Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18818-02-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 16.07.2020
Date of issue: 16.07.2020

Holder of certificate:

HygCen Germany GmbH
Bornhövedstraße 78, 19055 Schwerin

Field:	Medical devices in compliance with the requirements according to guidelines 93/42/EWG[2] and 90/385EWG[3] to the independence
Testing fields / test items:	Biological and microbiological-hygienic testing of medical devices inclusive disinfectants and microbiological-hygienic tests inclusive physical tests of washer disinfectors and disinfectors (RDG) and washing- and disinfection procedures as well as sterilizators and sterilization procedures; environmental monitoring

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

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
https://www.dakks.de/content/datenbank-akkreditierter-stellen

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Genotoxicity, carcinogenity and reproductive toxicity tests *in vitro*-Genotoxicity tests Bacterial Reverse Mutation (AMES-Test)	DIN EN ISO 10993-3 SOP 09-003 OECD-Guidelines 471 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Testing in the context of interaction with blood Hemolysis test • Cyanhemoglobin method Coagulation • Determination of the PTT Platelet activation • Platelet count Complement system • SC5b-9 hematology • PMN	DIN EN ISO 10993-4 SOP 09-004 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Cytotoxicity tests Cell-vitality-test after exposure to extracts (Colorimetric measurement (toluylene red)) Membraneintegrity after exposure to extracts (release of LDHe)	DIN EN ISO 10993-5 SOP 09-001

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological tests	Medical devices	Cell proliferation test after contact with extracts (BCA assay) Cell vitality test after contact with extracts (ATP assay)	Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Irritation and delayed-type hypersensitivity tests In vivo irritation test on human skin (Primary Skin irritation test)	DIN EN ISO 10993-10 SOP 09-013 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Quantitative detection of pyrogen contaminants based on a human whole blood assay using ELISA	SOP 09-006 (DIN EN 10993-11)
Microbiological-hygienic tests	Medical devices	Sterility test	DIN EN ISO 11737-2 SOP 09-012
		Determination of the total augmentable germs	Ph. Eur. 2.6.12 USP <61> SOP 09-011
		Test for antimicrobial activity	DIN EN ISO 20743 JIS Z 2801 JIS L 1902 SOP 02-058

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Quantitative suspension test for the evaluation of bactericidal, fungicidal, yeasticidal or sporicidal activity of chemical disinfectants and antiseptics (basis test – phase 1)	DIN EN 1040 DIN EN 1275 DIN EN 14347 SOP 02-050 Applicable: DIN EN 14885
		Determination of bacteriostatic and yeasticidal efficacy as well as evaluation of suitable inactivating substances	VAH – Methode 7 SOP 02-001 SOP 02-101
		Determination of the bactericidal and levurostatic activity in the qualitative suspension test	VAH – Methode 8 SOP 02-002 SOP 02-102
		Quantitative suspension test for the evaluation of bacteri-cidal, fungicidal, myco-baktericidal or sporicidal efficacy chemical disinfectants in human medicine area (phase 2, step1)	DIN EN 13727 DIN EN 13624 DIN EN 14348 SOP 02-051 Applicable: DIN EN 14885
		Quantitative suspension test for the determination of virucidal efficacy chemical disinfectants (phase 2, step1)	DIN EN 14476 Leitlinie DVV/RKI SOP 02-204 SOP 02-200
		Quantitative suspension test for the determination of sporicidal efficacy chemical disinfectants (phase 2, step 1)	DIN EN 17126 SOP 02-051
Microbiological-hygienic tests	Disinfectants	Determination of the sporocidal activity on non-porous surfaces in a practical test against Clostridium difficile spores	VAH-Methode 19 SOP 02-302

