DAkkS
Deutsche
Akkreditierungsstelle

# Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the testing laboratory

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

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

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.

This accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notices of 25.03.2025 with accreditation number D-PL-19887-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 10 pages.

Registration number of the accreditation certificate: **D-PL-19887-01-00**

Berlin, 25.03.2025
Uwe Zimmermann
Head of Department

Translation issued:
05.06.2025
p.p.a.
Uwe Zimmermann
Head of Department

*The certificate together with the annex 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 (www.dakks.de).*

This document is a translation. The definitive version is the original German accreditation certificate.

See notes overleaf

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The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

DAkkS is a signatory to the multilateral agreements for mutual recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Co-operation (ILAC).

The up-to-date state of membership can be retrieved from the following websites:
EA: www.european-accreditation.org
ILAC: www.ilac.org
IAF: www.iaf.nu

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# Annex to the Accreditation Certificate D-PL-19887-01-00 according to DIN EN ISO/IEC 17025:2018

**Valid from:** **25.03.2025**

Date of issue: 05.06.2025

Holder of 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.

## 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 | DIN EN ISO 10993-5<br>USP <87> |
| | | • Inhibition of cell growth after contact with extracts (colorimetric measurement using crystal violet or sulforhodamine B; protein determination) | SOP 15-43<br>SOP 15-82<br>SOP 15-70 |
| | | • Metabolic activity after contact with extracts (MTT test; ATP measurement) | SOP 15-51<br>SOP 15-102 |
| | | • Inhibition of cell growth after direct contact | ASTM F813<br>SOP 15-54<br><br>Applicable:<br>DIN EN ISO 10993-1<br>DIN EN ISO 10993-12 |
| Chemical tests | Medical Devices, Biomaterials | Chemical Characterization Testing<br>• Organic and inorganic solid surfaces or internal interfaces of medical devices as well as liquid medical devices via TOC | DIN EN ISO 10993-18<br><br>SOP 15-77<br><br><br><br>Applicable:<br>DIN EN ISO 10993-1<br>DIN EN ISO 10993-12<br>OECD Guideline 120 |

| Testing area | Test item device (category) | Type of testing test | Regulation testing method |
|---|---|---|---|
| Chemical tests | Medical Devices, Biomaterials | Inspections as part of the cleanliness verification<br>• Determination of total organic carbon (TOC)<br>• Determination of the hydrocarbon index (THC) | USP <643><br>Ph. Eur. 2.2.44<br>SOP 15-77<br>SOP 15-100<br>(DIN EN ISO 9377-2)<br>Applicable:<br>ISO 19227<br>DIN EN ISO 10993-18 |
| Microbiological-hygienic tests | Medical devices | Sterility testing<br>• Direct inoculation<br>• Elution method | DIN EN ISO 11737-2<br>SOP 15-65<br>SOP 15-78<br>SOP 15-78 |
| | | Establishing the radiation dose of radiation sterilization | DIN EN ISO 11137-2<br>Applicable:<br>DIN EN ISO 11737-1<br>DIN EN ISO 11737-2 |
| Microbiological-hygienic tests | 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<br>USP <1111><br>JP 17, General Information |
| | Medical devices, information for processing | Checks as part of the validation of information provided | DIN EN ISO 17664-1<br>DIN EN ISO 17664-2 |

| Testing area | Test item device (category) | Type of testing test | Regulation testing method |
|---|---|---|---|
| | | • Cleaning / disinfection<br>• Sterilisation with moist heat | SOP 15-57<br>SOP 15-58 |
| | Washer-disinfector<br>Washer-disinfector with using chemical or thermal disinfection for thermolabile endoscopes | Tests as part of routine monitoring<br>- via biological indicators | SOP 15-67<br>SOP 15-68<br>SOP 15-69<br>(Guideline from DGKH, DGSV, DGVS, DEGEA und AKI for validation of automated cleaning and disinfection processes for the processing of thermolabile endoscopes)<br>Applicable:<br>DIN EN ISO 15883-1<br>DIN EN ISO 15883-4<br>DIN EN ISO 15883-5 |
| | Sterile barrier and packaging systems, materials | Test as part of verification of conformity<br>- Microbial barrier<br>• Moisture | DIN EN ISO 11607-1<br>ASTM F1608<br>SOP 15-92<br>ANSI/AAMI ST77<br>SOP 15-91 |

