Deutsche Akkreditierungsstelle GmbH

# Annex to the Accreditation Certificate D-PL-12083-01-02 according to DIN EN ISO/IEC 17025:2018[1]

**Valid from:** **24.03.2021**

Date of issue: 05.07.2021

Holder of certificate:

**Hohenstein Laboratories GmbH & Co. KG**
**Schloss Hohenstein, 74357 Bönnigheim**

| | |
|---|---|
| **Field:** | Medical devices in compliance with the requirements according to Directive 93/42/EWG[3] and 90/385/EWG[4] on independence |
| **Testing fields/test items:** | Biological, chemical and physical tests of medical devices and microbiological-hygienic tests of medical devices including disinfectants, environmental monitoring |

*The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.*

*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 may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.*

| Testing field | Test item<br>Device(category) | Type of testing<br>Test | Regulation<br>Testing method |
|---|---|---|---|
| Biological testing | Medical devices | Cytotoxicity test<br>- Growth inhibition test after contact with extracts | DIN EN ISO 10993-5<br>SOP-QM-11.BM.02.031<br>applicable:<br>DIN EN ISO 10993-1<br>DIN EN ISO 10993-12 |
| | | Test on irritation<br>- In vitro irritation test (Hen`s Egg Test on the Chorioallantoic Membrane (HET CAM)) | DB-ALM Protokoll N°96<br>SOP-QM-11.BM.03.038<br>applicable:<br>DIN EN ISO 10993-1<br>DIN EN ISO 10993-10<br>DIN EN ISO 10993-12 |
| Chemical testing | Medical devices | Tests of chemical characterization<br>- Semi-quantitative evaluation of volatile substances after extraction with polar and non-polar solvents | DIN EN ISO 10993-18<br>SOP-QM-11.0.02.A5.025<br>applicable:<br>DIN EN ISO 10993-1 |
| Microbio-logical-hygienic testing | Disinfectants | Evaluation of bactericidal and yeasticidal activity with quantitative suspension test | VAH - Method 8 |
| | | Quantitative suspension test for the evaluation of bactericidal, fungicidal, yeasticidal or mycobactericidal activity of chemical disinfectants used in the medical area (phase 2, step 1) | DIN EN 13727<br>DIN EN 13624<br>DIN EN 14348 |

| Testing field | Test item<br>Device(category) | Type of testing<br>Test | Regulation<br>Testing method |
|---|---|---|---|
| Microbio-logical-hygienic testing | Disinfectants | Evaluation of bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal activity with quantitative suspension test | VAH - Method 9 |
| | | Evaluation of virucidal activity with quantitative suspension test | SOP-QM-11.HY.03.052<br>(VAH-Method 9) |
| | | Quantitative 4-field-test for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action in the medical area (phase 2, step 2)) | DIN EN 16615 |
| | | Evaluation of bactericidal, yeasticidal, fungicidal, tuberculocidal and mycobactericidal activity on non-porous surfaces with practical conditions<br>- Surface disinfection without mechanics<br>- Surface disinfection with mechanics - 4-field-test | <br>VAH - Method 14.1<br>VAH - Method 14.2 |
| | | Quantitative carrier test for the evaluation of bactericidal, fungicidal or yeasticidal, mycobactericidal activity used in the medical area (phase 2, step 2) | DIN EN 14561<br>DIN EN 14562<br>DIN EN 14563 |
| | | Chemical/Chemical-thermal instrument disinfection – practical quantitative carrier test | VAH - Method 15 |
| | | Chemical-thermal textile disinfection (phase 2, step 2) | DIN EN 16616 |