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
		Surface disinfection with mechanics - 4-field test	
		Test on bactericidal and fungicidal efficacy of chemical disinfection procedures in a quantitative suspension test	
		- bactericidal and fungicial	VAH – Methode 9.1 SOP 02-003 SOP 02-103
		- mycobacterium	VAH – Methode 9.2 SOP 02-010
		Determination of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal efficacy on non-pouros surfaces in a practical experiment	
		- surface disinfection without mechanics	VAH - Methode 14.1 SOP 02-007
		- surface disinfection with mechanics – 4-field test	VAH - Methode 14.2 SOP 02-006
		Quantitative germ carrier test for testing the bactericidal, fungicidal or yeasticidal, mycobactericidal effect in the field of human medicine (phase 2, step 2)	DIN EN 14561 DIN EN 14562 DIN EN 14563 SOP 02-054 Applicable: DIN EN 14885

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Chemical disinfectants and antiseptics - Quantitative test on non-porous surfaces without mechanical action to determine the virucidal effect in human medicine - Test method and requirements (phase 2, step 2)	DIN EN 16777 SOP 02-204
		Carrier test for testing instrument disinfectants on frosted glass (phase 2, step 2)	DIN EN 17111 SOP 02-204
		Chemical / chemothermic instrument disinfection – practical quantitative germ carrier test	VAH - Methode 15 SOP 02-054
		Chemical laundry disinfection – insertion process (practical experiment)	VAH - Methode 16 SOP 02-014
		Determination of the bactericidal and yeasticidal effects of chemical disinfectants on non-porous surfaces - Practical quantitative 4-field test with mechanics	DIN EN 16615 SOP 02-054 SOP 02-302
		Chemothermic laundry disinfection – One-bath process (practical experiment) - at temperatures from 30 °C to < 60 °C - at temperatures from ≥ 60 °C to 70 °C	 VAH - Methode 17.1 SOP 02-014 VAH - Methode 17.2 SOP 02-014

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Disinfectants	Chemical disinfectants and antiseptics – Quantitative suspension test for the determination of sporicidal activity	VAH – Methode 18 SOP 02-051 SOP 02-053
		Efficacy testing of disinfectants for chemical instrument disinfection in tuberculosis	Bundesgesundheitsbl. 11/94 SOP 02-011
		Efficacy testing of surface disinfectants for disinfection in tuberculosis	Bundesgesundheitsbl. 04/94 SOP 02-012
	Disinfectant proportioning-devices	Examination of decentralized disinfectant proportioning-devices	Bundesgesundheitsbl. 1/2004 SOP 07-010
	Sterile barrier and packaging systems, materials	Tests as part of the verification of compliance - Microbial barrier	DIN EN ISO 11607-1 ASTM F 1608 SOP 07-012
Microbiological-hygienic tests inclusive physical tests	Washer – disinfectors (WD) - employing thermal for surgical instruments, anaesthetic equipment, holloware, etc.	Device testing Type verification	DIN EN ISO 15883-1 (ohne EN 61010-2-040) DIN EN ISO 15883-2 SOP 16-001 SOP 16-002
	- employing thermal or chemo-thermal disinfection for human waste containers	Type verification	DIN EN ISO 15883-3 SOP 16-001 SOP 16-003
Microbiological-hygienic tests	Washer – disinfectors (WD)	Device testing	DIN EN ISO 15883-1 (ohne EN 61010-2-040)

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
inclusive physical tests			
	- employing chemical or thermal disinfection for thermolabile endoscopes	Type verification	DIN EN ISO 15883-4 SOP 16-001 SOP 16-004
	- employing chemical disinfection for non invasive, non critical medical devices and equipment in health care	Type verification	DIN EN ISO 15883-6 SOP 16-001 SOP 16-011
	- employing chemical disinfection for non invasive, non critical thermolabile medical devices and equipment in health care	Type verification	DIN EN ISO 15883-7 SOP 16-001 SOP 16-012 Applicable: DIN ISO/TS 15883-5 KRINKO/BfArM 2012

