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-000005613)

nopa instruments Medizintechnik GmbH

Weilatten 7-9
78532 Tuttlingen
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 2 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-08-15	Registration No.	D1121700028
Valid until:	2027-08-14	Evaluation Report No.	P21-01173-210644

Stuttgart, 2022-08-15

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: Endoscopes and Sheaths for Endoscopy

Risk class: IIa

Product: Clamping and Grasping Instruments

Risk class: I (reusable)

Product: Cutting Instruments

Risk class: I (reusable)

Product: Ablating Instruments

Risk class: I (reusable)

Product: Severing Instruments

Risk class: I (reusable)

Product: Retracting 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.