



# 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	170719855
Effective date	2018-08-03
Expiry date	2023-08-02
Frankfurt am Main	2018-08-03

### 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](mailto: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.



**Annex to certificate**  
**Certificate registration No.: 286629 MR2**  
**Certificate unique ID: 170719855**  
**Effective date: 2018-08-03**

## **RZ Medizintechnik GmbH**

Unter Hasslen 20  
78532 Tuttlingen  
Germany

<b>Device family</b>	<b>Device</b>	<b>Class</b>
Endoscopy and accessories	Arthroscopy System	Ila
	Laparoscopy System	Ila
	Hysteroscopy System	Ila
	Ureterorenoscopy System	Ila
	Nephroscopy System	Ila
	Cystoscopy System	Ila
	Discectomy System	Ila
Laparoscopy	Laparoscopy Instruments sterile/non sterile	Ilb
HF-surgery	Bipolar Instruments	Ilb
	Bipolar Electrodes	Ilb
	Monopolar Instruments	Ilb
	Monopolar Electrodes sterile/non-sterile	Ilb
Suction and irrigation system	Cannulas	Ila
	Suction and irrigation instruments (HF)	Ilb
Endoscopic sheath and accessories	Trocar systems	Ila
Resectoscopy	Resectoscopy System	Ilb + Ila
	Monopolar Electrodes sterile/non-sterile	Ilb
Equipment	Suction and irrigation pump and accessories	Ila
	Insufflator and accessories	Ilb + Ila