

EU Quality Management System Certificate

Certificate no. 7295GB448230914

Final Assessment Report no 7295AU09F

Effective date 2023-09-14

Expiry date 2026-04-22

This is to certify that the quality system of

Möller Medical GmbH

Wasserkuppenstrasse 29-31, 36043 Fulda, Germany

SRN: DE-MF-000005100

For design, production, and final product inspection/testing of Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX, Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date Hamburg, 2023-09-14



Benannt durch/Designated by

Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

BS-MDR-096

For the issuing office DNV MEDCERT GmbH – Notified Body 0482 Pilatuspool 2, 20355 Hamburg, Germany

Lorenz Runge
Director Certification Bod



Certificate no.: 7295GB448230914 Place and date: Hamburg, 2023-09-14

Preceding certificate

Certificate no.

Issue date

Identification of changes

7295GB448220906

2022-09-06

WO-008982

Sites covered by this certificate

Möller Medical GmbH, Wasserkuppenstrasse 29-31, 36043 Fulda, Germany





Certificate no.: 7295GB448230914 Place and date: Hamburg, 2023-09-14

Products covered by this certificate

Class IIa medical devices

ssues
38

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	Z12040214	Liposuction units

Intended purpose

Use for medical indications, including those accompanied by a change in fatty tissue, and for aesthetic body contouring / Administer tumescent local anaesthesia, other aqueous infusion solutions, as well as endogenous subcutaneous tissue and its components, into the body

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	030102	Irrigation controllers

Intended purpose

For ablation/irrigation, used with a sterile tube set and a container with physiological saline solution for the purpose of cooling the catheter tip