Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-19887-01-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **30.01.2024**

Date of issue: 04.06.2024

This annex is a part of the accreditation certificate D-PL-19887-01-00.

Holder of partial accreditation certificate:

CleanControlling Medical GmbH & Co. KG
Gehrenstraße 11a, 78576 Emmingen-Liptingen

with the location

CleanControlling Medical GmbH & Co. KG
Gehrenstraße 11a, 78576 Emmingen-Liptingen

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 and chemical tests of medical devices, microbiological-hygienic tests of medical devices, sterile barrier and packaging systems as well as substances as integral components with a supporting function of medical devices in accordance with Article 1 (8) of Regulation (EU) 2017/745 and physical tests of sterile barrier and packaging systems; Environmental monitoring,

outside of recognition in accordance with Section 18 of the Medical Devices Law Implementation Act.

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de.

CleanControlling Medical GmbH & Co. KG, Auf der Höhe 15, 78576 Emmingen-Liptingen

Testing area	Test item device (category)	Type of testing test	Regulation testing method
Biological tests	Medical devices, Biomaterials	Tests for cytotoxicity • Inhibition of cell growth after contact with extracts (colorimetric measurement using crystal violet or sulforhodamine B; protein determination) • Metabolic activity after contact with extracts (MTT test; ATP measurement) • Inhibition of cell growth after direct contact	DIN EN ISO 10993-5 USP <87> SOP 15-43 SOP 15-82 SOP 15-70 SOP 15-51 SOP 15-102 ASTM F813 SOP 15-54 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12

Testing area	Test item device (category)	Type of testing test	Regulation testing method
Chemical tests	Medical Devices, Biomaterials	Chemical Characterization Testing Organic and inorganic solid surfaces or internal interfaces of medical devices as well as liquid medical devices via TOC	DIN EN ISO 10993-18 SOP 15-77 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12 OECD Guideline 120
		Inspections as part of the cleanliness verification Determination of total organic carbon (TOC) • Determination of the hydrocarbon index (THC)	USP <643> Ph. Eur. 2.2.44 SOP 15-77 SOP 15-100 (DIN EN ISO 9377-2) Applicable: ISO 19227 DIN EN ISO 10993-18
Microbiological-hygienic tests	Medical devices	Sterility testing - Direct inoculation - Elution method	DIN EN ISO 11737-2 SOP 15-65 SOP 15-78 SOP 15-78

Testing area	Test item device (category)	Type of testing test	Regulation testing method
		Establishing the radiation dose of radiation sterilization	DIN EN ISO 11137-2 Applicable: DIN EN ISO 11737-1 DIN EN ISO 11737-2
	Substances as integral components with a supporting function of medical devices according to Article 1 (8) of Regulation (EU) 2017/745	Testing for microbiological quality	Ph. Eur. 5.1.4 USP <1111> JP 17, General Information
	Medical devices, information for processing	Checks as part of the validation of information provided Cleaning / disinfection Sterilisation with moist heat	DIN EN ISO 17664-1 ISO 17664-2 SOP 15-57 SOP 15-58

Testing area	Test item device (category)	Type of testing test	Regulation testing method
Microbiological-hygienic tests	Washer-disinfector Washer-disinfector with using chemical or thermal disinfection for thermolabile endoscopes	Tests as part of routine monitoring - via biological indicators	 SOP 15-67 SOP 15-68 SOP 15-69 (Guideline from DGKH, DGSV, DGVS, DEGEA und AKI for validation of automated cleaning and disinfection processes for the processing of thermolabile endoscopes) Applicable: DIN EN ISO 15883-1 DIN EN ISO 15883-4 DIN EN ISO 15883-5
	Sterile barrier and packaging systems, materials	Test as part of verification of conformity - Microbial barrier • Moisture	DIN EN ISO 11607-1 ASTM F1608 SOP 15-92 ANSI/AAMI ST77 SOP 15-91

Testing area	Test item device (category)	Type of testing test	Regulation testing method
Physical tests	Sterile barrier and packaging systems, materials: Reusable sterilizing containers for steam sterilizers according to EN 285	Tests as part of verification of conformity	DIN EN ISO 11607-1
		- Shape and dimensions	DIN EN 868-8 SOP 15-87
		- Endurance testing of carrying device	DIN EN 868-8, Annex C ANSI/AAMI ST77 SOP 15-88
		- Stack pressure test	DIN EN 868-8, Annex D SOP 15-86
		- Stackability check	DIN EN 868-8, Annex E ANSI/AAMI ST77 SOP 15-85
		- Determination of sterilization performance	DIN EN 868-8, Annex F
		- Inspection of the dryness of the load	DIN EN 868-8, Annex G

Testing area	Test item device (category)	Type of testing test	Regulation testing method
Environmental monitoring in the manufacture and testing of the cleanliness of the products in accordance with DIN EN ISO 13485: 2021[1], para. 6.4 and para. 7.5			
Microbiological-hygienic tests	Medical devices, biomaterials, water, and aqueous solutions	• Determination of the population of microorganisms on products (Bioburden determination) • Membrane filtration method • Streaking method	DIN EN ISO 11737-1 SOP 15-12 SOP 15-13
Microbiological-hygienic tests	Medical devices, biomaterials, water, and aqueous solutions	• Test for bacterial - endotoxins (LAL-Test)	Ph. Eur. 2.6.14 USP <85> JP 17, 4.01
	Medical devices	microbial examination of non-sterile products: microbial enumeration tests	Ph. Eur. 2.6.12 USP <61> JP 17, 4.05 I
	water, and aqueous solutions	Determination of microbial contamination • Determination of TOC (Total Organic Carbon)	SOP 15-77 USP <643> Ph. Eur. 2.2.44
Physical tests	Medical devices, biomaterials, water, and aqueous solutions	Testing for particulate contamination • microscopic method • by light blockage	Ph. Eur. 2.9.19 Ph. Eur. 2.9.20 USP <788>

