

EU Quality Management System Certificate

We hereby certify the company

nopa instruments Medizintechnik GmbH
Weilatten 7-9
78532 Tuttlingen
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 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-08-06
Valid until 2027-08-14

Registration No. D1121700033
Report No. P24-00296-322822

Stuttgart, 2025-08-06



Notified Body



Devices:

Endoscopes and Sheaths for Endoscopy

Risk class: IIa

Clamping and Grasping Instruments

Risk class: I (reusable)

Cutting Instruments

Risk class: I (reusable)

Ablating Instruments

Risk class: I (reusable)

Severing Instruments

Risk class: I (reusable)

Retracting Instruments

Risk class: I (reusable)

Suction and Irrigation Cannulae

Risk class: IIa

Self-retaining Retractors and Rib Spreaders

Risk class: IIa

Monopolar instruments, forceps for endoscopy with HF connection, scissors for endoscopy with HF connection

Intended purpose: Cutting and grasping tissue in endoscopic applications

Risk class: IIb

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

D1121700028 (2022-08-15)

D1121700031 (2025-01-10)

with the following changes to D1121700031:

Supplemented by HF-instruments