

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
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

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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



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



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





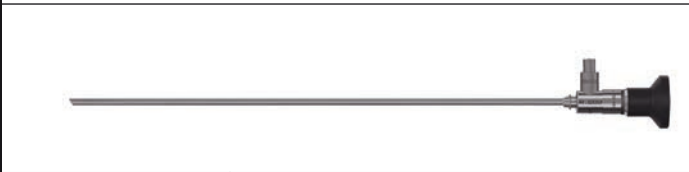








Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2021-11-29

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

 <p>8675426 8675324</p>	<p>Außenschafft, 26 Charr. Outer sheath, 26 Fr.</p> <p>Innenschafft, 24 Charr. Inner sheath, 24 Fr.</p>	<p>8675426</p> <p>8675324</p>								
	<p>Dilatationsobturator Dilation obturator</p>	<p>8673224</p>								
<p>alternativ / alternative</p>	<p>Sichtobturator Viewing obturator</p>	<p>8673124</p>								
<p>alternativ / alternative</p>	<p>Obturator Obturator</p>	<p>8673024</p>								
	<p>Arbeitselement, aktiv, bipolar Working element, active, bipolar</p>	<p>8680.205</p>								
	<p>PANOVIEW-Optik PANOVIEW telescope</p>	<table border="1"> <tr> <td>12°</td> <td>8654.431</td> </tr> <tr> <td>12° PDD blue</td> <td>8654.531</td> </tr> <tr> <td>30°</td> <td>8654.422</td> </tr> <tr> <td>30° PDD blue</td> <td>8654.522</td> </tr> </table>	12°	8654.431	12° PDD blue	8654.531	30°	8654.422	30° PDD blue	8654.522
12°	8654.431									
12° PDD blue	8654.531									
30°	8654.422									
30° PDD blue	8654.522									
 <p>4622.1313</p>	 <p>4623.0223</p>	 <p>46300243</p>								
	<p>Schneide-Elektrode / Cutting electrode Koag.-Elektrode / Coag. electrode BiVAP-Elektrode / BiVAP electrode</p>	<p>4622.1313 4623.0223 46300243</p>								
	<p>Bipolar Anschlusskabel Bipolar connecting cable</p>	<p>siehe Seite see page D 260</p>								
	<p>FLUID CONTROL 2225 Spülpumpe FLUID CONTROL 2225 Irrigation Pump</p>	<p>22250011</p>								
	<p>Urethrotom nach Otis Otis knife</p>	<p>8517.00</p>								
	<p>Ersatzmesser Spare knife</p>	<p>8517.90</p>								
 <p>822.13</p>	 <p>822.31</p>	<p>Blasenspritze Bladder syringe Flexibler Ansatz Flexible connector</p> <p>822.31 822.13</p>								






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

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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

HF Connecting Cables
for resection in saline

Bipolar Anschlusskabel
zur Resektion in Kochsalzlösung

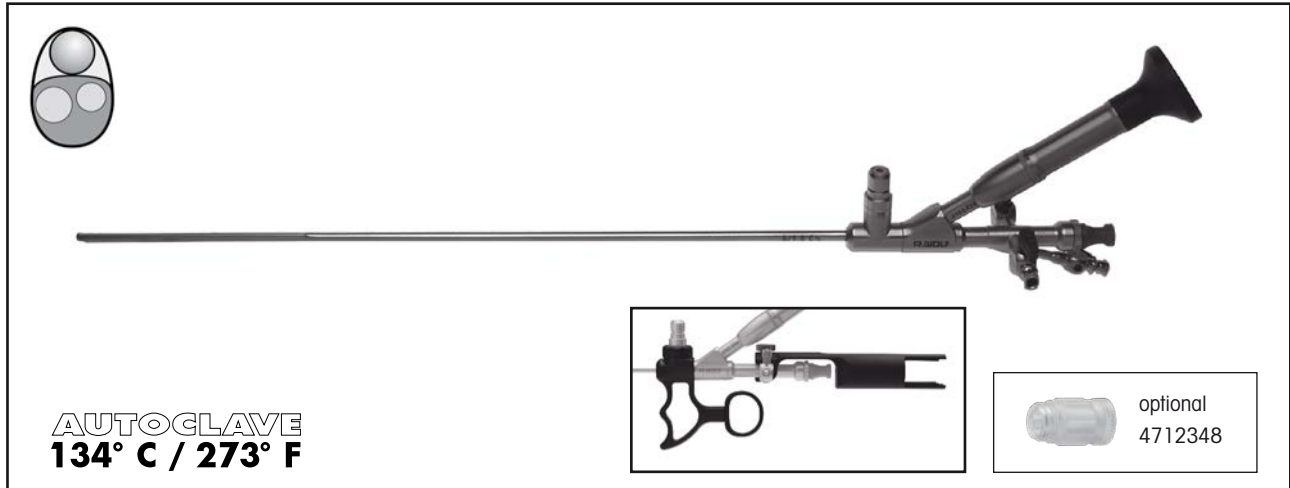
Anschluss Instrument <i>Connector for instrument</i>	Anschluss Gerät <i>Connector for unit</i>	Länge <i>Length</i>	Typen <i>Types</i>
		3 m	8108.232
	ERBE	5 m	8108.252
		3 m	8108.231
	Martin	5 m	8108.251

