

Certificate

mdc medical device certification GmbH
certifies that

**MEDE Technik GmbH
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 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2018-11-15
Valid until	2020-11-20
Registration no.	D1038800029
Report no.	P18-00892-124191
Stuttgart	2018-11-15


Head of Certification Body



EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

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

for the scope

**Implants for Osteosynthesis
(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	2018-09-05
Valid until	2022-11-20
Registration no.	D1038800028
Report no.	P18-00892-128525
Stuttgart	2018-09-05



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D1038800028

Date 2018-09-05

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Product category	Product	Class	Product code
Implants for Osteosynthesis	Bone Wire, Kirschner Wire of stainless steel and titan	IIb	16-104
	Steinmann Pin and Double Round Pin of stainless steel and titan	IIb	16-078
	Cerclage Wire of stainless steel	IIb	16-104



Head of Certification Body

