

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

ORTHO-MEDICAL GmbH
Hauptstraße 5
78589 Dürbheim
Germany

for the scope

implants for osteosynthesis and aneurysm clips
(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	2020-12-04
Valid until	2024-05-26
Registration no.	D1039700036
Report no.	P20-00059-193248
Stuttgart	2020-12-04

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. D1039700036

Date 2020-12-04

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Product category	Product	Class
implants for osteosynthesis	bone screws	IIb
	bone wires	IIb
	cerlage wires	IIb
	Schanz screws	IIb
	Steinmann pins, trochanter/interlocking nails, bone nails	IIb
	bone plates, angled bone plates	IIb
aneurysm clips	temporary and permanent aneurysm clips	III



A handwritten signature in blue ink, appearing to be "ALC", is written above a horizontal line.

Head of Certification Body