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests inclusive physical tests	Washer – disinfectors Processes	Validation	DIN EN ISO 15883-1 (ohne EN 61010-2-040)
	- employing thermal for surgical instruments, anaesthetic equipment, holloware, etc.	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-2 SOP 16-001 SOP 16-002 SOP 16-008
	- employing thermal or chemo-thermal disinfection for human waste containers	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-3 SOP 16-001 SOP 16-003 SOP 16-008
	- employing chemical or thermal disinfection for thermolabile endoscopes	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-4 SOP 16-001 SOP 16-004 SOP 16-008
	- employing thermal disinfection for non invasive, non critical medical devices and equipment in health care	Installation qualification Operation qualification Performance qualification	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 tests inclusive physical tests	Washer – disinfectors Processes	Validation	DIN EN ISO 15883-1
	- employing chemical disinfection for non invasive, non critical thermolabile medical devices and equipment in health care	Installation qualification Operation qualification Performance qualification	DIN EN ISO 15883-7 SOP 16-001 SOP 16-012 Applicable: DIN ISO/TS 15883-5 KRINKO/BfArM, Empfehlung Aufbereitung MP
	Washer – disinfectors Processes	Tests in the context of validation	
	- employing thermal disinfection for surgical instruments, anaesthetic equipment, holloware, etc.	Performance qualification	DGKH, DGSV und AKI, Guideline from DGKH, DGSV and AKI for the validation and routine monitoring of mechanical cleaning and disinfection processes for thermostable medical products and for the principles of device selection SOP 16-009
	- employing chemical or thermal disinfection for thermolabile endoscopes	Performance qualification	DGKH, DGSV, DGVS, DGEA und AKI, Leitlinie Guideline from DGKH, DGSV, DEGEA, DGVS and AKI for the validation of automated cleaning and disinfection processes

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
			for the reprocessing of thermolabile endoscopes SOP 16-008
Microbiological-hygienic tests inclusive physical tests	Steam sterilizers	Type verification Manufacture verification Specification test	DIN EN 285 (ohne EN 61010-2-040) SOP 07-015 SOP 07-001
	Small steam sterilizers	Type verification Manufacture verification Specification test	DIN EN 13060 (ohne EN 61010-1, EN 61010-2-040, EN 61326) SOP 07-015
	Sterilization Processes With moist heat	Validation Installation qualification Operation qualification Performance qualification	DIN EN ISO 17665-1 SOP 07-016 Applicable: DIN EN 13060 DIN EN 285
	With ethylene oxide	Installation qualification Operation qualification Performance qualification	DIN EN ISO 11135 DIN EN 1422 (ohne EN 61010-1, EN 61010-2-042) SOP 07-016
	With low temperature steam-formaldehyde (NTDF)	Installation qualification Operation qualification Performance qualification	DIN EN 14180 (ohne EN 61010-1, EN 61010-2-040, EN 61326) SOP 07-016
	With hydrogen peroxide (H_2O_2)	Installation qualification Operation qualification Performance qualification	DIN EN ISO 14937 (ohne EN 61010-1, EN 61010-2-040, EN 61326) SOP 07-016

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	With moist heat	Installation qualification Operation qualification Performance qualification	DIN EN ISO 17665-1 SOP 07-016 Applicable: DIN EN 13060 DIN EN 285

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests inclusive physical tests	Controlled environment storage cabinet for processed thermolabile endoscopes	Type verification Manufacture verification Specification test	DIN EN 16442 SOP 16-013 (ohne EN 61010-1, EN 61010-2-040, EN 61326)
	Maintaining the condition of the endoscopes	Installation qualification Operation qualification Performance qualification	DIN EN 16442 SOP 16-013 (ohne EN 61010-1, EN 61010-2-040, EN 61326)
	Information fort he reprocessing of medical devices	Tests in the context of validation Cleaning Disinfection Drying Sterilization - with moist heat - with ethylene oxide - with formaldehyde - with peroxide / peroxide-plasma	DIN EN ISO 17664 FDA Guideline Validation Methods AAMI TIR 30 AAMI TIR 12 ANSI/AAMI ST79 SOP 19-001 SOP 19-002 SOP 19-002 SOP 19-002 SOP 19-003
Environmental control in manufacture and testing of cleanness of the products according to DIN EN ISO 13485 : 2016[4], Abs. 6.4 und Abs. 7.5			
Chemical tests	Water and water solution	Quantitative determination of free NH2-groups of proteins with the OPA-method	SOP 17-008 (DIN ISO/TS 15883-5)
		Determination of the concentration of proteins in liquids with the BCA Protein Assay Kit	SOP 17-015 (DIN ISO/TS 15883-5)

