EU Technical Documentation Assessment Certificate

This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

SRN: DE-MF-000005616

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

Products listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Certificate registration no.	286629 MDR2017B
Certificate ID	170782062
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)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005616
Certificate ID: 170782062

Device categories and variants covered by this certificate:

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suture Passer incl. sterile and reusable needles
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	40491975225-820-SPSQW
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_02 dated 2022-12-22

Further conditions for or limitations to the validity of the certificate:
Products listed on the certificate may bear the CE marking with the identification number of the Notified Body (0297).

Reference to previous certificates:

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