EU Quality Management Certificate

This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

SRN: DE-MF-000005616

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Certificate registration no.	286629 MDR2017Q
Certificate ID	170782063
Effective date	2023-01-05
Expiry date	2028-01-04
Frankfurt am Main,	2023-01-05

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 4.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005616
Certificate ID: 170782063

Device categories covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Risk classification:	IIa
Intended purpose:	The Suture Passer in combination with the Suture Passer Needle is suitable for guiding sutures through tissue in orthopedic surgery.

Examinations and tests performed:
286629_A210107MED_01 dated 2022-11-08

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a