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

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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

Herr Tobias Zubrod

Unter Hasslen 20 / 22

78532 Tuttlingen

2024-06-12

Notified Body Confirmation Letter

Reference: 170769034

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 / 22

78532 Tuttlingen

Germany

SRN: DE-MF-000005616

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,

Ronny Doms

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	Class IIa	TF-01 Endoscopes	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2
TF-02 Insufflator Gas Insufflator 40491975LAP-300-INTBJ Silicon Tubes 40491975LAP-300-INSBG	Class IIa	TF-02 Insufflator	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2
310-HF_Instruments & TF-14 Elektrosurgical Unit Electrosurgical Unit 4049197GEN-700-TOR6U 310_001_Bipolar_Devices Handle MIC / open surgery 40491973BIO-XXX-HANLS	Class IIb (no implantable devices)	TF-03 bipolar instruments TF-04 monopolar instruments TF-05 Bipolar Forceps and Electrodes	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2

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
Bipolar Scissors open surgery 40491973BIO-XXX-SCIND Bipolar Scissors MIC 40491973BIM-XXX-SCILX Bipolar Forceps open surgery 40491973BIO-XXX-FCPLS Bipolar Forceps MIC 40491973BIM-XXX-FCPKC Bipolar Clamp 40491973BIP-XXX-CLMMP Bipolar Electrodes open surgery 40491973BIO-XXX-ELELS Bipolar Electrodes MIC 40491973BIM-XXX-ELEKC Bipolar Electrodes MIC – Sterile 40491973BIM-XXX-ELSL8 310_002_Monopolar_Devices Handle 40491973MON-XXX-HAN49 Monopolar Forceps open surgery 40491973MON-XXX-FOP5D Monopolar Forceps MIC 40491973MON-XXX-FCM43		TF-06 Suction and Irrigation Instruments - HF TF-08 Laparoscopic instruments TF-14 Electrosurgical Unit	

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
Monopolar Electrodes MIC 40491973MON-XXX-EMI4L Monopolar Electrodes MIC sterile 40491973MON-XXX-MIE58 Suction Irrigation Handle with HF connector 40491973SIH-300-HANFR Suction Irrigation Electrodes MIC 40491973SIH-300-ELEFR Monopolar Electrodes MIC STERIL 40491973MON-XXX-SEE5S			
210-000_Suction-& Irrigation Instruments & TF-11 Suction & Irrigation Pumps Suction & Irrigation Pumps 40491973PUM-300-PEEUD Suction & Irrigation Tube / Cannula Insuflation Cannula Suction and Irrigation Cannula 40491973SIS-300-CANNV Suction and Irrigation Handpiece 40491973SIS-300-HANPN	Class IIa	TF-07 Suction and Irrigation Instruments TF-16 Suction Tube TF-11 Suction & Irrigation Pumps	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2
TF-09 Endoscopic Sheats 40491973END-XXX-SHEN5	Class IIa	TF-09 Endoscopic Sheats	Certificate ID: 170769034

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
			Certificate Registration No.: 286629 MR2
TF-12 Resectoscope System Resectoscope Sheath / Guide 40491973RES-253-SHHPL Resectoscope Working Element 40491973RES-253-WEEPR Resectoscope Electrodes 40491973RES-253-EEELX Resectoscope Electrodes Sterile 40491973RES-253-SEEP5	Class IIb excluding Class IIb implantable non-WET	TF-12 Resectoscope System	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2
220_Retractors (TF-15) Spreader / Retractor 40491973SRR-170-SYS59	Class IIa	TF-15 Retractor	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2
TF-18 Shaver System 40491973SHA-227-SYSGS	Class IIa	TF-18 Shaver System	Certificate ID: 170769034 Certificate Registration No.: 286629 MR2

