

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

STEMA Medizintechnik GmbH
H.-E.-Bussestrasse 4
78333 Stockach
Germany

for the scope

**active, electrical devices,
instruments for high frequency surgery and endoscopy
(see annex)**

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 – 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 II, Section 5.

Valid from 2009-09-29
Valid until 2014-09-29
Registration no. 0481.02.11/0
Report no. E 0481.02 / 2009-09-23
Stuttgart 2009-09-23



Head of Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>

Annex of the certificate

No. 0481.02.11/0 dated 2009-09-29

product	UMDNS	risk class			
		I	Ila	Ilb	III
dissectors, high-frequency	11-290			X	
bipolar dissectors	11-290			X	
insufflators	12-144		X		
pumps, suction-irrigation	13-192		X		
working element	13-335			X	
snares, polypectomy	13-631			X	
graspers, high-frequency	15-221			X	
bipolar graspers	15-221			X	
probes, other, high-frequency	15-237			X	
scissors, other, high-frequency	15-245			X	
bipolar scissors	15-245			X	
electrodes, high-frequency	15-579			X	
bipolar electrodes	15-579			X	
flexible electrodes, high-frequency	15-579			X	
electrodes for resectoscopy	15-579			X	
papillotomes	15-625			X	
forceps, biopsy, flexible endoscopic, high-frequency	16-268			X	
micromotorsystem	16-868		X		
arthroscopic shaver systems	17-918		X		



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