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Environmental control in manufacture and testing of cleanness of the products according to DIN EN ISO 13485 : 2016[4], Abs. 6.4 und Abs. 7.5			
Chemical tests	Water and water solution	Testing for microbial contamination - Determination of the TOC (Total Organic Carbon)	USP <643> SOP 17-019 Applicable: AAMI TIR12 AAMI TIR30
Microbiological-hygienic tests	Medical devices	Estimation of the population of micro-organisms on product (Determination of Bioburden)	DIN EN ISO 11737-1 SOP 07-014
		Test for bacterial endotoxins (LAL –test)	Ph. Eur. 2.6.14 USP <85> SOP 09-010
	Surfaces	Germ content of surfaces	DIN EN ISO 14698-2 SOP 11-001 Applicable: DIN EN ISO 14968-1
	Clean room technology air	Determination of the airborne germ count	DIN EN ISO 14698-2 SOP 11-001 Applicable: DIN EN ISO 14968-1
		Determination of the number of particles in the air	DIN EN ISO 14644-1 SOP 11-001
	Water and water solution	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

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Microbiological-hygienic tests	Textile medical devices and laundry (reprocessed)	Testing the efficacy of disinfection in chemothermical procedures for laundry	RKI Richtlinie Krankenhaushygiene Anlage Hygiene Wäsche SOP 02-030 Applicable: VAH 4.2
Physical tests	Clean room technology air	Determination of the number of particles in the air	DIN EN ISO 14644-1 SOP 11-001

Regelwerke

DIN EN 285 : 2016-05	Sterilization - Steam sterilizers - Large sterilizers
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 sterilizers - Requirements and 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
DIN EN ISO 7899-2 : 2000-11	Water quality - Detection and enumeration of intestinal enterococci - Part 2: Membrane filtration method
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
DIN EN ISO 10993-1 : 2010-04	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
DIN EN ISO 10993-3 : 2015-02	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
DIN EN ISO 10993-4 : 2017-12	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
DIN EN ISO 10993-5 : 2009-10	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
DIN EN ISO 10993-10 : 2014-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

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DIN EN ISO 10993-11 : 2018-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
DIN EN ISO 10993-12 : 2012-10	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
DIN EN ISO 11135 : 2014-10	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
DIN EN ISO 11607-1 : 2017-10	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11731 : 2019-03	Water quality - Enumeration of Legionella
DIN EN ISO 11737-1 : 2018-11	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2 : 2010-04	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN 13060 : 2019-02	Small steam sterilizers
DIN EN 13624 : 2013-12	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase2, 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 sterilizers - 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

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	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
DIN EN ISO 14698-1 : 2004-04	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
DIN EN ISO 14698-2 : 2004-02	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
DIN EN 14885 : 2019-10	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
DIN EN ISO 15883-1 : 2014-10	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
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.
DIN EN ISO 15883-3 : 2009-09	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers
DIN EN ISO 15883-4 : 2019-06	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
DIN ISO/TS 15883-5 : 2006-02	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy
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
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
DIN EN ISO 16266 : 2008-05	Water quality - Detection and enumeration of Pseudomonas aeruginosa - Method by membrane filtration
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 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)

