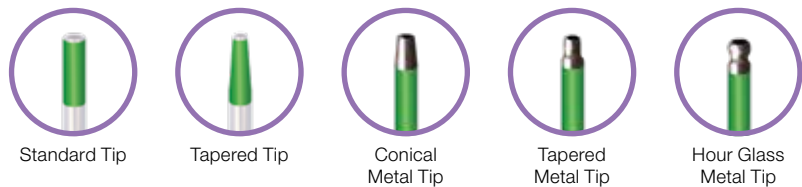


ERCP Catheters – Single Use



ERCP Catheter – with Standard Stylet

With colored markers; compatible with guide wire .035"

Catalogue No.	Tip Shape	Catheter Outer Diameter (mm)	Working Length (cm)	Min. Accessory Channel (mm)
E4318-GW	Standard	1.8	200	2.0
E4418-GW	Tapered	1.8	200	2.0
E4518-GW	Conical Metal	1.8	200	2.0
E4618-GW	Tapered Metal	1.8	200	2.0
E4818-GW	Hour Glass Metal	1.8	200	2.0



ERCP Catheter – with Standard Stylet

Compatible with guide wire .035"

Catalogue No.	Tip Shape	Catheter Outer Diameter (mm)	Working Length (cm)	Min. Accessory Channel (mm)
E43162FD35	Standard	1.65	200	2.0



LEF-GER-SU-00-EN / LL-0371 Vers. 1.0 (10/2020)

ERCP Catheters

Single Use



Guide Wire Compatibility

Color-Marked

Versions with Metal Tip



ENDO-FLEX GmbH
Alte Hünxer Str. 115 • 46562 Voerde • Germany
Tel.: +49 281 94400-0 • Fax: +49 281 94400-11
Email: sales@endo-flex.de • www.endo-flex.de

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/RU¹
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.

¹ 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

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	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
	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
	Clip applicator set SU	Ila
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
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



Head of Certification Body

