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 Valid until Registration no. Report no. Stuttgart 2020-04-21 2024-05-26 D1314600027 P19-01750-164770 2020-04-21

Head of Certification Body





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Attachment of the certificate

No. D1314600027

Date 2020-04-21

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



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