

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

**reusable surgical instruments,
instruments for endoscopy, implants for osteosynthesis
(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. 0481.01.11/0
Report no. E 0481.01 / 2009-09-23
Stuttgart 2009-09-23

M. Hauer
Head of Certification Body



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-976.94.05

mdc medical device certification GmbH
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Annex of the certificate
No. 0481.01.11/0 dated 2009-09-29

product	UMDNS	risk class			
		I	Ila	Ilb	III
burs	10-519		X		
cannulas	10-561		X		
shaver blades	12-234		X		
plates, bone, non-active	13-050			X	
saw blades	13-447		X		
inflow and irrigation cannulas	15-206		X		
hysteroscope sheaths with obturators	15-206		X		
resectoscope sheaths with obturators	15-206		X		
urethrotome sheaths with obturators	15-206		X		
cysto-urethroscope sheaths with obturators	15-206		X		
needles, other	15-234		X		
suction punches	15-239		X		
trocars and obturators	15-260		X		
interference screw	16-055			X	
screws, bone, non-active	16-101			X	
reamers	17-760		X		
suction/irrigation instruments	17-795		X		
handpieces, surgical	17-949		X		

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