



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.
7295GB451260302

Final assessment report no.
7295AU14F

Effective date
2026-03-02

Expiry date
2027-04-22

This is to certify that

Moeller Medical GmbH

Wasserkuppenstrasse 29-31, 36043 Fulda, Germany

has introduced, applies and maintains a management system at the site(s) listed on the following page(s).

This management system has been audited and found to conform to the quality management systems standard

ISO 13485:2016 and the following country-specific requirements

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (without 1.6)
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 (Subparts A to D); 21 CFR 820

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

Place and date
Hamburg, 2026-03-02

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



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


Annika Chilli
Certification Body Operations

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

820114 EN Rev 6 2025.07.16

MDSAP RECOGNISED AUDITING ORGANIZATION: DNV MEDCERT GmbH
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, www.dnv.com

Activities and products/services covered by this certificate

Design and development, manufacturing, and distribution of

- Liquor drainage devices, associated sterile tube sets, drainage bags and modul-software
- Ablation coolant pumps, associated foot switches, sensors, tube sets and modul-software
- Liposuction pumps, associated foot switches and tube sets
- Suction pumps
- Vibration drives for liposuction cannulas
- Blood mixing scales
- Biopsy cannulas, biopsy kits
- 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
- Cannulas
- Needles
- Tube sets

Service of

- Liquor drainage devices
- Ablation coolant pump
- Liposuction pumps
- Suction pumps
- Vibration drives
- Blood mixing scales
- Biopsy devices

Sites covered by this certificate and associated (partial) scopes

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

Design and development, manufacturing, and distribution of

- Liquor drainage devices, associated sterile tube sets, drainage bags and modul-software
- Ablation coolant pumps, associated foot switches, sensors, tube sets and modul-software
- Liposuction pumps, associated foot switches and tube sets
- Suction pumps
- Vibration drives for liposuction cannulas
- Blood mixing scales
- Biopsy cannulas, biopsy kits
- Cannulas and application systems for vertebroplasty
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Contract manufacturing of

- Electrical and fine-mechanical devices
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- Cannulas
- Needles
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DNV

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Service of

- Liquor drainage devices
- Ablation coolant pumps
- Liposuction pumps
- Suction pumps
- Vibration drives
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- Biopsy devices

