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	1000205211
Effective date	2024-12-05
Expiry date	2028-01-04
Frankfurt am Main,	2024-12-05

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

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

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 the certification can only be verified by the QR-code.

420.90Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005616
Certificate ID: 1000205211

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.

Device category:	**MDA 0312 - Other active non-implantable products for surgery**
Product name:	Insufflator (gas insufflator + silicon tubes)
Risk classification:	IIa
Basic-UDI-DI:	40491975LAP-300-INTBJ + 40491975LAP-300-INSBG
Intended purpose:	Insufflator with integrated heating: CO2 insufflators are intended for use during diagnostic/or therapeutic endoscopic procedures to distend and fill a peritoneal cavity with gas during a laparoscopic procedure. Insufflators with heating mode are designed to pre-heat the CO2, gas proir insufflation into the body to eliminate the cooling oft he human body with cold gas. Insufflator without integrated heating: CO2 insufflators are intended for use during diagnostic and/or therapeutic endoscopic procedures to distend and fill a peritoneal cavity with gas during a laparoscopic procedure.

Device category:	**MDA 0312 - Other active non-implantable products for surgery**
Product name:	Shaver System
Risk classification:	IIa
Basic-UDI-DI:	40491973SHA-227-SYSGS
Intended purpose:	Arthroscopic Shaver System has been specifically designed for driving of blades and surgical cutters, which are used during treatments of orthopedic reconstruction by using an endoscopic method named arthroscopy. Shaver System consists of: Shaver Control Unit, Shaver Handpiece and Shaver Footswitch.

Device category:	**MDA 0312 - Other active non-implantable products for surgery**
Product name:	Suction & Irrigation Pumps
Risk classification:	IIa
Basic-UDI-DI:	40491973PUM-300-PEEUD
Intended purpose:	The device creates a field of vision for the surgeon by pressure-defined expansion of the organs or joints to be treated. Further more the device rinses blood or tissue parts out of the body which became detached or released as a result of the treatment.

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Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Endoscopes
Risk classification:	IIa
Basic-UDI-DI:	40491975END-XXX-OPEQK
Intended purpose:	The use of RZ Medizintechnik endoscopes is indicated to visualization of the intraoperative site during endoscopic procedures and minimally invasive surgery.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Suction & Irrigation Instruments
Risk classification:	IIa
Basic-UDI-DI:	40491973SIS-300-CANNV
Intended purpose:	Instrument to be connected with a suction / irrigation device for suction of substances and for rinsing of the operation field.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Endoscopic Sheaths
Risk classification:	IIa
Basic-UDI-DI:	40491973END-XXX-SHEN5
Intended purpose:	The devices are intended to be used as a protective sheath/barrier for endoscopes and/or endoscopic instruments to enable access to the operation site during diagnostic and therapeutic endoscopic procedures.

Device category:	**MDN 1208 - Non-active non-implantable instruments**
Product name:	Retractors / Spreaders
Risk classification:	IIa
Basic-UDI-DI:	40491973SRR-170-SYS59
Intended purpose:	Spreaders and retractors are used to keep the surgical field open. This means keeping tissue, organs or bones away during the operation.

Examinations and tests performed:
286629_A210107MED_01 dated 2022-11-08
286629_A210107MED_02 dated 2022-12-22
286629_A212069MED_Insufflator dated 2024-05-02
286629_A211037MED_Endoscopes dated 2024-10-12

Further conditions for or limitations to the validity of the certificate:
n/a

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Certificate ID: 1000205211

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-01-05	170782063	New certificate template
02	2024-08-08	1000169509	Addition of the products “Insufflator (gas insufflator + silicon tubes), Shaver System, Suction & Irrigation Pumps, Endoscopes, Suction & Irrigation Instruments, Endoscopic Sheaths, Retractors / Spreaders