| Testing area | Test item device (category) | Type of testing test | Regulation testing method |
|---|---|---|---|
| Physical tests | Sterile barrier and packaging systems, materials:<br>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<br>SOP 15-87 |
| | | - Endurance testing of carrying device | DIN EN 868-8, Annex C<br>ANSI/AAMI ST77<br>SOP 15-88 |
| | | - Stack pressure test | DIN EN 868-8, Annex D<br>SOP 15-86 |
| | | - Stackability check | DIN EN 868-8, Annex E<br>ANSI/AAMI ST77<br>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)<br>• Membrane filtration method<br>• Streaking method | DIN EN ISO 11737-1<br>SOP 15-12<br>SOP 15-13 |
| | Medical devices, biomaterials, water, and aqueous solutions | • Test for bacterial - endotoxins (LAL-Test) | Ph. Eur. 2.6.14<br>USP <85><br>JP 4.01<br>SOP 15-32<br>SOP 15-99 |
| | Medical devices | microbial examination of non-sterile products: microbial enumeration tests | Ph. Eur. 2.6.12<br>USP <61><br>JP 4.05 I |
| | water, and aqueous solutions | Determination of microbial contamination<br>• Determination of TOC (Total Organic Carbon) | SOP 15-77<br>USP <643><br>Ph. Eur. 2.2.44 |
| Physical tests | Medical devices, biomaterials, water, and aqueous solutions | Testing for particulate contamination<br>• microscopic method<br>• by light blockage | Ph. Eur. 2.9.19<br>USP <788><br>SOP 15-56 |

## Regulations:

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|---|---|
| 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: 2023-03 | 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: 2023-11 | Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013) |
| DIN EN ISO 11607-1: 2024-02 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) |
| 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 |

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| | devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021) |
| ISO 17664-2: 2024-02 | 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 F895:2011 (2016) | Standard Test Method for Microbial ranking of Porous Packaging Materials (Exposure Chamber Method) |
| ASTM F1608: 2021 | Standard Test Method for Microbial ranking of Porous Packaging Materials (Exposure Chamber Method) |
| JP 18, General Information | Japanese Pharmocopoeia, General Information |
| JP 18, 4.01 | Bacterial Endotoxins Test |
| JP 18, 4.05 I | Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests |
| OECD Guideline 120: 2001-01 | OECD guideline for testing of chemicals<br>Solutions/extraction behaviour of polymers in water |
| Ph. Eur. 11, 2.2.44 | Total Organic Carbon in Water for Pharmaceutical Use |
| Ph. Eur. 11, 2.6.12 | Microbiological testing of non-sterile products: counting of reproducible microorganisms |
| Ph. Eur. 11, 2.6.14 | Testing for bacterial endotoxins |
| Ph. Eur. 11, 2.9.19 | Particle contamination – invisible particles |
| Ph. Eur. 11, 2.9.20 | Particle contamination – visible particles |
| Ph. Eur. 11, 5.1.4 | Microbiological quality of non-sterile pharmaceutical preparations and of substances for pharmaceutical use |
| USP 43<61> | Microbiological Examination of nonsterile products: microbial enumeration tests |
| USP 43 <85> | Bacterial Endotoxin Test |
| USP 43 <87> | Biological Reactivity Tests, in vitro |
| USP 43 <643> | Total Organic Carbon |

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| USP 43 <788> | Particulate Matter in Injections |
| USP 43 <1111> | Microbiological Examination of nonsterile products: acceptance criteria for pharmaceutical preparations and substances for pharmaceutical use |
| SOP 15-12 Vers. 14 | Validation of quantitative bioburden determination |
| SOP 15-13 Vers. 18 | Bioburden determination (quantitative) |
| SOP 15-32 Vers. 05 | LAL-Test Endosafe-PTS |
| SOP 15-43 Vers. 17 | In vitro cytotoxicity test (extract) crystal violet |
| SOP 15-51 Vers. 13 | In vitro cytotoxicity test (extract) MTT |
| SOP 15-54 Vers. 6 | In vitro cytotoxicity test (direct contact) |
| SOP 15-57 Vers. 8 | Validation of processing – Chapter cleaning and disinfection |
| SOP 15-58 Vers. 10 | Validation of processing – Chapter Sterilization (with steam) |
| SOP 15-65 Vers. 4 | Sterility test |
| SOP 15-67 Vers. 4 | 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. 6 | In vitro cytotoxicity testing (extract) protein |
| SOP 15-77 Vers. 2 | TOC determination |
| SOP 15-78 Vers. 1 | Test for bacteriostatic or fungistatic properties |
| SOP 15-82 Vers. 5 | 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. 2 | Sterile barrier test containers |
| SOP 15-92 Vers. 0 | Sterile barrier test for flexible materials |
| SOP 15-100 Vers. 2 | Determination of THC |
| SOP 15-102 Vers. 3 | In vitro cytotoxicity test (extract) CellTiter Glo |

**Abbreviations used:**

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| AAMI | Association for the Advancement of Medical Instrumentation |

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| 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