EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

H. + H. Maslanka Chirurgische Instrumente GmbH Stockacher Straße 172 78532 Tuttlingen Germany

for the scope

instruments for high frequency surgery (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
 2020-03-18

 Valid until
 2024-05-26

 Registration no.
 D1038400066

 Report no.
 P20-00154-168305

 Stuttgart
 2020-03-18

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

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Product category	Product	Class	Product code
instruments for high frequency surgery	Handle with high frequency connection	IIb	11-499
	Biopsy forceps with high frequency connection	IIb	11-502
	Sphincterotome	IIb	15-625
	Sphincterotome (disposable)	Ilb	15-625
	Polypectomy snare	IIb	15-989
	Polypectomy snare (disposable)	IIb	15-989
	Coagulation probe	Ilb	16-860



Head of Certification Body

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