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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 ISO 17664 : 2018-04	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of 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
DIN EN ISO 19250 : 2013-06	Water quality - Detection of Salmonella spp.
DIN 19643-1 : 2012-11	Treatment of water of swimming pools and baths - Part 1: General requirements
DIN EN ISO 20743 : 2013-12	Textiles - Determination of antibacterial activity of textile products
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
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
EN 61010-1 : 2010	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements
EN 61010-2-040 : 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials
EN 61010-2-042 : 1997	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes
EN 61326 : 2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
AAMI TIR 12 : 2010	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 : 2010, A1:2010, A2:2011, A3:2012, A4:2013	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ASTM F 1608 – 16	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
Bundesgesundheitsbl. 04/94, S. 274-278 : 1994-04	Testing the effectiveness of surface disinfectants for disinfecting tuberculosis

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Bundesgesundheitsbl. 11/94, S. 474-476 : 1994-11	Testing of the effectiveness of disinfectants for chemical instrument disinfection in tuberculosis
Bundesgesundheitsbl. 1/2004, S. 67-72	Requirements for the design, properties and operation of decentralized disinfectant dosing devices
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	Testing for antibacterial activity and efficacy on textile products
Japanese Industrial Standard, JIS Z 2801	Antimicrobial products – Tests for antimicrobial activity and efficacy
KRINKO/BfArM 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)Bundesgesundheitsbl. 55: 1244-1310, 2012 Hygiene requirements for the reprocessing of medical devices
Leitlinie von DGKH, DGSV und AKI : 2013	Guideline from DGKH, DGSV and AKI for the validation and routine monitoring of mechanical cleaning and disinfection processes for thermostable medical products and for the principles of device selection
Leitlinie von DGKH, DGSV und AKI : 2013	Guideline from DGKH, DGSV, DEGEA, DGVS and AKI for the validation of automated cleaning and disinfection processes for the reprocessing of thermolabile endoscopes
Leitlinie DVV und RKI	Guideline of the German Association for Combating Virus Diseases (DVV) and the Robert Koch Institute (RKI) for testing chemical disinfectants for effectiveness against viruses in human medicine
OECD-Guidelines 471 : 1997	Bacterial Reverse Mutation Test
Ph. Eur. 9, 2.6.12	Microbiological testing of non-sterile products: Counting the total number of germs capable of reproduction
Ph. Eur. 9, 2.6.14	Testing for bacterial endotoxins
R-RKI 4.4.3	Hygiene requirements for laundry from health care facilities, laundry and the washing process and conditions for subcontracting laundry to commercial laundries
USP 41 <85>	Pyrogen and Endotoxins Testing
USP 41 <61>	Microbial Enumeration Tests
USP 41 <643>	Total organic carbon
VAH - Methode 7 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Determination of bacteriostatic and yeastatic effectiveness as well as suitable neutralizing agents"

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VAH - Methode 8 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: Determination of the bactericidal and yeasticidal effectiveness in a qualitative suspension test
VAH - Methode 9 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: Determination of the bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobatericidal effectiveness in a quantitative suspension test
VAH - Methode 14 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Surface disinfection - practical test"
VAH - Methode 15 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Chemical / chemothermal instrument disinfection - practical, quantitative germ carrier test"
VAH - Methode 16 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Chemical laundry disinfection - loading process (practical test)"
VAH - Methode 17 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Chemothermal laundry disinfection - single bath process (practical test)"
VAH - Methode 18 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Determination of the sporicidal effectiveness against Clostridium difficile spores in a quantitative suspension test"
VAH-Methode 19 : 2018-10	Requirements and methods for VAH certification of chemical disinfection processes: "Surface disinfection against Clostridium difficile spores"
SOP 02-001 Rev. 005	Determination of the bacteriostatic and fungistatic effectiveness of chemical disinfection processes as well as suitable inactivating agents (VAH)
SOP 02-002 Rev. 006	Determination of the bacteriostatic and fungistatic effectiveness of chemical disinfection processes in the qualitative suspension test (VAH)
SOP 02-003 Rev. 007	Determination of the bactericidal effectiveness of chemical disinfection processes in the quantitative suspension test (VAH)
SOP 02-006 Rev. 004	Determination of the fungicidal effectiveness of chemical disinfection processes in surface disinfection tests under practical conditions (VAH)
SOP 02-007 Rev. 010	Determination of the bactericidal effectiveness of chemical disinfection processes in surface disinfection tests under practical conditions (VAH)
SOP 02-010 Rev. 007	Quantitative suspension test with M. terrae for testing the effectiveness of instrument disinfectants (VAH)
SOP 02-011 Rev. 004	Testing of the effectiveness of disinfectants for chemical instrument disinfection in tuberculosis (Robert Koch Institute)
SOP 02-012 Rev. 004	Testing the effectiveness of surface disinfectants for disinfection in tuberculosis (Robert Koch Institute)
SOP 02-014 Rev. 015	Chemothermal laundry disinfection (VAH)

