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-000006113)

endox Feinwerktechnik GmbH

Paul-Lechler-Straße 14
72581 Dettingen
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I and III 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:	2023-07-21	Registration No.	D1201100009
Valid until:	2028-05-04	Evaluation Report No.	P22-00597-272417

Stuttgart, 2023-07-21

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: stone extraction baskets

Risk class: IIa

Product: guidewires

Risk class: IIa

Product: Polypectomy snares

Intended purpose: Polypectomy snares are used for endoscopic electrosurgical or mechanical removal of polyps and adenomas in the gastrointestinal tract.

Risk class: IIb

Notes:

The certificate is based on the previous certificate D1201100008 dated 05.05.2023 with the following changes:
Supplemented by the product "Polypectomy snares"