



EU Quality Management Certificate



This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20/22
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 in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

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

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	286629 MDR2017Q
Certificate ID	1000169509
Effective date	2024-08-08
Expiry date	2028-01-04
Frankfurt am Main,	2024-08-08



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.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005616
Certificate ID: 1000169509

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
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_01 dated 2022-11-08
286629_A210107MED_02 dated 2022-12-22
286629_A213310MED_03 Standorterweiterung dated 2024-08-02

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-05	170782063	Adjustment of street number + new certificate template