

EU Quality Management System Certificate

We hereby certify the company

Risa GmbH
Industriestraße 7
78234 Engen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 2 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-09-30
Valid until 2029-06-17

Registration No. D1084100035
Report No. P24-01701-340000

Stuttgart, 2025-09-30



Notified Body



Devices:

Saw Blades for Orthopaedics

Risk class: IIa

Bone Drills and Reamers

Risk class: IIa

The certificate is based on the previous certificate
D1084100033 (2024-07-11)

with the following changes to D1084100033:
Supplemented by the products "Saw Blades for Orthopaedics"