

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**TREU-Instrumente GmbH
take-off Gewerbepark 130-132
78579 Neuhausen ob Eck
Germany**

for the scope

**skeletal implants and surgical instruments
(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	2017-02-21
Valid until	2021-05-31
Registration no.	D1268900037
Report no.	P16-00523-86814
Stuttgart	2016-12-09



Head of Certification Body



Attachment of the certificate

No. D1268900037

Date 2016-12-09

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Product category	Product	Class	Product code
surgical instruments	guide, drill	Ila	11-930
	saw – sawblades, bone	Ila	13-449
	burs, orthopedic	Ila	17-995
skeletal implants	plates, bone, sterile and nonsterile	IIb	13-050
	orthopedic external fixations system, fracture, nonsterile	IIb	15-767
	orthopedic external fixations system, spinal, nonsterile	IIb	16-046
	orthopedic external fixations system, other, nonsterile	IIb	16-059
	nail, bone, sterile and nonsterile	IIb	16-078
	screws, bone, sterile and nonsterile	IIb	16-101
	staple, bone, nonsterile	IIb	16-103
wire, bone, nonsterile	IIb	16-104	



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