

Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Deutschland

herewith certifies that the company

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda
Germany

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard and country-specific requirements of the following jurisdictions¹ has been verified by an audit:

ISO 13485:2016
Australia, Brazil, Canada, United States of America

This certification is subject to surveillance by MEDCERT.

Effective date: 2022-03-29
Expiry date: 2022-05-18

Report No.: 7295SA11F
Procedure No.: QS – 7295
Certificate No.: 7295GB451220329A

Hamburg, 2022-03-29

MEDCERT Certification Body
Markus Bianchi

¹ Individual country-specific requirements are listed in the appendix.

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is an MDSAP authorised auditing organisation.

Appendix of certificate

Procedure No.: QS – 7295
Certificate No.: 7295GB451220329A

Activities and products/services in the scope of certification

Design and development, manufacture, distribution and servicing of

- Liquor drainage devices, associated sterile tube sets, drainage bags and module-software
- Ablation coolant pumps, associated foot switches, sensors, tube sets and module-software
- Liposuction pumps, associated foot switches and tube sets
- Suction pumps
- Vibration drives for liposuction cannulas
- Blood mixing scales
- Biopsy devices, biopsy cannulas, biopsy kits
- Localization needles and cannulas
- Cannulas and application systems for vertebroplasty
- Bone penetration needles
- Liposuction- and transfer cannulas
- Vacuum stents

Contract manufacturing of:

- Electrical and fine-mechanical devices;
- Assemblies and components;
- Spinal implants;
- Cannulas;
- Needles;
- Tube sets

Country-specific requirements implemented in the quality management system

Australia – Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 (without 1.6)

Brazil – RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009

Canada – Medical Devices Regulations SOR/98-282, Part 1 (applicable requirements)

United States of America – 21 CFR 803; 21 CFR 806; 21 CFR 807 (Subparts A to D); 21 CFR 820

This appendix is integral part of the above-referenced certificate.
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Locations in the scope of certification

Möller Medical GmbH
Wasserkuppenstrasse 29-31
36043 Fulda
Germany
Facility ID: F006013

Design and development, manufacture, distribution and servicing of

- Liquor drainage devices, associated sterile tube sets, drainage bags and module-software
- Ablation coolant pumps, associated foot switches, sensors, tube sets and module-software
- Liposuction pumps, associated foot switches and tube sets
- Suction pumps
- Vibration drives for liposuction cannulas
- Blood mixing scales
- Biopsy devices, biopsy cannulas, biopsy kits
- Localization needles and cannulas
- Cannulas and application systems for vertebroplasty
- Bone penetration needles
- Liposuction- and transfer cannulas
- Vacuum stents

Contract manufacturing of

- Electrical and fine-mechanical devices
- Assemblies and components
- Spinal implants
- Cannulas
- Needles
- Tube sets

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