

# 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	2021-04-15
Valid until	2024-05-26
Registration no.	D1033500044
Report no.	P20-01643-203710
Stuttgart	2021-04-15



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-ce.de>

For electronic publication only

**Attachment of the certificate**

**No. D1033500044**

Date 2021-04-15

Page 1 of 1

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



  
 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-ce.de>

For electronic publication only