

EU Quality Management System Certificate

Certificate no. 2879GB448240201

Final Assessment Report no. 2879AU23F

Effective date 2024-02-01

Expiry date 2028-05-10

This is to certify that the quality system of

Meyer-Haake GmbH Medical Innovations

Daimlerstraße 4, 61239, Ober-Mörlen, Germany

SRN: DE-MF-000013583

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, 2024-02-01



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

Dr. Ralf Reimer-Guénon Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de



Certificate no.: 2879GB448240201 Place and date: Hamburg, 2024-02-01

Sites covered by this certificate

Meyer-Haake GmbH Medical Innovations, Daimlerstraße 4, 61239, Ober-Mörlen, Germany





Certificate no.: 2879GB448240201 Place and date: Hamburg, 2024-02-01

Products covered by this certificate

Class IIb medical devices

Category

EMDN code

Medical devices/groups of medical devices

MDA 0312

K020399

Devices for surgery with radiofrequency generator, single-use - other

Intended purpose

These high-frequency surgical devices are used to cut and coagulate biological tissue by means of electrical energy. They are used in operating theaters in medical practices and clinics. The use on the central nervous system, the central circulatory system and bones is excluded.

