



DNV

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7295GB451240502

Final assessment report no.
7295AU13F

Effective date
2024-05-02

Expiry date
2027-04-22

This is to certify that the management system of

Möller Medical GmbH

Wasserkuppenstraße 29-31, 36043 Fulda, Germany

Facility ID: F006013

With the sites as mentioned on the following pages

Has been found to conform to the quality management system standard

ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations (SOR/98-282) – Part 1 (applicable requirements)
United States: 21 CFR 803; 21 CFR 806; 21 CFR 807; 21 CFR 820

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date
Hamburg, 2024-05-02

For the issuing office
DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany

DNV MEDCERT is an MDSAP
authorised auditing organisation

Markus Bianchi
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

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AUTHORISED UNIT: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.med-cert.com, www.dnv.com

Activities and products/services covered by this certificate

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

Sites covered by this certificate

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

Site-specific scope

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
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- Vibration drives for liposuction cannulas
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- Electrical and fine-mechanical devices
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