For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

STEMA Medizintechnik GmbH
take-off GewerbePark 74
78579 Neuhausen ob Eck
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 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-11-18	Registration No.	D1093700045
Valid until	2027-01-28	Report No.	P24-00876-303060

Stuttgart, 2024-11-18

Notified Body

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

Devices:

Working sleeves (trocars/tubes)

Risk class: IIa

Reusable surgical cutting instruments
Reusable surgical ablating instruments
Reusable surgical retaining instruments
Reusable surgical rotary instruments
Reusable surgical exerting strength instruments
Reusable surgical examining instruments
Reusable surgical widening instruments
Reusable surgical insertable instruments
Reusable surgical puncturing 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 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

D1093700042 (2022-08-11)

with the following changes to D1093700042:
Addition of: Reusable surgical instruments - Risk Class: I (reusable)