

EU Quality Management System Certificate

Certificate no.
7295GB448240618

Final Assessment Report no.
7295AU13F

Effective date
2024-06-18

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,
Chapters I and III of Regulation (EU) 2017/745 on Medical Devices**

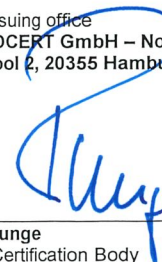
Any applicable limitations for certain medical devices are included in the following list or recorded
in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-06-18

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096



Lorenz Runge
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



DNV

Certificate no.: 7295GB448240618
Place and date: Hamburg, 2024-03-01

Preceding certificate

Certificate no.	Issue date	Identification of changes
7295GB448220906	2022-09-06	WO-008982
7295GB448230914	2023-09-14	Correction of Typo, WO-0111241

Sites covered by this certificate

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





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Products covered by this certificate

Class I medical devices

For class I medical devices placed on the market in sterile condition (class Is), the audit of the quality management system was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

For class I medical devices with a measuring function (class Im), the audit of the quality management system was limited to the aspects relating to the conformity of the devices with the metrological requirements.

For class I medical devices that are reusable surgical instruments (class Ir), the audit of the quality management system was limited to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilisation, maintenance and functional testing, and the related instructions for use.

Category	Class	Medical devices/groups of medical devices
MDA 0318	Im	Other active non implantable devices

Class IIa medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0306	Z12040214	Liposuction units
MDA 0306	A018099	Needles – other accessories
MDN 1202	A010201	Needles and kits – histologic and cytologic biopsy of small tissues
MDN 1202	A010202	Needles and kits – osteomedullary biopsy
MDN 1202	A018003	Needle introducers
MDN 1202	A019011	Needles – bone infusion and vertebroplastic
MDN 1202	Z12040214	Liposuction units
MDN 1202	A030402	Irrigation kits

Class IIb medical devices, excluding implantable non-WET*

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	A030102	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

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.