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SOP 02-030 Rev. 003	Testing of the disinfecting effect of chemothermal laundry disinfection processes in laundries
SOP 02-050 Rev. 004	Quantitative suspension test to determine the bactericidal, fungicidal or sporicidal effects of chemical disinfectants and antiseptics (basic test - phase 1)
SOP 02-051 Rev. 009	Quantitative suspension test to determine the bactericidal, fungicidal, mycobactericidal or sporicidal effects of chemical disinfectants and antiseptics in human medicine (phase 2, step 1)
SOP 02-053 Rev. 015	Quantitative suspension test to determine the bactericidal, fungicidal, mycobactericidal or sporicidal effects of chemical disinfectants and antiseptics in the areas of food, industry, household and public facilities (phase 2, step 1)
SOP 02-054 Rev. 013	Practical tests to determine the bactericidal, fungicidal, mycobactericidal or sporicidal effects of chemical disinfectants and antiseptics in human medicine (phase 2, step 2)
SOP 02-058 Rev. 003	Testing of the antimicrobial effect of surfaces in surface tests
SOP 02-101 Rev. 007	Determination of the bacteriostatic and fungistatic effectiveness of chemical disinfection processes as well as selection of suitable inactivating agents
SOP 02-102 Rev. 003	Determination of the bactericidal and fungicidal effectiveness of chemical disinfection processes in the qualitative suspension test
SOP 02-103 Rev. 005	Determination of the bactericidal effectiveness in a quantitative suspension test
SOP 02-200 Rev. 006	Quantitative suspension test Virucidal for chemical disinfectants and antiseptics used in human medicine (phase 2, step 1)
SOP 02-204 Rev. 006	Quantitative testing of the virucidal effectiveness of chemical disinfectants on surfaces (phase 2, step 2)
SOP 02-302 Rev 002	Surface disinfection with mechanics - practical 4-field test against spores (phase 2, stage 2)
SOP 03-009 Rev. 005	Microbiological analysis of industrial water
SOP 07-001 Rev. 003	Biological testing of large steam sterilizers with test loading (testing for effectiveness according to DIN 58946 part 3)
SOP 07-010 Rev. 006	Testing of proportioning systems according to RKI
SOP 07-012 Rev. 002	Packaging for medical devices to be sterilized in the final packaging according to EN ISO 11607
SOP 07-014 Rev. 004	Determination of the population of microorganisms on a product (DIN EN ISO 11737-1)
SOP 07-015 Rev. 004	oist heat sterilization; Requirements and tests according to DIN EN 285, DIN EN 13060, DIN EN ISO 17665
SOP 07-016 Rev. 003	Low temperature sterilization; Requirements and tests according to ISO 14937, EN 14180, EN ISO 11135, EN 1422
SOP 09-001 Rev. 010	Biological assessment of medical devices ISO 10993-5 cytotoxicity
SOP 09-003 Rev. 004	Biological assessment of medical devices ISO 10993-3