E-line

Fiber Ureterorenoscope
by Bichler
with oblique eyepiece

E-line

Fiber Ureterorenoskop
nach Bichler
mit seitlichem Einblick



- Stone therapy with laser, ultrasound, electrohydraulic or ballistic lithotripsy
- Rigid accessory instruments can be used through the straight instrument channel
- Use of flexible accessory instruments or two different instruments such as laser fibre or electrohydraulic probe and stone baskets to stabilise and retrieve the concretum

- Steintherapie mit Laser, Ultraschall, elektrohydraulischer oder ballistischer Lithotripsie
- Einsatz von robusten, starren Hilfsinstrumenten im geraden Sondenkanal möglich
- Verwendung von flexiblen Hilfsinstrumenten oder zwei verschiedenen Instrumenten wie z.B. Laser-Faser oder elektrohydraulische Sonde und Steinfangkörbchen zur Fixierung und Bergung des Konkrements

7

Fiber Ureterorenoskop E-line mit ovalem Spül- und Sondenkanal, einschließlich automatischem Ventil zur Instrumenteneinführung Fiber ureterorenoscope E-Line with oval irrigation and instrument channel, including automatic valve for inserting instrument	Nutzlänge <i>Working length</i>	Gesamtlänge <i>Total length</i>	Optik <i>Telescope</i>	Charr. <i>Fr.</i>	Spül- und Sondenkanal Charr. <i>Irrigation and instrument channel Fr.</i>	für Hilfsinstrumente Charr. <i>for accessory instruments Fr.</i>	Type
Fiber-Uretero-Renoskop E-line nach Bichler Fiber uretero-renoscope E-line by Bichler	430 mm	563 mm	12°	8 / 9.8	5.2 x 6.2	1 x 5 oder / or 2 x 3	8703.534

Accessories:

- Handle** 8702.261
- Guide** for Lithoclast handpiece 8702.251
- For inserting accessory instruments of 1 – 6 Fr.:
- Universal sealing valve, sterile (pack of 5)** 4712348
- Membrane retainer, standard**..... 15256.393
- Membrane retainer with Luer** 15256.456
- Membrane seal (pack of 10)**..... 89.101
- Fiber light cable set, Ø 2.5 mm, 2.3 m long consisting of:**
Fiber light cable (80662523), adapter projector side (8095.07) and
adapter endoscope side (809509) 806625231

Zubehör:

- Handgriff** 8702.261
- Führungsteil** für Lithoclast-Handstück..... 8702.251
- Zum Einführen von Hilfsinstrumenten von 1 – 6 Charr.:
- Universal Dichtventil, steril (VE = 5 St.)**..... 4712348
- Membranaufnahme, Standard**..... 15256.393
- Membranaufnahme mit Luer**..... 15256.456
- Membrandichtung (VE = 10 Stück)** 89.101
- Fiber Lichtleiter Set, Ø 2,5 mm, 2,3 m lang bestehend aus:**
Fiber Lichtleiter (80662523), Adapter projektorseitig (8095.07) und
Adapter endoskopseitig (809509) 806625231

Hilfsinstrumente siehe Seite / Accessory instruments see page D 355