EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

RISA GmbH Industriestraße 7 78234 Engen Germany

for the scope

surgical cutting tools (see attachment)

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 Valid until Registration no.

> Report no. Stuttgart

2020-03-23

2024-05-26 D1084100027

P20-00096-167646

2020-03-23

Head of Certification Body





Attachment of the certificate

No. D1084100027

Date 2020-03-23

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Product category	Product	Class	Product code
Surgical cutting tools	Acetabulum reamers, non sterile	lla	12-845
	Saw blades for orthopedics, non sterile	lla	13-447
	Intra medullary reamers, non sterile Bone Drills and Reamers, non sterile	lla	17-995



Head of Certification Body

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