

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	2018-01-31
Valid until	2019-01-31
Registration no.	D1033500034
Report no.	P17-01195-104482
Stuttgart	2018-01-31



Head of Certification Body



Attachment of the certificate

No. D1033500034

Date 2018-01-31

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



Head of Certification Body