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

Digitally signed by Rusu Ghenadie
Date: 2021.12.15 07:18:20 EET
Reason: MoldSign Signature
Location: Moldova

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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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.

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

RZ Medizintechnik GmbH
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RZ-Medizintechnik GmbH · Unter Hasslen 20 · 78532 Tuttlingen, Germany

Declaration of Conformity

We

RZ Medizintechnik GmbH
Unter Hasslen 20
78532 Tuttlingen, Germany

herewith declare under our sole responsibility, that following products

253-950-004 Stone Grasping Forceps, 4 Charr., double action, 60cm length

Class I according to rule 6, of MDD 93/42/EEC annex IX,
have been manufactured under consideration of European Medical Device Directive 93/42/EEC, annex VII. The Products are conform to the Essential Requirements of the Medical Device Directive 93/42/EEC Annex I and may therefore be placed into market, labelled with CE. The conformity assessment of the devices according to MDD 93/42/EEC, Annex VII has been performed under our sole responsibility.

Validity of this Declaration of Conformity until 25.05.2024

14.12.2021
Date

General Manager/QM/RA

RZ Medizintechnik GmbH
progress in surgery
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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

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