

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

disposable medical devices
(see annex)

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	2010-12-14
Valid until	2013-01-23
Registration no.	0204.07.11/2
Report no.	E 0204.07 / 2010-12-14
Stuttgart	2010-12-14

A handwritten signature in blue ink, appearing to read 'P. Maurer', is written over a light blue rectangular background.

Head of Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-976.94.05

Annex of the certificate

No. 0204.07.11/2 dated 2010-12-14

product	risk class			
	Is	Ila	Ilb	III
Guiding Catheters, Pushers, Stent Application Systems	x			
Guide Wires	x			
Disposable E.R.C.P. Catheters	x			
Disposable Extraction Baskets	x			
Disposable Mechanical Lithotripter	x			
Mandrins	x			
Polyp & Foreign Body Retriever	x			
Biliary Dilatation Catheters	x			


Head of Certification Body

