EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

Digitally signed by Dubalari Pavel
Date: 2022.03.24 11:43:46 EET
Reason: MoldSign Signature
Location: Moldova

for the scope

Endoscopic instruments, HF-instruments and accessories,
Needle systems and Drainage systems
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500036
Report no.	P18-01361-131197
Stuttgart	2019-01-04

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

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Fax: +49-(0)711-253597-10
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Attachment of the certificate

No. D1033500036 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
Drainage systems	Nasal Biliary Drainage Probes SU	IIa
Endoscopic instruments	Stone extraction Balloons SU	IIa
	Scissors RU	IIa
	Cytology Brushes SU	IIa
	Spray Catheters SU/RU	IIa
	Suture Punches RU	IIa
	Foreign Body Retrievers / Polyp Retrievers SU/RU	IIa
	Biopsy Forceps SU/RU	IIa
	Multi Band Ligation Device SU	IIa
Needle systems	Fibrin Application Needles SU/RU	IIa
	FNA Systems for ultrasound endoscopy SU	IIa
	Transbronchial Aspiration Needles SU	IIa
	Injection Needles SU/RU	IIa
Drainage systems	Biliary Stents SU	IIb
	Pancreatic Stents SU	IIb
	Self-expanding Stents SU (Biliary, Bronchial/Tracheal, Colonic, Duodenal, Esophageal)	IIb
HF-instruments and accessories	Handles incl. HF connector RU	IIb
	Cysto Gastro Sets SU	IIb
	Sphincterotomes SU/RU	IIb
	Polypectomy Snares, Mukosectomy Snares SU/RU	IIb
	HOT Biopsy Forceps SU/RU	IIb

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EC Certificate

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herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

endoscopic instruments
(see attachment)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with securing and maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2019-01-04
Valid until	2023-01-23
Registration no.	D1033500037
Report no.	P18-01361-131199
Stuttgart	2019-01-04

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Attachment of the certificate

No. D1033500037 Date 2019-01-04 Page 1 of 1

Product category	Product	Class
endoscopic instruments	E.R.C.P. Catheters SU/RU Suction / Flushing Catheters SU Stone Extraction Baskets SU/RU Lithotripsy Baskets / Lithotripsy Spirals SU/RU Guiding Catheters SU/RU Pushers SU/RU Stent Placement Sets SU/RU Biliary Dilation Catheters SU Polyp & Foreign Body Retriever "EasyCollect" SU Guide Wires SU/RU Dilation Balloons SU	I (steril)

Head of Certification Body

medical device certification mdc

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Certificate

mdc medical device certification GmbH
certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

for the scope

design, development, production, storage and distribution of instruments and accessories for the diagnostic and therapeutic endoscopy

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2019-03-11
Valid until	2021-01-23
Registration no.	D1033500038
Report no.	P18-01361-131193
Stuttgart	2019-03-11

Head of Certification Body

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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