EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005528)

Zepf Medical Instruments GmbH

Gunninger Straße 21
78606 Seitingen-Oberflacht
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils 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 consists of 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2023-02-17	Registration No.	D1485000003
Valid until:	2027-09-16	Evaluation Report No.	P21-00686-260237

Stuttgart, 2023-02-17

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product:
sterile scalpel blades and sterile scalpels single use

Risk class: IIa

Product:
suction tubes and suction cannulas

Risk class: IIa

Product:
self-retaining retractors and spreaders

Risk class: IIa

Product:
monopolar, bipolar forceps

Intended purpose: Monopolar, bipolar forceps are used for grasping, dissecting and coagulating tissue

Risk class: IIb

Product:
retaining surgical instruments

Risk class: I (reusable)

Product:
through cutting surgical instruments

Risk class: I (reusable)

Product:
guiding instruments

Risk class: I (reusable)

Product:
holding and clamping surgical instruments

Risk class: I (reusable)

Product:
separating surgical instruments

Risk class: I (reusable)

Product:
scraping surgical instruments

Risk class: I (reusable)

Notes:

In the case of class I devices that are reusable surgical instruments the involvement of mdc is limited to the assessment of the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing as well as the related instructions for use.

The certificate is based on the previous certificate D1485000002 dated 28.10.2022 with the following changes:
Supplemented by the products: monopolar, bipolar forceps

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