

EU Quality Management System Certificate

We hereby certify the company

Erbe Vision GmbH
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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 2026-09-01
Valid until 2028-05-21

Registration No. D1192000035
Report No. P26-00591-371167

Stuttgart, 2026-08-21



Notified Body



Devices:

Laparoscope with and without working channel

Risk class: IIa

Hysteroscope without working channel

Risk class: IIa

Hysteroscopy Sleeves

Risk class: IIa

Cystoscope with and without working channel

Risk class: IIa

Endoscopes for disectomy with working channel

Risk class: IIa

Genitourinary endoscope with working channel

Risk class: IIa

Arthroscope without working channel

Risk class: IIa

Nephroscope with working channel

Risk class: IIa

Ureterorenoscope with working channel

Risk class: IIa

Cystoscopy and Urethroscopy Sheaths and working element

Risk class: IIa

Urethrotomy Instruments - sleeves and guide tube

Risk class: IIa

Lithotripsy instruments - sheath and telescope bridge

Risk class: IIa

The certificate is based on the previous certificate

D1192000026 (2023-11-20)

D1192000030 (2025-12-18)

D1192000031 (2026-06-11)

D1192000034 (2026-08-21)

with the following changes to D1192000034:

Supplemented by the following products from Blazejewski Meditech:

Endoscopes for disectomy with working channel

Genitourinary endoscope with working channel

Arthroscope without working channel

Nephroscope with working channel

Ureterorenoscope with working channel

Change to the name of the following product group:

Sleeves- Hysteroscopy system to Hysteroscopy sleeves

Cystoscope to Cystoscope with and without working channel

Hysteroscope to Hysteroscope without working channel

Laparoscope to Laparoscope with and without working channel

Correction: Lithiotripsy instruments - sheath and telescope bridge to Lithotripsy instruments - sheath and telescope bridge