

# 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



**Attachment of the certificate**

**No. D1033500044**

Date 2021-04-15

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



Head of Certification Body

