

EU Quality Management System Certificate

We hereby certify the company

REGER Medizintechnik GmbH
Gewerbestraße 10
78667 Villingendorf
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 4 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-09-23
Valid until 2027-12-13

Registration No. D1228500021
Report No. P23-00884-340038

Stuttgart, 2025-09-23



Notified Body



Devices:

Shaver non-sterile

Risk class: IIa

Bur non-sterile

Risk class: IIa

Shaver sterile

Risk class: IIa

Bur sterile

Risk class: IIa

HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, sterile, single-use

Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.

Risk class: IIb

HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, non-sterile, single-use

Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.

Risk class: IIb

HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, non-sterile, reusable

Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of Application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.

Risk class: IIb

HF forceps bipolar non-sterile

Intended purpose: Product for grasping, manipulating and coagulating biological tissue. Only to be used by medically trained specialists.

Risk class: IIb

HF electrodes, bipolar and monopolar, non-sterile

Intended purpose: Product for cutting, coagulating and vaporising biological tissue. Only to be used by medically trained specialists.

Risk class: IIb

HF handles (controllable)

Intended purpose: The product serves as a contact element between the HF generator and monopolar or bipolar HF accessory.

Risk class: IIb

HF handles (not controllable)

Risk class: IIa

Nebuliser, sterile for single use

Intended purpose: The nebulizer is used in combination with other system components as a passive nozzle for nebulizing homogeneous liquids (e.g. medicine, cytostatic drugs, chemotherapeutic substances, physiological saline solution, etc.) in body cavities (e.g. thorax, abdomen and pleura, etc.) in the context of minimally invasive or laparoscopic surgery.

Risk class: IIb

Nebuliser, non-sterile for single use

Intended purpose: The nebulizer is used in combination with other system components as a passive nozzle for nebulizing homogeneous liquids (e.g. medicine, cytostatic drugs, chemotherapeutic substances, physiological saline solution, etc.) in body cavities (e.g. thorax, abdomen and pleura, etc.) in the context of minimally invasive or laparoscopic surgery.

Risk class: IIb

The certificate is based on the previous certificate

D1228500020 (2025-01-28)

D1228500016 (2022-12-14)

with the following changes to D1228500020:

Supplemented by:

- HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, sterile, single-use
Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.
- HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, non-sterile, single-use
Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.
- HF electrodes for arthroscopy/endoscopy, monopolar and bipolar, non-sterile, reusable
Intended purpose: Product for cutting, coagulating and vaporizing biological tissue.
Field of Application: endoscopic / arthroscopic surgical procedures. Use restricted to skilled medical professionals.