EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

RADIX Implants & biomaterials GmbH Hirzenrott 2-4 52076 Aachen Germany

for the scope

Radix implant system, abutments, drills and accessories (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 Valid until
 2019-05-29

 Valid until
 2024-05-26

 Registration no.
 D1444600002

 Report no.
 P18-01105-127099

Stuttgart 2019-05-29

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

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Product category	Class
Radix implant system	IIb
abutments	IIb
drills and accessories	lla



Head of Certification Body

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