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 Uhlenhaut
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

This annex is only valid in connection with the above-mentioned certificate.

Annex to certificate
Certificate registration No.: 286629 MR2
Certificate unique ID: 170772556
Effective date: 2020-11-14

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

Device family	Device	Class
Endoscopy and accessories	Arthroscopy System	IIa
	Laparoscopy System	IIa
	Hysteroscopy System	IIa
	Ureterorenoscopy System	IIa
	Nephroscopy System	IIa
	Cystoscopy System	IIa
	Discectomy System	IIa
Laparoscopy	Laparoscopy Instruments sterile/non sterile	IIb
HF-surgery	Bipolar Instruments	IIb
	Bipolar Electrodes	IIb
	Monopolar Instruments	IIb
	Monopolar Electrodes sterile/non-sterile	IIb
	High frequency generators	IIb
Suction and irrigation system	Cannulas	IIa
	Suction and irrigation instruments (HF)	IIa
	Suction and irrigation cannulas	IIa
Endoscopic sheath and accessories	Trocar systems	IIa
Resectoscopy	Resectoscopy System	IIb + IIa
	Monopolar Electrodes sterile/non-sterile	IIb
Equipment	Suction and irrigation pump and accessories	IIa
	Insufflator and accessories	IIb + IIa
	Shaver System	IIb
Retractors	Self-Retaining Retractors	IIa

This annex is only valid in connection with the above-mentioned certificate.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Endoscopic Systems for minimal-invasive surgery, Equipment and accessories for minimal-invasive surgery, Monopolar/Bipolar instruments and Electrodes for HF-surgery according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	286629 MR2
Certificate unique ID	170772556
Effective date	2020-11-13
Expiry date	2023-08-02
Frankfurt am Main	2020-11-13

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 286629 MR2
Certificate unique ID: 170772556
Effective date: 2020-11-14

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

Device family	Device	Class
Endoscopy and accessories	Arthroscopy System	IIa
	Laparoscopy System	IIa
	Hysteroscopy System	IIa
	Ureterorenoscopy System	IIa
	Nephroscopy System	IIa
	Cystoscopy System	IIa
	Discectomy System	IIa
Laparoscopy	Laparoscopy Instruments sterile/non sterile	IIb
HF-surgery	Bipolar Instruments	IIb
	Bipolar Electrodes	IIb
	Monopolar Instruments	IIb
	Monopolar Electrodes sterile/non-sterile	IIb
	High frequency generators	IIb
Suction and irrigation system	Cannulas	IIa
	Suction and irrigation instruments (HF)	IIa
	Suction and irrigation cannulas	IIa
Endoscopic sheath and accessories	Trocar systems	IIa
Resectoscopy	Resectoscopy System	IIb + IIa
	Monopolar Electrodes sterile/non-sterile	IIb
Equipment	Suction and irrigation pump and accessories	IIa
	Insufflator and accessories	IIb + IIa
	Shaver System	IIb
Retractors	Self-Retaining Retractors	IIa

This annex is only valid in connection with the above-mentioned certificate.

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Endoscopic Systems for minimal-invasive surgery, Equipment and accessories for minimal-invasive surgery, Monopolar/Bipolar instruments and Electrodes for HF-surgery according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	286629 MR2
Certificate unique ID	170772556
Effective date	2020-11-13
Expiry date	2023-08-02
Frankfurt am Main	2020-11-13

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

CERTIFICATE

This is to certify that the company

RZ Medizintechnik GmbH

Unter Hasslen 20
78532 Tuttlingen
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Development, manufacture and sales of reusable surgical instruments and optics for minimally invasive surgery (MIS) and video-endoscopy, camera, light source, devices and equipment for minimally invasive surgery (MIS) and video endoscopy.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	286629 MP2016
Certificate unique ID	170773838
Effective date	2021-08-03
Expiry date	2024-08-02
Frankfurt am Main	2021-05-16

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

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Head of Certification Body

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410.90.en Version 1.0

Rotating products	40491975SCR-200-DRIKX 40491975DRI-200-BITC3
Exerting strength products	40491975BON-XXX-FORV3
Examining products	40491975PRO-XXX-OBEDJ 40491975PRO-XXX-OBXEQ 40491975TES-XXX-ICE7N
Expanding products	40491975DIL-XXX-TORSB
Suction/rinsing/draining products	40491975CAT-XXX-TERNW 40491975CAN-XXX-ULAJC 40491975CAN-XXX-NLAH9 40491975ADA-XXX-PTRAT 40491975ADA-XXX-TERA2 40491975COM-XXX-RESWB
Introducing products	40491975CHI-XXX-OSTMZ 40491975DEN-500-INS6Y 40491975GUI-XXX-INS4A 40491975PRO-XXX-TECEG
Puncturing products	40491975NEE-180-DEL99 40491975PER-XXX-TOR6Q 40491975TRO-XXX-CARG9 40491975AWL-210-AWLGW
Accessories products	40491975POSXXX-DEVDB

Yours Sincerely,
DQS Medizinprodukte GmbH

David Heil

David Heil
Regulatory Affairs Manager

Furthermore, the following items are reusable surgical instruments under Regulation (EU) 2017/745. The corresponding applications that were submitted and signed by RZ Medizintechnik GmbH are subject to approval by DQS Medizinprodukte GmbH:

General product name	Basic UDI-DI covered
Cutting products	40491975LOO-XXX-OOP8U
	40491975LOO-XXX-OPX9F
	40491975TRE-XXX-PHIB7
	40491975TRE-XXX-INEAE
	40491975CHI-XXX-ELXL2
	40491975CHI-XXX-OSTMZ
	40491975SAW-XXX-BLA5F
	40491975HAN-110-DEL3F
	40491975CUT-210-FCPMX
	40491975FOR-XXX-HOL3U
	40491975PUN-XXX-FORG6
	40491975SCI-XXX-SCIXE
	40491975SCI-XXX-ORXZ5
	40491975KNI-110-AMPF3
	40491975SCI-400-NEUFM
Ablating products	40491975SPO-XXX-OONGE
	40491975CUR-XXX-RAS73
	40491975DIS-210-TORER
	40491975DIS-210-ERABM
	40491975EXC-410-TORJV
Holding products	40491975HOO-170-LETM2
	40491975HOO-170-KETLV
	40491975DIS-210-ERABM
	40491975WIR-210-PLIWY
	40491975TRE-XXX-INEAE
	40491975SAW-XXX-BLA5F
	40491975CLA-XXX-AMPGV
	40491975COT-XXX-PLI36
	40491975CUT-210-FCPMX
	40491975NEE-180-HOLAT
	40491975FOR-130-CEPHY
	40491975FOR-130-EPSKH
	40491975FOR-XXX-EPX48
	40491975FOR-XXX-HOL3U
	40491975CLA-XXX-MPXKJ
	40491975CLA-140-AMPYV
	40491975RET-XXX-RAX8U
	40491975RET-XXX-TOXAG
	40491975FOR-300-CLPJG
	40491975SPA-XXX-ULA67
	40491975SPA-XXX-LAX57
	40491975SCI-XXX-SCIXE
	40491975SCI-XXX-ORXZ5
	40491975RET-XXX-RAC7J
	40491975OBS-XXX-FCPY8
	40491975STR-XXX-PERMN
	40491975STR-XXX-IPELS
	40491975LIG-340-TORFM
	40491975CLA-320-AMPZ5
	40491975MAG-XXX-ETXNP

Here you can find an overview of the products that are part of the submitted applications for class IIb:

General product name	Basic UDI-DI covered
Bipolar Scissors open surgery	40491973BIO-XXX-HANLS
Bipolar Scissors MIC	40491973BIO-XXX-SCIND
Bipolar Forceps open surgery	40491973BIM-XXX-SCILX
Bipolar Forceps MIC	40491973BIO-XXX-FCPLS
Bipolar Clamp	40491973BIM-XXX-FCPKC
Bipolar Electrodes openn surgery	40491973BIP-XXX-CLMMP
Bipolar Electrodes MIC	40491973BIO-XXX-ELELS
Bipolar Electrodes MIC - Sterile	40491973BIM-XXX-ELEKC
Handle	40491973BIM-XXX-ELSL8
Monopolar Forceps open surgery	40491973MON-XXX-HAN49
Monopolar Forceps MIC	40491973MON-XXX-FOP5D
Monopolar Electrodes MIC	40491973MON-XXX-FCM43
Monopolar Electrodes MIC	40491973MON-XXX-EMI4L
Suction Irrigation Handle with HF connector	40491973MON-XXX-MIE58

3c. *Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:*

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;
(b) there are no significant changes in the design and intended purpose;
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);
(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

The following items listed on the certificates are covered by assessments under Regulation (EU) 2017/745 by DQS Medizinprodukte GmbH and the corresponding agreements have been signed by RZ Medizintechnik GmbH and DQS Medizinprodukte GmbH:

Endoscopy and accessories	Arthroscopy System IIa Laparoscopy System IIa Hysteroscopy System IIa Ureterorenoscopy System IIa Nephroscopy System IIa Cystoscopy System IIa Discectomy System IIa
Laparoscopy	Suction and irrigation system Cannulas IIa
Endoscopic sheath and accessories	Trocar systems IIa Resectoscopy Resectoscopy System IIa
Equipment	Suction and irrigation pump and accessories IIa Insufflator and accessories IIa

You can find the list of products in a separate confirmation letter.

The following items listed on the certificates are part of applications under Regulation (EU) 2017/745. The applications that were submitted and signed by RZ Medizintechnik GmbH are subject to approval by DQS Medizinprodukte GmbH:

Laparoscopy	Laparoscopy Instruments sterile/non sterile IIb HF-surgery Bipolar Instruments IIb Bipolar Electrodes IIb Monopolar Instruments IIb Monopolar Electrodes sterile/non-sterile IIb High frequency generators IIb Suction and irrigation instruments (HF) IIb
Endoscopic sheath and accessories	Resectoscopy Resectoscopy System IIb Monopolar Electrodes sterile/non-sterile IIb
Equipment	Shaver System IIb

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

RZ Medizintechnik GmbH
Unter Hasslen 20
78532 Tuttlingen

Frankfurt a. M.,
2023-07-20

CONFIRMATION OF CERTIFICATION AND APPLICATION TO FULFILL THE REQUIREMENTS FOR REGULATION (EU) 2023/607

To whom it may concern,

DQS Medizinprodukte GmbH hereby confirms that the company:

RZ Medizintechnik GmbH
Unter Hasslen 20
78532 Tuttlingen

has implemented and maintains a Quality Assurance System that fulfils the requirements of MDD 93/42/EEC. Therefore, devices listed on the certificate with the registration number of 286629 MR2, and the unique ID 170769034 (issued on 2020-04-27 and valid until 2023-08-02) can be placed on the market within the European Union bearing CE-0297 under the responsibility of RZ Medizintechnik GmbH.

According to REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 Article 1, Article 120 of Regulation (EU) 2017/745 is amended as follows:

3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;
(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

DQS Medizinprodukte GmbH
Managing Director:
Sigrid Uhlemann

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