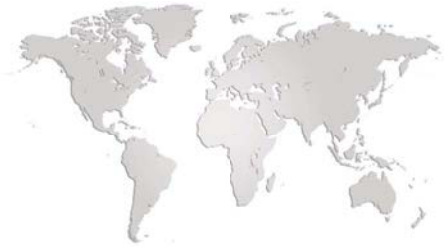
EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z6-00, the decision dated 2017-05-17 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2017-05-17 to 2020-05-16

Registration No.: 50593-16-04

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2017-05-17
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50593-16-04

Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Suction system filter, plume particulate

Class I m:

For the products listed below, the review of the Quality System refers exclusively to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

- Robotic surgical navigation system application software

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone punch
- Bronchoscopy tube
- Cannulated surgical drill, reusable
- Endoscope assembly adaptor
- Endoscope leak tester, mechanical
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic irrigation/aspiration pump
- Endoscopic needle, general-purpose, reusable
- ENT probe
- Flexible fibreoptic bronchoscope
- Flexible fibreoptic choledochoscope
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope
- Fluted surgical drill, reusable
- Fluted surgical drill, single use, sterile
- General-purpose suction system, line-powered
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laparoscopic sleeve
- Laser lithotripsy system
- Line-powered surgical drilling system motor

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Revision status: 0

Valid from 2017-05-17 to 2020-05-16

Devices/device categories included in the certificate:

Class II a:

- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic burr, reusable
- Orthopaedic burr, single use
- Oscillating surgical saw blade, reusable
- Oscillating surgical saw blade, single use
- Particulate water purification filter
- Proctoscope, reusable
- Rectoscope
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscopic cannula, reusable
- Rigid endoscopic cannula, single use
- Rigid endoscopic grasping forceps, reusable
- Rigid endoscope sheath
- Rigid endoscope telescope
- Rigid endoscope working guide
- Rigid hysteroscope
- Rigid intubation laryngoscope
- Rigid mediastinoscope
- Rigid nephroscope
- Rigid oesophagoscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Rigid video laparoscope
- Sagittal surgical saw blade, reusable
- Sagittal surgical saw blade, single use
- Self-retaining surgical retraction system ring
- Spring-loaded pneumoperitoneum needle, reusable
- Stereotactic surgery system probe, reusable
- Suction cannula, reusable
- Suction system tubing
- Surgical drill chuck
- Surgical fluid/smoke waste management system suction unit
- Surgical gouge
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical irrigation tubing set, single-use
- Surgical power tool system control unit, line-powered
- Surgical power tool system handpiece, rotary, pneumatic
- Surgical utensil washer/decontaminator
- Tissue extraction bag
- Tissue morcellation system
- Uterine manipulator

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Revision status: 0

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Devices/device categories included in the certificate:

Class II b:

- Clip, surgical, suture
- Electrohydraulic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system
- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, single-use
- Endoscopic electrosurgical electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- Gastrointestinal endoscopic insufflator
- Hysteroscopic irrigation/insufflation system
- Laser lithotripsy system
- Nasal snare, reusable
- Operating room audiovisual data/device management system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Polymeric ureteral stent
- Ultrasonic lithotripsy system
- Ureteral stent-placement set

DEKRA Certification GmbH * D-70565 Stuttgart, Handwerkstraße 15 * DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2017-05-17
Notified Body ID-number: 0124