

# 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	2018-01-31
Valid until	2019-01-31
Registration no.	D1033500032
Report no.	P17-01195-104480
Stuttgart	2018-01-31



Head of Certification Body



**Attachment of the certificate**

**No. D1033500032**

Date 2018-01-31

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



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