| Testing field | Test item<br>Device(category) | Type of testing<br>Test | Regulation<br>Testing method |
|---|---|---|---|
| Microbio-logical-hygienic testing | Disinfectants | Chemical-thermal textile disinfection – Single-bath process (practical conditions)<br>- at temperatures of 30 °C to < 60 °C<br>- at temperatures of ≥ 60 °C to 70 °C | VAH - Method 17<br>VAH - Method 17.1<br>VAH - Method 17.2 |
| | | Testing of the virucidal activity of disinfectants at chemical-thermal textile disinfection (practical conditions) | SOP-QM-11.HY.03.055<br>SOP-QM-11.HY.03.056<br>(VAH-Method 17) |
| | Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment | Determination of the resistance to wet bacterial penetration<br>(Wet-Penetration) | DIN EN ISO 22610<br>applicable<br>DIN EN 13795-1 |
| | | Determination of the resistance to dry microbial penetration<br>(Dry-Penetration) | DIN EN ISO 22612<br>applicable<br>DIN EN 13795-1 |
| Physical testing | Compression Hosiery | Testing of product characteristics | RAL-GZ 387/1<br>SOP-QM-11 2 03 002<br>DIN 58133 |
| | Compression armsleeves | Testing of product characteristics | RAL-GZ 387/2<br>SOP-QM 11-2 03 004 |
| | Stocking systems for Ulcus Cruri | Testing of product characteristics | RAL-GZ 387/3<br>SOP-QM 11-2 03 003 |

| Testing field | Test item<br>Device(category) | Type of testing<br>Test | Regulation<br>Testing method |
|---|---|---|---|
| Physical testing | Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment | Testing for particle release in the dry state | DIN EN ISO 9073-10<br><br>applicable:<br>DIN EN 13795-1 |
| | Medical face masks | Testing for splash resistance of synthetic blood | ISO 22609<br><br>applicable:<br>DIN EN 14683 |
| | | In vitro test of bacterial filtration efficiency (BFE) | DIN EN 14683<br>Annex B |
| | | Testing for breathability (differential pressure) | DIN EN 14683<br>Annex C |
| **Environmental monitoring in the process of production and testing of cleanliness of the products according to DIN EN ISO 13485[2] : 2016, Par. 6.4 and Par. 7.5** | | | |
| Microbio-logical-hygienic testing | Medical devices | Evaluation of a population of microorganisms on products<br>(Bioburden) | DIN EN ISO 11737-1 |

## 19.1 Regulations:

| | |
|---|---|
| DIN EN ISO 9073-10 : 2005-03 | Textiles – Test methods for nonwovens – Part 10: Lint and other particles generation in the dry state |
| 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 10993-5 : 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 |
| DIN EN ISO 10993-12 : 2012-10 | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials |
| DIN EN ISO 10993-18 : 2009-08 | Biological evaluation of medical devices – Part 18: Chemical characterization of materials |
| 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 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 13795-1 : 2019-06 | Surgical clothing and drapes – Requirements and test methods – Part 1: Surgical drapes and gowns |
| DIN EN 14348 : 2005-04 | Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1) |
| DIN EN 14561 : 2006-08 | Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2) |

| | |
|---|---|
| DIN EN 14562 : 2006-08 | Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2) |
| DIN EN 14563 : 2009-02 | Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2) |
| DIN EN 14683 : 2019-10 | Medical face masks – Requirements and test methods |
| DIN EN 14683 : 2019-10 Anhang B | Medical face masks – Requirements and test methods<br>Annex B – Method for in vitro determination of bacterial filtration efficiency (BFE) |
| DIN EN 14683 : 2019-10 Anhang C | Medical face masks – Requirements and test methods<br>Annex C – Method for determination of breathability (differential pressure) |
| DIN EN 16615 : 2015-06 | Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2) |
| DIN EN 16616 : 2015-10 | Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2) |
| ISO 22609 : 2004-12 | Clothing for protection against infectious agents- Medical face masks- Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected) |
| DIN EN ISO 22610 : 2006-10 | Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration |
| DIN EN ISO 22612 : 2005-05 | Clothing for protection against infectious agents -<br>Test method for resistance to dry microbial penetration |
| DIN 58133 : 2008-07 | Medical compression hosiery |
| DB-ALM-Protokoll n° 96 2010-02 | The Hen´s Egg Test on the Chorioallantoic Membrane (HET-CAM) |
| RAL-GZ 387/1 : 2008-01 | Quality Assurance for Medical Compression Hosiery |
| RAL-GZ 387/2 : 2008-01 | Quality Assurance for Medical Compression Armsleeves |

