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.

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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