Regulations:

DIN EN 868-8: 2019-03	Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
DIN EN ISO 9377-2: 2001-07	Water quality - Determination of hydrocarbon oil index - Part 2: Method using solvent extraction and gas chromatography
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
DIN EN ISO 10993-12: 2021-08	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
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 + Amd 1:2022)
DIN EN ISO 11137-2: 2015-11	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
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 11737-1: 2021-10	Sterilisation von Produkten für die Gesundheitsfürsorge - Mikrobiologische Verfahren – Teil 1: Bestimmung der Population von Mikroorganismen auf Produkten (ISO 11737-1: 2018 + Amendment 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 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 15883-4: 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 efficacy (ISO 15883-5:2021)
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
ISO 19227: 2018-03	Implants for surgery – Cleanliness of orthopedic implants – General requirements
Guideline von DGKH, DGSV, DGVS, DEGEA und AKI: 2011	Guideline from DGKH, DGSV, DGVS, DEGEA and AKI for validation of automatic cleaning and disinfection processes for preparation thermolabile endoscopes
ANSI-AAMI ST77: 2013/(R)2018	American National Standard: Containment devices for reusable medical devices sterilization
ASTM F813: 2020	Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices
ASTM F1608: 2021	Standard Test Method for Microbial ranking of Porous Packaging Materials (Exposure Chamber Method)
JP 17, General Information	Japanese Pharmocopoeia, General Information
JP 17, 4.01	Bacterial Endotoxins Test
JP 17, 4.05 I	Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests
OECD Guideline 120: 2001-01	OECD guideline for testing of chemicals Solutions/extraction behaviour of polymers in water
Ph. Eur. 10, 2.2.44	Total Organic Carbon in Water for Pharmaceutical Use
Ph. Eur. 10, 2.6.12	Microbiological testing of non-sterile products: counting of reproducible microorganisms
Ph. Eur. 10, 2.6.14	Testing for bacterial endotoxins
Ph. Eur. 10, 2.9.19	Particle contamination – invisible particles
Ph. Eur. 10, 2.9.20	Particle contamination – visible particles
Ph. Eur. 10, 5.1.4	Microbiological quality of non-sterile pharmaceutical preparations and of substances for pharmaceutical use
USP 39<61>	Microbiological Examination of nonsterile products: microbial enumeration tests
USP 39 <85>	Bacterial Endotoxin Test
USP 39 <87>	Biological Reactivity Tests, in vitro
USP 39 <643>	Total Organic Carbon
USP 39 <788>	Particulate Matter in Injections

USP 39 <1111>	Microbiological Examination of nonsterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use
SOP 15-12 Vers. 11	Validation of quantitative bioburden determination
SOP 15-13 Vers. 17	Bioburden determination (quantitative)
SOP 15-43 Vers. 14	In vitro cytotoxicity test (extract) crystal violet
SOP 15-51 Vers. 10	In vitro cytotoxicity test (extract) MTT
SOP 15-54 Vers. 3	In vitro cytotoxicity test (direct contact)
SOP 15-57 Vers. 7	Validation of processing – Chapter cleaning and disinfection
SOP 15-58 Vers. 9	Validation of processing – Chapter Sterilization (with steam)
SOP 15-65 Vers. 2	Sterility test
SOP 15-67 Vers. 3	Production of a test contamination for the validation of washer-disinfectors for endoscopes
SOP 15-68 Vers. 2	Analyses of test specimens as part of the validation of washer-disinfectors for endoscopes
SOP 15-69 Vers. 1	Validation sets for washer-disinfectors for endoscopes
SOP 15-70 Vers. 4	In vitro cytotoxicity testing (extract) protein
SOP 15-77 Vers. 0	TOC determination
SOP 15-78 Vers. 1	Test for bacteriostatic or fungistatic properties
SOP 15-82 Vers. 2	In vitro cytotoxicity testing (extract) SRB
SOP 15-85 Vers. 0	Stackability container
SOP 15-86 Vers. 0	Stack pressure test container
SOP 15-87 Vers. 0	Shape and dimensions container
SOP 15-88 Vers. 0	Load capacity handles container
SOP 15-91 Vers. 1	Sterile barrier test containers
SOP 15-92 Vers. 0	Sterile barrier test for flexible materials
SOP 15-100 Vers. 0	Determination of THC
SOP 15-102 Vers. 2	In vitro cytotoxicity test (extract) CellTiter Glo

Abbreviations used:

AAMI	Association for the Advancement of Medical Instrumentation

AKI	Working group: instrument preparation
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
DEGEA	German Society for Endoscopy Professions e.V.
DGKH	German Society for Hospital Hygiene
DGSV	German Society for Sterile Supply e.V.
DGVS	German Society for Digestive and Metabolic Diseases e.V.
DIN	German Institute for Standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
JP	Japanese Pharmacopoeia
OECD	Organisation for Economic Co-operation and Development
Ph. Eur.	European Pharmacopoeia
SOP	Standard operation procedure der CleanControlling Medical GmbH & Co. KG
TIR	Technical Information Report
USP	United States Pharmacopeial Convention

[1] DIN EN ISO 13485 : 2021-12 Medical devices - Quality management systems - Requirements for regulatory purposes