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

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

RZ Medizintechnik GmbH

Herrn Tobias Zubrod
Unter Hasslen 20
78532 Tuttlingen

2023-07-20

Notified Body Confirmation Letter

Reference: 170782063

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

RZ Medizintechnik GmbH
Unter Hasslen 20
78532 Tuttlingen
Germany
SRN: N/A

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a

written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

David Heil

DQS Medizinprodukte GmbH HRB 83350 August-Schanz-Str. 21 60433 Frankfurt am Main

David Heil

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TF-01 Endoscopes **40491975END-XXX-OPEQK** **Cystoscopes** **Hysteroscopes** **Nephroscopes** **Ureterorenoscopes** **Bronchoscopes** **Spinoscopes** **Laryngoscopes** **Otoscopes** **Rhinoscopes** **Arthroscopes** **Laparoscopes** **Thoracoscopes**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**
TF-02 Insufflator **40491975LAP-300-INTBJ** **&** **40491975LAP-300-INSBG** **Gas Insufflator** **Silicon Tubes**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**

TF07 & TF-11 & TF-16 **Suction & Irrigation Instruments** **40491973SIS-300-CANNV & 40491973SIS-300-HANPN** **&** **40491973PUM-300-PEEUD** **Suction & Irrigation Tube / Cannula** **Insuflation Cannula** **Suction and Irrigation Cannula**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**
TF-09 **Endoscopic Sheats** **40491973END-XXX-SHEN5**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**
TF-15 **Spreader / Retractor** **40491973SRR-170-SYS59**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**

TF-18 **Shaver System (Control Unit, Hand Piece, Foot Switch)** **40491973SHA-227-SYSGS**	**IIa**	**N/A**	**Certificate ID: 170772556** **Certificate Registration No.:** **286629 MR**

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
20.07.2023	170782063 -1	Initial issue

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

August-Schanz-Str. 21
60433 Frankfurt am Main
Germany

Phone +49 69 95427-300
Fax +49 69 95427-388
info@dqs-med.de
www.dqsglobal.com

Registered in Frankfurt a.M.
AG HRB 83350
VAT: DE 260 263 917
Tax-No. 045 231 74323

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

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

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

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