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
Tweezer 40491975FOR-130-CEPHY 40491975FOR-130-EPSKH	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Trocar 40491975TRO-XXX-CARG9	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Trephine 40491975TRE-XXX-INEAE 40491975TRE-XXX-PHIB7	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Tonsillectomy instrument 40491975CUR-XXX-RAS73	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Thread guide 40491975NEE-180-HOLAT	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Tester 40491975TES-XXX-ICE7N	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Stripper 40491975STR-XXX-IPELS 40491975STR-XXX-PERMN	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Spreader 40491975RET-XXX-RAC7J	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
Spoon 40491975CUR-XXX-RAS73 40491975SPO-XXX-OONGE	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Spatula 40491975SPA-XXX-LAX57 40491975SPA-XXX-ULA67	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Snare 40491975LOO-XXX-OOP8U 40491975LOO-XXX-OPX9F	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Screwdriver 40491975SCR-200-DRIKX	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Scraper 40491975CUR-XXX-RAS73	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Scissors 40491975SCI-400-NEUFM 40491975SCI-XXX-ORXZ5 40491975SCI-XXX-SCIXE	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Saw 40491975SAW-XXX-BLA5F	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
Retractor 40491975RET-XXX-RAX8U 40491975RET-XXX-TOXAG 40491975SAW-XXX-BLA5F 40491975SCI-XXX-ORXZ5 40491975SCI-XXX-SCIXE 40491975TRE-XXX-INEAE	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Raspatory 40491975DIS-210-ERABM	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Rasp 40491975CUR-XXX-RAS73	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Punch 40491975PUN-XXX-FORG6 40491975SCI-XXX-ORXZ5 40491975SCI-XXX-SCIXE	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Probe 40491975PRO-XXX-OBEDJ 40491975PRO-XXX-OBXEQ	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Positioning guide	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
40491975POS-XXX-DEVDB			
Perforator 40491975PER-XXX-TOR6Q	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Obturator 40491975PRO-XXX-TECEG	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Needle holder 40491975NEE-180-HOLAT	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Needle 40491975NEE-180-DEL99 40491975PER-XXX-TOR6Q	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Magnet 40491975MAG-XXX-ETXNP	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Knife Handle 40491975HAN-110-DEL3F	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Knifes 40491975KNI-110-AMPF3 40491975SCI-XXX-ORXZ5 40491975SCI-XXX-SCIXE	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Hooklet 40491975HOO-170-KETLV	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
40491975HOO-170-LETM2			
Hook 40491975HOO-170-KETLV 40491975HOO-170-LETM2	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Guide 40491975GUI-XXX-INS4A	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Forceps 40491975BON-XXX-FORV3 40491975CLA-XXX-MPXKJ 40491975CUT-210-FCPMX 40491975FOR-300-CLPJG 40491975FOR-XXX-EPX48 40491975FOR-XXX-HOL3U 40491975LIG-340-TORFM 40491975OBS-XXX-FCPY8 40491975PUN-XXX-FORG6 40491975SCI-XXX-ORXZ5 40491975TRE-XXX-INEAE	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
40491975WIR-210-PLIWY			
Filling Instrument 40491975DEN-500-INS6Y	Class I (Rule 6) reusable surgical instruments	N/A	N/A
File 40491975CUR-XXX-RAS73	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Excavator 40491975EXC-410-TORJV	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Elevator 0491975DIS-210-ERABM	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Drill 40491975DRI-200-BITC3	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Dissector 40491975DIS-210-ERABM 40491975DIS-210-TORER	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Dilatator 40491975DIL-XXX-TORSB	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Depressor 40491975HOO-170-KETLV 40491975HOO-170-LETM2	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Curette 40491975CUR-XXX-RAS73	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
40491975SPO-XXX-OONGE			
Cotton carrier 40491975COT-XXX-PLI36	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Compressor 40491975COM-XXX-RESWB	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Clip 40491975CLA-XXX-AMPGV	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Clamp 40491975CLA-140-AMPYV 40491975CLA-320-AMPZ5 40491975CLA-XXX-MPXKJ	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Chisel 40491975CHI-XXX-ELXL2 40491975CHI-XXX-OSTMZ	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Catheter 40491975CAT-XXX-TERNW	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Cannula 40491975CAN-XXX-NLAH9 40491975CAN-XXX-ULAJC	Class I (Rule 6) reusable surgical instruments	N/A	N/A

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
Awl 40491975AWL-210-AWLGW	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Approximator 40491975CLA-140-AMPYV	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Amniotome 40491975PER-XXX-TOR6Q	Class I (Rule 6) reusable surgical instruments	N/A	N/A
Adapter 40491975ADA-XXX-PTRAT 40491975ADA-XXX-TERA2	Class I (Rule 6) reusable surgical instruments	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-06-12	170769034	Initial issue