

Ø 2.3 mm



STERILE EO

EasyCollect, large

- for gastroscopes and colonoscopes



bag size

length	packing unit	bag size
230 cm	10 pieces	NE 15 22-G35



Ø 1.8 mm



STERILE EO

EasyCollect, small

- for bronchoscopes and pediatric endoscopes



bag size

length	packing unit	bag size
160 cm	10 pieces	NE 15 18-B15



STERILE EO

Foreign Body Protection Hood

- for safe removal of sharp edged foreign bodies



131 000
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single-use

Polyp & Foreign Body Retrievers

# 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	2019-11-19
Valid until	2023-01-23
Registration no.	D1033500039
Report no.	P14-01606-30841
Stuttgart	2019-11-19



Head of Certification Body



**Attachment of the certificate**

**No. D1033500039**

Date 2019-11-19

Page 1 of 1

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
	Scissors RU	IIa
	Cytology Brushes SU	IIa
	Spray Catheters SU/RU	IIa
	Suture Punches RU	IIa
	Foreign Body Retrievers / Polyp Retrievers SU/RU	IIa
	Biopsy Forceps SU/RU	IIa
	Multi Band Ligation Device SU	IIa
	Clip applicator set SU	IIa
HF-instruments and accessories	Handles incl. HF connector RU	IIb
	Cysto Gastro Sets SU	IIb
	Sphincterotomes SU/RU	IIb
	Polypectomy Snares, Mukosectomy Snares SU/RU	IIb
	HOT Biopsy Forceps SU/RU	IIb
Needle systems	Fibrin Application Needles SU/RU	IIa
	FNA Systems for ultrasound endoscopy SU	IIa
	Transbronchial Aspiration Needles SU	IIa
	Injection Needles SU/RU	IIa



Head of Certification Body



## Konformitätserklärung

### Declaration of Conformity

Wir  
We

**Name und Adresse des Herstellers:** ENDO-FLEX GmbH  
*Name and address of manufacturer:* Alte Hünxer Straße 115  
 46562 Voerde  
 Germany

erklären in alleiniger Verantwortung, dass das Medizinprodukt  
 declare on our own responsibility that the medical device

**Name / Produktgruppe:** Polypektomie-Schlingen, Mukosektomie-Schlingen SU/RU<sup>1</sup>  
*Name/ Name group:* Polypectomy Snares, Mucosectomy Snares SU/RU

**Klasse:** **Artikelnummer:**  
*Class:* *Article number :*

IIb

SU:

NOE3222-G	NOE342214M-G	NOE372214-G
NOE3322-G	NOE342216-C	NOE372216-G
NOE341816-C	NOE342216-G	NOE372217-G
NOE342212M-G	NOE342216M-C	OE3322-G
NOE342213-G	NOE342216M-G	OE342214M-G
NOE342213M-G	NOE342217-C	OE342215-G
NOE342214-C	NOE342217-G	OE342216-G
NOE342214-G	NOE342217-M	OE342217-C
NOE342214-M	NOE342217M-G	OE342217-G
NOE342214M-C		OE342246-G

RU:

3222-G	D342206-G	OK342215-G
3322-G	D342207-C	OK342215M-G
341815-G	D342207-G	OK342216-C
341815M-G	D342215-G	OK342216-G
342214-G	D342216-G	OK342216M-G
342215-G	D342217-G	OK342217-C
342216-G	OK3122-G	OK342217-G
342217-G	OK3222-G	OK342237-G
D3022-G	OK3322-G	OK342267-G
D3222-G	OK342205-G	OK372206-G
D3322-G	OK342206-G	OK372207-G
D342205-G	OK342207-G	OK6522601-G

allen anwendbaren Anforderungen der Richtlinie 93/42/EWG Anhang I entspricht.  
 meets all applicable requirements of the Directive 93/42/EEC Annex I.

<sup>1</sup> SU: Single use / RU: Reusable

**Konformitätserklärung**  
*Declaration of Conformity*

**Benannte Stelle:**

*Notified body:*

mdc medical device certification GmbH  
Kriegerstraße 6  
70191 Stuttgart  
Germany  
0483

**Konformitätsbewertungsverfahren:**

*Conformity assessment procedure:*

Richtlinie 93/42/EWG, Anhang II ohne (4)  
Directive 93/42/EEC, Annex II excluding (4)

**Zertifikatsnummer :**

*Certificate No. :*

D1033500039

**Erstmalige CE-Kennzeichnung:**

*first CE mark:*

1997

**Gültig bis:**

*Valid until:*

23.01.2023

Voerde 09.01.2020

ENDO-FLEX GmbH



Jens Kühnemund  
Sicherheitsbeauftragter  
Safety Representative

ENDO-FLEX GmbH, Alte Hünxer Straße 115, 46562 Voerde, Germany

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17.09.2021

### Authorization

We, the undersigned Endo-Flex GmbH, hereby we appoint F.C.P.C. "DataControl" S.R.L., 20, Melestiu street, MD-2001, Chişinău, Republic of Moldova, to be authorized distributor/representative for registration, renewal, amendments of registration, at the responsible authorities of the Republic of Moldova.

Armands Strauss  
Area Sales Manager  
Gastroenterology and Urology

Representing  
Medi-Globe GmbH, Endo-Flex GmbH,  
Urotech GmbH, UroVision GmbH



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