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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 jurisdictions[1] 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:	**2022-09-06**
Expiry date:	**2024-04-22**

Report No.:	7295AU10F
Procedure No.:	QS – 7295
Certificate No.:	7295GB451220906

Hamburg, 2022-09-06

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.

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Appendix of certificate

Procedure No.: QS – 7295
Certificate No.: 7295GB451220906

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
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- Vacuum stents

Contract manufacturing of:
- Electrical and fine-mechanical devices
- Assemblies and components
- Spinal implants
- Cannulas
- Needles
- Tube sets