

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-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



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. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

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.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

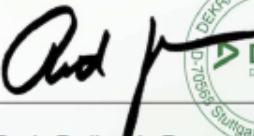
Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/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
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system


Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.
Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization)

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-R2-00.

Certificate registration no.:	50593-14-02	Certificate valid from:	2021-11-29
Validity of previous certificate:	2021-11-28	Certificate valid to:	2024-11-28

DEKRA Certification GmbH • St. 11
70565 Stuttgart, Handwerksstraße 11

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

 **DAkkS**
Deutsche
Akkreditierungsstelle
D-ZM-16029-08-00

Annex to the Certificate No. 50593-14-02

Revision status: 0

valid from 2021-11-29 to 2024-11-28

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Germany	see page 1
	at the following locations / at the companies at the following locations		Scope of certification
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Germany	Manufacture of flexible and rigid endoscopes



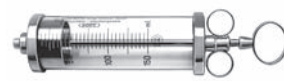
Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

Basic Set for TUR

Shark Resectoscope, bipolar
telescope 4 mm, 12° / 30°
24/26 Fr., active,
Continuous irrigation

Basis Set zur TUR

Shark Resektoskop, bipolar
Optik 4 mm, 12° / 30°
24/26 Charr., aktiv,
Dauerspülung

			Außenschaft, 26 Charr. Outer sheath, 26 Fr.	8675426	
			Innenschaft, 24 Charr. Inner sheath, 24 Fr.	8675324	
			Dilatationsobturator Dilation obturator	8673224	
alternativ / alternative				Sichtobturator Viewing obturator	8673124
alternativ / alternative				Obturator Obturator	8673024
			Arbeitselement, aktiv, bipolar Working element, active, bipolar	8680.205	
			PANOVIEW-Optik	12°	8654.431
			PANOVIEW telescope	12° PDD blue	8654.531
				30°	8654.422
				30° PDD blue	8654.522
 4622.1313	 4623.0223	 46300243	Schneide-Elektrode / Cutting electrode	4622.1313	
			Koag.-Elektrode / Coag. electrode	4623.0223	
			BiVAP-Elektrode / BiVAP electrode	46300243	
			Bipolar Anschlusskabel Bipolar connecting cable	siehe Seite see page D 260	
			FLUID CONTROL 2225 Spülpumpe FLUID CONTROL 2225 Irrigation Pump	22250011	
			Urethrotom nach Otis Otis knife	8517.00	
			Ersatzmesser Spare knife	8517.90	
			Blasenspritze Bladder syringe	822.31	
822.13			Flexibler Ansatz Flexible connector	822.13	



Bipolare Electrodes

for multiple use

12°/30°



Bipolare Elektroden

zum Mehrfachgebrauch

12°/30°

für Dauerspül-Schaft for continuous-irrigation sheath	Bügel Loop	Stiel Stem	Für Schaftgrößen in Charr. / for sheath sizes in Fr.			
			DS 22/24	iS 24	DS 24/26	iS 26
Schneide-Elektrode Cutting electrode 	Schlinge Loop 0.3 mm	Gabel Branches	blau / blue	blau / blue	blau / blue	blau / blue
			8622133	8622131	8622131	8622131
		Stiel Stem	gelb / yellow	gelb / yellow	gelb / yellow	gelb / yellow
Koagulations-Elektrode Coagulating electrode 	Zylinder Cylinder 1.2 mm	Gabel Branches	blau / blue	blau / blue	blau / blue	blau / blue
			8623022	8623022	8623022	8623022
		Stiel Stem	gelb / yellow	gelb / yellow	gelb / yellow	gelb / yellow
Haken-Elektrode Hook electrode 	Haken Hook	Gabel Branches	blau / blue	blau / blue	blau / blue	blau / blue
			862309	862309	862309	862309
		Stiel Stem	gelb / yellow	gelb / yellow	gelb / yellow	gelb / yellow

DS = Dauerspülung / Continuous irrigation

iS = intermittierende Spülung / intermittent irrigation



Protective Sterilization Sleeve for a maximum of
5 resection or vaporisation electrodes
or urethrotome knives,
outer Ø 20 mm, length 328 mm 8428.901

Sterilisations-Schutzhülse zur Aufnahme von
max. 5 Resektions- oder Vaporisations-Elektroden
oder Urethrotommesser,
Außen-Ø 20 mm, Länge 328 mm 8428.901

Unique – the variety of COMFORT instruments



Monopolar resectoscope	Storz/Wolf	106-145
	Storz	106-245
	Olympus	106-345
Bipolar resectoscope	Storz	352-145
	Wolf	354-145
	Olympus	355-145
Argon	Flexible	932-146
TissueSeal	190 mm	760-319
	230 mm	760-323
	280 mm	760-328
TissueSeal PLUS	160 mm	760-216
	190 mm	760-219
	230 mm	760-223
	280 mm	760-228
BIZZER fine	145 mm	795-545