For electronic distribution only
Nur zur elektronischen Verbreitung

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	2026-10-06	Registration No.	D1084100036
Valid until	2029-06-17	Report No.	P25-01218-375227

Stuttgart, 2026-10-06

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Bone Drills and Reamers

Risk class: IIa

Saw Blades for Orthopaedics

Risk class: IIa

Medullary Reamers

Risk class: IIa

The certificate is based on the previous certificate

D1084100033 (2024-07-11)
D1084100035 (2025-09-30)

with the following changes to D1084100035:
Supplemented by product group: Medullary Reamers