

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	2019-06-14
Valid until	2022-06-22
Registration no.	D1314600024
Report no.	P17-00553-95676
Stuttgart	2019-06-14



Head of Certification Body



Attachment of the certificate

No. D1314600024

Date 2019-06-14

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



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