| | |
|---|---|
| RAL-GZ 387/3:<br>2020-02 | Stocking systems for the therapy of Ulcus cruris patients |
| VAH - Method 8 : 2019-06 | Evaluation of bactericidal and yeasticidal activity with quantitative suspension test |
| VAH - Method 9 : 2019-06 | Evaluation of bactericidal, yeasticidal, fungicidal, tuberculocidal or mycobactericidal activity with quantitative suspension test |
| VAH - Method 14.1 : 2019-06 | Surface disinfection without mechanics – practical conditions |
| VAH - Method 14.2 : 2019-06 | Surface disinfection with mechanics – practical 4-field-test |
| VAH - Method 15 : 2019-06 | Chemical/Chemical-thermal instrument disinfectants – practical quantitative carrier test |
| VAH - Method 17.1 : 2019-06 | Chemical-thermal textile disinfection – Single bath method (practical conditions)<br>Testing of chemical-thermal textile disinfection at temperatures of 30 °C to < 60 °C |
| VAH - Method 17.2 : 2019-06 | Chemical-thermal textile disinfection – Single bath method (practical conditions)<br>Testing of chemical-thermal textile disinfection at temperatures of ≥ 60 °C to 70 °C |
| SOP-QM-11.0.02.A5.025 | Chemical characterization of medical devices<br>Semi-quantitative screening with GC-MS according to DIN EN ISO 10993-18 |
| SOP-QM-11 2 03 002 | Testing of medical compression hosiery according to RAL-GZ 387/1, chapter 4 |
| SOP-QM-11 2 03 003 | Testing of stocking systems for the treatment of Ulcus Cruris patients according to the amendment for RAL-GZ 387/1, chapter 4 |
| SOP-QM-11 2 03 004 | Testing of medical compression stockings according to RAL-GZ 387/2, chapter 4 |
| SOP-QM-11.BM.02.031 | Cytotoxicity test |
| SOP-QM-11.BM.03.038 | Testing on irritation: The Hens´s Egg Test on the Chorioallantoic Membrane (Het-CAM) |
| SOP-QM-11.HY.03.052 | Testing chemothermal textile disinfection for its efficiency against virus with quantitative suspension test |
| SOP-QM-11.HY.03.055 | Testing chemothermal textile disinfection for its efficiency against virus with practical conditions by MS2 bio-indicators |
| SOP-QM-11.HY.03.056 | Testing chemothermal textile disinfection for its efficiency against virus in practice by MS2 bio-indicators |

**Abbreviations used:**

| | |
|---|---|
| AW-QM | Standard Operating Procedure of the Hohenstein Laboratories GmbH & Co. KG |
| DIN | Deutsches Institut für Normung [German Institute for Standardisation] |
| EN | Europäische Norm [European Standard] |
| IEC | International Electrotechnical Commission |
| ISO | International Organization for Standardization |
| SOP-QM | Standard Operating Procedure of the Hohenstein Laboratories GmbH & Co. KG |
| RAL-GZ | Quality and test specifications of RAL Deutsches Institut für Gütesicherung und Kennzeichnung e.V. [RAL German Institute for Quality Assurance and Certification] |
| VAH | Verband für Angewandte Hygiene e.V. [German Association for Applied Hygiene] |

[1] DIN EN ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories

[2] DIN EN ISO 13485 : 2016-08 Medical devices — Quality management systems — Requirements for regulatory purposes

[3] COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

[4] COUNCIL DIRECTIVE of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices