

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
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

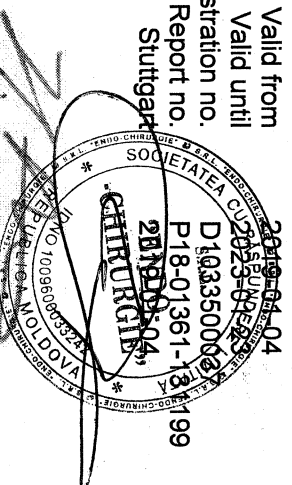
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

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



Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ca.de>

For electronic publication only

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)



mdc medical device certification GmbH
 Kriegerstraße 6
 D-70191 Stuttgart, Germany
 Phone: +49-(0)711-253597-0
 Fax: +49-(0)711-253597-10
 Internet: <http://www.mdc-ce.de>

A handwritten signature in black ink, appearing to be 'J. K.' or similar, written over a horizontal line.

Head of Certification Body

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

ENDO-FLEX GmbH
Alte Hünxer Straße 115
46562 Voerde
Germany

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

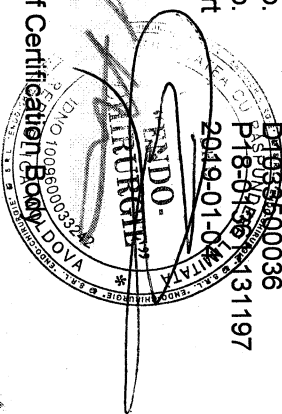
Annex II – excluding Section 4 of the Council Directive 93/42/EEC

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. D1993500036
Report no. P18-0126131197
Stuttgart 2019-01-04

Head of Certification Board



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ca.de>

For electronic publication only

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



[Signature]
Head of Certification Body