

# 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.	D1033500036
Report no.	P18-01361-131197
Stuttgart	2019-01-04



Head of Certification Body



**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
	Foreign Body Retrievers / Polyp Retrievers SU/RU	Ila
	Biopsy Forceps SU/RU	Ila
	Multi Band Ligation Device SU	Ila
Needle systems	Fibrin Application Needles SU/RU	Ila
	FNA Systems for ultrasound endoscopy SU	Ila
	Transbronchial Aspiration Needles SU	Ila
	Injection Needles SU/RU	Ila
Drainage systems	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

  
Head of Certification Body

