For electronic distribution only
Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

Blazejewski MEDI-TECH GmbH
Rheinstraße 1
79350 Sexau
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	2025-08-12	Registration No.	D1038900030
Valid until	2030-04-23	Report No.	P24-00315-292900

Stuttgart, 2025-08-12

Notified Body

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

Devices:

Rigid endoscopes with and without working channel:
Arthroscope, Discectomy system, Hysteroscope, Laparoscope, Nephroscope, Ureterorenoscope, Cystoscope, Genitourinary Urogenital endoscope

Risk class: IIa