 Ph. Eur. 2.6.14 USP <85> SOP 09-010
		Biofilm inhibition and removal	DIN EN ISO 16954, chap. 7 SOP 19-004
		Purity, risk-oriented validation	DIN/TS 5343 SOP 19-009
		Requirements for products - STERILE	DIN EN 556-1 SOP 09-012
	Surfaces	Germ content of surfaces	DIN EN 17141 SOP 11-001
	Cleanroom technology air	Determination of the airborne germ count	DIN EN 17141 SOP 11-001
		Determination of the particle number in the air	DIN EN ISO 14644-1 SOP 11-001

Testing field	Test item Device (category)	Type of testing Test	Regulation Testing method
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	Water and aqueous solutions	Detection of specified microorganisms	SOP 03-009 DIN EN ISO 6222 DIN EN ISO 19250 DIN EN 26461-1 DIN EN 26461-2 DIN 19643-1 DIN EN ISO 11731 DIN EN ISO 16266 DIN EN ISO 7899-2 DIN EN ISO 9308-1
	Textile medical devices and linen (reprocessed)	Testing the disinfecting activity of chemo-thermal laundry processes	RKI Guideline Hospital Hygiene Annex Hygiene Laundry 4.4.3 SOP 02-030 Also applicable: VAH 4.2
Physical tests	Medical devices	Testing for particulate contamination Particulate contamination	DIN EN ISO 8536-4, Chap. 7 ISO 19227, Chap. 5.7 SOP 19-005
	Cleanroom technology air	Determination of the particle number in the air	DIN EN ISO 14644-1 SOP 11-001

Rules and Regulations:

DIN EN 285 : 2021-12	Sterilization - Steam sterilisers - Large sterilisers
DIN EN 556-1 : 2002-03	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
DIN EN 556-1 : 2006-12 Berichtigung 1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
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)
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)
DIN EN 1422 : 2014-08	Sterilizers for medical purposes - Ethylene oxide sterilisers - Requirements and test methods
DIN EN ISO 4628-1 : 2016-07	Paints and varnishes - Evaluation of degradation of coatings - Designation of quantity and size of defects, and of intensity of uniform changes in appearance - Part 1: General introduction and designation system (ISO 4628-1:2016)
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 6222 : 1999-07	Water quality - Enumeration of culturable micro-organisms - Colony count by inoculation in a nutrient agar culture medium (ISO 6222:1999)
DIN EN ISO 7405 : 2019-03	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry (ISO 7405:2018, Corrected version 2018-12)
DIN EN ISO 7899-2 : 2000-11	Water quality - Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method (ISO 7899-2:2000)
DIN EN ISO 8536-4 : 2020-05	Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2019)
DIN EN ISO 9308-1 : 2017-09	Water quality - Enumeration of Escherichia coli and coliform bacteria - Part 1: Membrane filtration method for waters with low bacterial background flora (ISO 9308-1:2014 + Amd 1:2016)

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 10993-3 : 2015-02	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
DIN EN ISO 10993-4 : 2017-12	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
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 10993-11 : 2018-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
DIN EN ISO 10993-12 : 2021-08	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
DIN EN ISO 10993-18 : 2021-03	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
DIN EN ISO 10993-23:2021-10	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
DIN EN ISO 11135 : 2020-04	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014 + Amd.1:2018)
DIN EN ISO 11607-1 : 2020-05	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
DIN EN ISO 11607-1 / A11 : 2022-08	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
DIN EN ISO 11731 : 2019-03	Water quality - Enumeration of Legionella (ISO 11731:2017)
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)
DIN EN ISO 11737-2 : 2020-07	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
DIN EN 13060 : 2019-02	Small steam sterilisers

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 14180 : 2014-09	Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilisers - Requirements and testing
DIN EN 14347 : 2005-08	Chemical disinfectants and antiseptics - Basic sporicidal activity - Test method and requirements (phase 1)
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 14476 : 2019-10	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method 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 ISO 14644-1 : 2016-06	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
DIN EN 14885 : 2022-10	Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics
DIN EN ISO 14937 : 2010-03	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
DIN EN ISO 15883-1 : 2014-10	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006 + Amd 1:2014)

