

# Certificate

**mdc medical device certification GmbH**  
certifies that

**MEDE Technik  
Rudolf-Diesel-Straße 13  
78576 Emmingen  
Germany**

for the scope

**manufacturing, distribution and repair service of  
reusable surgical instruments,  
manufacturing and distribution of implants for osteosynthesis**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

### EN ISO 13485

**Medical devices – Quality management systems –  
Requirements for regulatory purposes**

(EN ISO 13485:2003 + AC:2009)

Valid from	2010-12-16
Valid until	2012-11-20
Registration no.	0202.48.11/3
Report no.	E 0202.48 / 2010-12-16
Stuttgart	2010-12-16

  
Head of Certification Body



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-976.00.03-46

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**MEDE Technik  
Rudolf-Diesel-Straße 13  
78576 Emmingen  
Germany**

for the scope

**suction cannula, surgically invasive,  
in connection with an active medical device (UMDNS: 16-883)**

has introduced and applies a

## Quality System

for the manufacture of the products concerned and carries out a  
final inspection as specified in Annex V, Section 3.

The mdc audit has proven that this quality system  
meets all requirements according to

## Annex V – 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 V, Section 4.

Valid from	2010-12-08
Valid until	2012-11-20
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Report no.	E 0202.03 / 2010-12-08
Stuttgart	2010-12-08

  
Head of Certification Body



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

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**MEDE Technik  
Rudolf-Diesel-Straße 13  
78576 Emmingen  
Germany**

for the scope

**reusable surgical instruments for the use in connection with  
an active medical device, 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 – 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	2010-12-08
Valid until	2012-11-20
Registration no.	0202.15.11/2
Report no.	E 0202.15 / 2010-12-08
Stuttgart	2010-12-08

  
Head of Certification Body



**Annex of the certificate**

**No. 0202.15.11/2**      dated 2010-12-08

product	UMDNS	risk class			
		I	IIa	IIb	III
Bone plate	13-050			X	
Medulla pins, double round pins, femoral neck pins, Steinmann pins	16-078			X	
Bone screw, Schanzsche screw	16-101			X	
Kirschner wire	16-104			X	
Bone wire	16-104			X	
Drills for connection with electrical/pneumatic drilling machine	17-760		X		



Head of Certification Body

