

# 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**  
**(see attachment)**

has introduced and applies a

**Quality System**

for the aspects of manufacture concerned with securing and  
maintaining sterile conditions as specified in Annex V, Section 3.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex V – Section 3**  
**of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from	2021-05-14
Valid until	2024-05-26
Registration no.	D1033500045
Report no.	P20-01767-205939
Stuttgart	2021-05-14

Head of Certification Body



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-246.10.06

**Attachment of the certificate**

**No. D1033500045**

Date 2021-05-14

Page 1 of 1

Product category	Product	Class
endoscopic instruments	E.R.C.P. Catheters SU Suction / Flushing Catheters SU Stone Extraction Baskets SU/RU Lithotripsy Baskets / Lithotripsy Spirals SU/RU Guiding Catheters SU Pushers SU Stent Placement Sets SU Biliary Dilation Catheters SU Polyp & Foreign Body Retriever "EasyCollect" SU Guide Wires SU/RU Dilation Balloons SU	I (steril)



Head of Certification Body

