

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**Medi-Globe GmbH
Medi-Globe Straße 1-5
83101 Achenmühle
Germany**

for the scope

**Endoscopic instruments, Drainage systems,
HF - instruments and accessories, Needle 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	2017-09-22
Valid until	2019-06-22
Registration no.	D1314600019
Report no.	P16-00421-69537
Stuttgart	2017-09-22



Head of Certification Body



Attachment of the certificate

No. D1314600019

Date 2017-09-22

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Product category	Product	Class
Drainage systems	Nasal biliary drainages / sets	Ila
	Self-expanding metal stents (biliary, esophageal, intestinal)	IIb
	Biliary stents / sets	IIb
	Pancreatic stents / sets	IIb
Endoscopic instruments	Extraction bags	Ila
	Hemostasis-Clip-System	Ila
	Multi-band ligator	Ila
HF - instruments and accessories	High frequency handle for polypectomy snares and sphincterotomes	IIb
	HOT Biopsy Forceps	IIb
	Sphincterotomes	IIb
	Polypectomy snares	IIb
Needle systems	Aspiration needles for bronchoscopy and gastroscopy	Ila
	Aspiration needle systems for ultrasound endoscopy	Ila
	Fibrin needles	Ila
	Injection needles	Ila



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