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	Genotoxicity, carcinogenicity and reproductive toxicity tests
SOP 09-004 Rev. 005	Biological assessment of medical devices ISO 10993-4 Selection of tests on the interaction of blood with foreign surfaces
SOP 09-006 Rev. 010	Quantitative detection of pyrogenic contamination in a human whole blood model using ELISA
SOP 09-010 Rev. 005	Quantitative detection of endotoxin in liquids and eluates using the LAL test (Limulus - Amoebocytes - Lysate - Test)
SOP 09-011 Rev. 002	Testing for microbial contamination in non-sterile products: counting of the total number of aerobic germs capable of reproduction according to the European Pharmacopoeia (Ph.-Eur. 2.6.12)
SOP 09-012 Rev. 007	Testing for microbial contamination in sterile products: Counting of the total, reproductive, aerobic and anaerobic germs according to the European Pharmacopoeia (Ph.-Eur. 2.6.1)
SOP 09-013 Rev. 007	Patch test, check for irritation
SOP 11-001 Rev. 007	Hygienic environmental studies
SOP 16-001 Rev. 006	Type testing of washing / disinfection devices - general requirements, definitions and tests DIN EN ISO 15883-1
SOP 16-002 Rev. 006	Requirements and tests of washing disinfection devices for surgical instruments, anesthesia equipment, hollow bodies, utensils, glass equipment, etc.
SOP 16-003 Rev. 006	Requirements and tests for bedpan washer-disinfectors
SOP 16-004 Rev. 005	Requirements and tests for endoscope washer-disinfectors
SOP 16-008 Rev. 005	Soiling of test bodies with internal laboratory test soiling and soiling in accordance with EN ISO 15883-5
SOP 16-009 Rev. 004	Testing of the cleaning performance of cleaning and disinfection devices for thermostable medical products in accordance with the guidelines of DGKH, DGSV and AKI
SOP 16-011 Rev. 002	Requirements and test methods for washer-disinfectors with thermal disinfection for non-invasive, non-critical medical devices and accessories in the healthcare sector
SOP 16-012 Rev. 002	Requirements and test methods for washer-disinfectors with chemical disinfection for non-invasive, non-critical thermolabile medical devices and accessories in the healthcare sector
SOP 16-013 Rev. 003	Storage of reprocessed, thermally unstable endoscopes with regulated ambient conditions
SOP 17-008 Rev. 010	Quantitative determination of free NH2 groups in blood proteins using 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 the total organic carbon in liquids by the TOC method
SOP 19-001 Rev. 003	Information to be provided by the manufacturer for the reprocessing of medical devices (ISO 17664)

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SOP 19-002 Rev. 004	Soiling of products with test soiling for testing cleaning and disinfection and recovery of the test soiling based on EN ISO 15883-5
SOP 19-003 Rev. 003	Soiling of products with test soiling for testing the sterilization and recovery of the test soiling

Abbreviations used

AAMI	Association for the Advancement of Medical Instrumentation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
Bundesgesundheitsbl.	Federal Health Gazette / Bundesgesundheitsblatt
CEN	European Committee for Standardization / Europäische Normungsorganisation
CEN/TC	Technical Committees of CEN / Technisches Komitee des CEN
DIN	German institute for standardization e.V. / Deutsches Institut für Normung e.V.
DVV	German association for combating virus diseases / Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten
DGKH	German Society for Hospital Hygiene / Deutsche Gesellschaft für Krankenhaushygiene
EN	European Standard / Europäische Norm
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 / Richtlinie für Krankenhaushygiene und Infektionsprävention des Robert-Koch Instituts
SOP	Standard operating procedure in house method / Arbeitsanweisung der HygCen GmbH
TS	Technical Standard

[1] DIN EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories
[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices
[3] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
[4] DIN EN ISO 13485 : 2016-08 Medical devices - Quality management systems - Requirements for regulatory purposes

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