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-000006428)

EMOS Technology GmbH

Gewerbestraße 10
88636 Illmensee
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 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-11-23	Registration No.	D1485100003
Valid until:	2027-07-17	Evaluation Report No.	252956

Stuttgart, 2022-11-23

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: Rigid Arthroscopes

Risk class: IIa
Basic-UDI-DI: 42506288Z12021101SOAUS

Product: Rigid Hysteroscopes

Risk class: IIa
Basic-UDI-DI: 42506288Z12020704SOAXC

Product: Rigid Laparoscopes

Risk class: IIa
Basic-UDI-DI: 42506288Z12029009SOA2G

Product: Rigid Cystoscopes

Risk class: IIa
Basic-UDI-DI: 42506288Z12020701SOAWP

Product: Rigid Ureterorenoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020709SMAY9

Product: Rigid Nephroscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020705SMAXD

Product: Rigid Hysteroscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020704SMAX6

Product: Rigid Laparoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12029009SMA2A

Product: Rigid Cystoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020701SMAWH

Product: Rigid Surgical Endoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020706SMAXL

Product: Flexible Naso-Pharyngo-Laryngoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12021005FMAT2

Product: Flexible Ureterorenoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020709FMAW8

Product: Flexible Bronchoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020801FMAUV

Product: Flexible Cystoscopes with working channel

Risk class: IIa
Basic-UDI-DI: 42506288Z12020701FMAUG

The certificate is based on the previous certificate D1485100002 dated 18.07.2022 with the following changes:
Adaptation Basic-UDI-DI for product group "Surgical Endoscopes:
Old: 42506288Z12020706SMAYJ, New: 42506288Z12020706SMAXL
Adaptation/precision of all product groups.
Inclusion of the wording "rigid" or "flexible" product and "with working channel".

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