DIN EN ISO 15883-2 : 2009-09	Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)
DIN EN ISO 15883-3 : 2009-09	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)
DIN EN ISO 15883-4 : 2019-06	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)
DIN EN ISO 15883-5 : 2021-11	Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning activity (ISO 15883-5:2021)
DIN EN ISO 15883-6 : 2016-04	Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment (ISO 15883-6:2011)
DIN EN ISO 15883-7 : 2016-10	Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO 15883-7:2016)
DIN EN ISO 16266 : 2008-05	Water quality - Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration (ISO 16266:2006)
DIN EN 16442 : 2015-05	Controlled environment storage cabinet for processed thermolabile endoscopes
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 16777 : 2019-03	Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2)
DIN EN ISO 16954 : 2015-11	Dentistry - Test methods for dental unit waterline biofilm treatment (ISO 16954:2015)

DIN EN 17111 : 2018-12	Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
DIN EN 17126 : 2019-02	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)
DIN EN 17141:2021-02	Cleanrooms and associated controlled environments - Biocontamination control
DIN EN 17272 : 2020-06	Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities
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)
ISO 17664-2 : 2021-02	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
DIN EN ISO 17665-1 : 2006-11	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
ISO 18184 : 2019-06	Textiles – Determination of antiviral activity of textile products
DIN EN ISO 18562-1 : 2020-05	Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process (ISO 18562-1:2017)
DIN EN ISO 18562-4 : 2020-05	Biocompatibility evaluation of breathing gas pathways in healthcare application - Part 4: Tests for leachables in condensate (ISO 18562-4:2017)
ISO 19227:2018-03	Implants for surgery – Cleanliness of orthopedic implants – General requirements
DIN EN ISO 19250 : 2013-06	Water quality - Detection of Salmonella spp. (ISO 19250:2010)

DIN 19643-1 : 2022-06	Treatment of water of swimming pools and baths - Part 1: General requirements
DIN EN ISO 21530 : 2004-09	Dentistry - Materials used for dental equipment surfaces - Determination of resistance to chemical disinfectants (ISO 21530:2004)
ISO 21702 : 2019-05	Measurement of antiviral activity on plastics and other non-porous surfaces
ISO 22196 : 2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces
ISO 22441 – 2022-08	Sterilization of health care products – Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN EN ISO 25424 : 2022-07	Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018 + Amd 1:2022)
DIN EN 26461-1 : 1993-04	Water quality; detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia); part 1: method by enrichment in a liquid medium (ISO 6461-1:1986)
DIN EN 26461-2 : 1993-04	Water quality; detection and enumeration of the spores of sulfite-reducing anaerobes (clostridia); part 2: method by membrane filtration (ISO 6461-2:1986)
AAMI TIR 12 : 2020	Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
AAMI TIR 30 : 2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ANSI/AAMI ST79 : 2017	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ASTM F1608 : 2021	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
ASTM F1980 : 2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
German Federal Health Gazette 04/94, S. 274-278 : 1994-04	Testing the activity of surface disinfectants for the disinfection of tuberculosis
German Federal Health Gazette 11/94, S. 474-476 : 1994-11	Testing the activity of disinfectants for chemical instrument disinfection in tuberculosis

