



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

RUDOLF

RUDOLF Medical GmbH + Co. KG

Zollerstrasse 1
78567 Fridingen
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:

Non-active instruments (MD 0106), Non-active orthopaedic implants (MD 0202), Non-active functional implants (MD 0203) and Active surgical devices (MD 1104) 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.	492576 MR2
Certificate unique ID	170702227
Effective date	2018-11-21
Expiry date	2023-11-20
Frankfurt am Main	2018-11-21

DQS Medizinprodukte GmbH

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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.



Annex to certificate
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Device family	Device	Class
	Suction / irrigation units for Minimally Invasive Surgery	IIa
	CO2 insufflators for laparoscopy and hysterectomy	IIa
	Irrigation units for arthroscopy	IIa
	Rigid endoscopes for arthroscopy, cystoscopy, hysterectomy, laparoscopy, nephroscopy, neuroendoscopy, otoscopy, resectoscopy, sinuscopy, thoracoscopy, ureterorenoscopy, ventriculoscopy, and microdissectomy	IIa
	Saw blades for bone surgery	IIa
	Self-retaining retractors	IIa
	Endoscope element, sheath / trocar	IIa
Implants for orthopedics and traumatology:	Drillwire, Kirschner	IIb
	Bone nails, Steinmann	IIb
HF generators and Instruments for Open and Minimally Invasive Surgery:	Electro surgical electrode holder	IIb
	Electro surgical return electrode	IIb
	Electro surgical biopsy forceps	IIb
	Electro surgical electrodes	IIb
	HF-electro surgical unit with foot switch	IIb
	Bipolar / monopolar scissors	IIb
	Bipolar / monopolar forceps	IIb
	Electro surgical suction tip	IIb
	Resectoscopes	IIb
	Endoscopic snares	IIb
	Retrieval baskets	IIb