German Federal Health Gazette 1/2004, S. 67-72	Requirements for the design, characteristics and operation of decentralised disinfectant dispensers
FDA Guideline Validation Methods : 2017	FDA: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. March 2015. Update Appendix E: June 2017.
Japanese Industrial Standard, JIS L 1902 : 2015-07	Testing for antibacterial activity and activity on textile products
Japanese Industrial Standard, JIS Z 2801 : 2010-12 + Am. 1 : 2012-05	Antimicrobial products – Tests for antimicrobial activity and activity
KRINKO/BfArM, Recommendation Reprocessing MP : 2012	Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) German Federal Health Gazette 55: 1244-1310, 2012 Requirements for hygiene in the reprocessing of medical devices
Guideline DGKH, DGSV and AKI, mechanical cleaning and thermal disinfection processes for MP : 2017	Guideline of DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices
Guideline DGKH, DEGEA, DGSV, DGVS and AKI, Reprocessing of thermolabile endoscopes : 2011	Guideline of DGKH, DGSV, DEGEA, DGVS and AKI for the validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes
Guideline DVV and RKI, chemical disinfectants against viruses : 2015	Guideline of the German Association for Combating Viral Diseases (DVV) and the Robert Koch Institute (RKI) on testing chemical disinfectants for activityiveness against viruses in human medicine.
OECD Guideline 442D : 2018	OECD Guideline for the Testing of Chemicals: In Vitro Skin Sensitisation - ARE-Nrf2 Luciferase Test Method
OECD Guideline 442E : 2018	OECD Guideline for the Testing of Chemicals: In Vitro Skin Sensitisation - In Vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation
OECD Guideline 471 : 2020	OECD Guideline for the Testing of Chemicals: Bacterial Reverse Mutation Test
OECD Guideline 490 : 2016	OECD Guideline for the Testing of Chemicals: In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene
OECD Test Guideline 439 : 2021	OECD Guideline for the Testing of Chemicals: In Vitro Skin Irritation: Reconstructed Human Epidermis Test Methods

Ph. Eur. 10, 2.6.1	Sterility test
Ph. Eur. 10, 2.6.12	Microbiological testing of non-sterile products: Counting of total reproducible germs
Ph. Eur. 10, 2.6.14	Testing for bacterial endotoxins
Ph. Eur. 10, 2.6.30	Monocyte-activation test (MAT)
Ph. Eur. 10, 5.1.3	Testing for sufficient preservation
RKI Guideline Hospital Hygiene Annex Hygiene Laundry 4.4.3	Hygiene requirements for laundry from health service facilities, the laundry and the washing process and conditions for contracting laundry to commercial laundries
USP 41 <61>	Microbial Enumeration Tests
USP 41 <85>	Pyrogen and Endotoxins Testing
USP 41 <87>	Biological Reactivity Tests, in vitro
USP 41 <643>	Total organic carbon
VAH – Method 4.2 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Activity testing against specific pathogens, viruses
VAH - Method 7 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Determination of bacteriostatic and levurostatic activity as well as suitable neutralising agents
VAH - Method 8 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Determination of bactericidal and yeasticidal activity in a qualitative suspension test
VAH - Method 9 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity in the quantitative suspension test
VAH - Method 14.1 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - surface disinfection without mechanics - practical test
VAH - Method 14.2 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - surface disinfection with mechanics - practical test (4 fields test)
VAH - Method 15 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Chemical/chemothermal instrument disinfection - practical quantitative germ carrier test
VAH - Method 16 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures: - Chemical laundry disinfection - Insertion procedure (practical test)

VAH - Method 17 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Chemothermal laundry disinfection - Single bath procedure (practical test)
VAH - Method 18 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - Determination of sporicidal activity against Clostridioides difficile spores in the quantitative suspension test
VAH-Method 19 : 2022-09	Requirements and methods for VAH certification of chemical disinfection procedures - surface disinfection against Clostridioides difficile spores
VDI-EE 4300 Blatt 14 : 2021-09	Measurement of indoor air contaminants - Requirements for mobile air purifiers to reduce aerosol-borne transmission of infectious diseases
SOP 02-001 Rev. 006	Determination of the bacteriostatic and fungistatic activity of chemical disinfection methods and suitable inactivation agents (VAH)
SOP 02-002 Rev. 007	Determination of the bacteriostatic and fungistatic activity of chemical disinfection methods in the qualitative suspension test (VAH)
SOP 02-003 Rev. 008	Determination of the bactericidal activity of chemical disinfection methods in the quantitative suspension test (VAH)
SOP 02-006 Rev. 004	Determination of the fungicidal activity of chemical disinfection methods in surface disinfection tests under practical conditions (VAH)
SOP 02-007 Rev. 011	Determination of the bactericidal activity of chemical disinfection methods in surface disinfection tests under practical conditions (VAH)
SOP 02-010 Rev. 008	Quantitative suspension test with M. terrae for testing the activity of instrument disinfectants (VAH)
SOP 02-011 Rev. 004	Testing the activity of disinfectants for chemical instrument disinfection in tuberculosis (Robert Koch Institute)
SOP 02-012 Rev. 004	Testing the activity of surface disinfectants for disinfection in tuberculosis (Robert Koch Institute)
SOP 02-014 Rev. 017	Chemo-thermal laundry disinfection (VAH)
SOP 02-030 Rev. 003	Testing the disinfecting activity of chemo-thermal laundry disinfection processes in laundries
SOP 02-050 Rev. 004	Quantitative suspension test to determine the bactericidal, fungicidal or sporicidal activity of chemical disinfectants and antiseptics (basic test - phase 1)

SOP 02-051 Rev. 012	Quantitative suspension test to determine the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in the field of human medicine (phase 2, step 1)
SOP 02-053 Rev. 015	Quantitative suspension test for the determination of the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in the areas of food, industry, household and public facilities (phase 2, step1)
SOP 02-054 Rev. 016	Practical trials to determine the bactericidal, fungicidal, mycobactericidal or sporicidal activity of chemical disinfectants and antiseptics in the field of human medicine (phase 2, step 2)
SOP 02-057 Rev. 003	Chemical disinfectants and antiseptics - Quantitative suspension test for the determination of sporicidal activity in the field of human medicine - Test method and requirements (phase 2, step 1), EN 17126
SOP 02-058 Rev. 004	Testing the antimicrobial activity of surfaces in surface tests
SOP 02-059 Rev. 002	Airborne aerosol or gas disinfection of surfaces (Airborne disinfection of surfaces)
SOP 02-101 Rev. 007	Determination of bacteriostatic and fungistatic activity of chemical disinfection methods and selection of suitable inactivating agents
SOP 02-102 Rev. 003	Determination of the bactericidal and fungicidal activity of chemical disinfection methods in the qualitative suspension test
SOP 02-103 Rev. 005	Determination of bactericidal activity in the quantitative suspension test
SOP 02-200 Rev. 007	Quantitative suspension test virucidity for chemical disinfectants and antiseptics used in human medicine (phase 2, step 1)
SOP 02-204 Rev. 009	Quantitative testing of the virucidal activity of chemical disinfectants on surfaces (phase 2, step 2)
SOP 02-206 Rev. 002	Antiviral activity
SOP 02-302 Rev. 004	Surface disinfection with mechanics - practical 4-field test against spores (phase 2 step 2)
SOP 02-303 Rev. 001	Activityiveness of antimicrobial preservation - Preservation Load Test
SOP 03-009 Rev. 005	Microbiological examination of industrial water
SOP 07-010 Rev. 006	Testing of dosing admixing systems according to RKI
SOP 07-012 Rev. 003	Packaging for medical devices to be sterilised in the final packaging according to EN ISO 11607

SOP 07-014 Rev. 006	Determination of the population of microorganisms on a product (DIN EN ISO 11737-1)
SOP 07-015 Rev. 004	Sterilisation with moist heat; requirements and tests according to DIN EN 285, DIN EN 13060, DIN EN ISO 17665
SOP 07-016 Rev. 004	Low temperature sterilisation; requirements and tests according to ISO 14937, EN 14180, EN ISO 11135, EN 1422
SOP 09-001 Rev. 013	Biological evaluation of medical devices ISO 10993-5 Cytotoxicity
SOP 09-003 Rev. 005	Biological evaluation of medical devices ISO 10993 - 3 Tests for genotoxicity, carcinogenicity and reproductive toxicity
SOP 09-004 Rev. 007	Biological evaluation of medical devices ISO 10993-4 Selection of tests for the interaction of blood with foreign surfaces
SOP 09-006 Rev. 011	Quantitative detection of pyrogenic impurities in the human whole blood model by ELISA
SOP 09-010 Rev. 006	Quantitative detection of endotoxin in liquids and eluates by means of the LAL test (Limulus - Amoebocyte - Lysate - Test)
SOP 09-011 Rev. 002	Testing for microbial contamination in non-sterile products: Counting of total, reproducible, aerobic germs according to the European Pharmacopoeia (Ph.-Eur. 2.6.12)
SOP 09-012 Rev. 008	Testing for microbial contamination in sterile products: Counting of total, reproducible, aerobic and anaerobic germs according to the European Pharmacopoeia (Ph.-Eur. 2.6.1)
SOP 09-013 Rev. 009	Epicutaneous test, test for irritation
SOP 09-015 Rev. 001	Agar diffusion test
SOP 11-001 Rev. 009	Hygienic environmental testing
SOP 16-001 Rev. 007	Washer-disinfectors - General requirements, terminology and test methods DIN EN ISO 15883-1
SOP 16-002 Rev. 007	Washer-disinfectors - Requirements and test methods Washer-disinfectors with thermal disinfection for surgical instruments, anaesthetic equipment, vessels, utensils glassware etc. (DIN EN ISO 15883-2)
SOP 16-003 Rev. 007	Washer-disinfectors - Requirements and test methods for washer-disinfectors with thermal disinfection for containers for human excreta (DIN EN ISO 15883-3)
SOP 16-004 Rev. 006	Washer-disinfectors - Requirements and test methods for washer-disinfectors with chemical disinfection for thermolabile endoscopes (DIN EN ISO 15883-4)

SOP 16-008 Rev. 006	Soiling of test specimens with internal laboratory test soils and soils according to ISO TS 15883-5
SOP 16-009 Rev. 005	Testing of the cleaning performance of washer-disinfectors for thermostable medical devices according to the guideline of DGKH, DGSV and AKI
SOP 16-011 Rev. 003	Washer-disinfectors - Requirements and test methods for washer-disinfectors with thermal disinfection for non-invasive, non-critical healthcare medical devices and accessories (EN ISO 15883-6)
SOP 16-012 Rev. 003	Washer-disinfectors - Requirements and test methods for washer-disinfectors with chemical disinfection for non-invasive, non-critical thermolabile medical devices and accessories in health care (DIN EN ISO 15883-7)
SOP 16-013 Rev. 004	Storage cabinet with regulated environmental conditions for reprocessed, thermolabile endoscopes (DIN EN 16442)
SOP 16-014 Rev. 001	Testing the activity of indoor air decontamination procedures
SOP 17-008 Rev. 010	Quantitative determination of free NH2 groups of blood proteins by the modified OPA method (1,2)
SOP 17-015 Rev. 003	Determination of the protein content of liquids with the BCA Protein Assay Kit
SOP 17-019 Rev. 002	Determination of total organic carbon in liquids by the TOC method
SOP 17-020 Rev. 001	Extraction of medical devices according to DIN EN ISO 10993-12/-18 for chemical test methods
SOP 17-021 Rev. 001	GC/MS and headspace GC/MS analyses for the chemical characterisation of medical devices
SOP 17-022 Rev. 001	LC/MS analyses for the chemical characterisation of medical devices
SOP 19-001 Rev. 004	Information to be provided by the manufacturer for the reprocessing of medical devices (ISO 17664)
SOP 19-002 Rev. 005	Soiling of products with test soils for testing cleaning and disinfection and recovery of test soils following EN ISO 15883-5
SOP 19-003 Rev. 004	Soiling of products with test soils for sterilisation testing and recovery of test soils
SOP 19-004 Rev. 001	Test for biofilm treatment of the water-bearing pipes of a dental treatment unit
SOP 19-005 Rev. 001	Particulate impurities Filter

SOP 19-006 Rev. 001	Implants for surgery - Cleanliness of orthopaedic implants - General requirements
SOP 19-007 Rev. 001	Materials for surfaces of dental equipment Determination of resistance to chemical disinfectants (ISO 21530:2004)
SOP 19-008 Rev. 001	Accelerated ageing of sterile barrier systems and medical devices
SOP 19-009 Rev. 001	Purity of medical devices in the production process

Abbreviations used:

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
German Federal Health Gazette	German Federal Health Gazette
CEN	European Committee for Standardization
CEN/TC	Technical Committee of CEN
DIN	German Institute for Standardisation
DVV	German Association for the Control of Viral Diseases e.V.
DGKH	German Society for Hospital Hygiene
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
OECD	Organization for Economic Cooperation and Development
Ph. Eur.	European Pharmacopoeia
R-RKI	Guideline for Hospital Hygiene and Infection Prevention of the Robert Koch Institute
SOP	standard operating procedure
TS	Technical Standard