

# 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

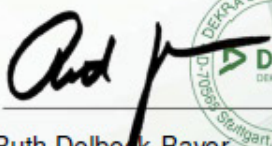
**Certified location:**

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](http://www.dekra-certification.de)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://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](http://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).

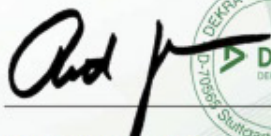
### Certified location:

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-Z7-00.

Certificate registration no.:	50593-14-01	Certificate valid from:	2020-04-01
Validity of previous certificate:	2020-03-31	Certificate valid to:	2023-03-31

  
Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-04-01



# Annex to the Certificate No. 50593-14-01

Revision status: 0

valid from 2020-04-01 to 2023-03-31

The following locations / companies belong to the certificate above:








	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	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 Deutschland	Manufacture of flexible and rigid endoscopes



Ruth Dellbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2020-04-01

**vision EF**  
flexible Sensor Cystoscope  
Accessories and auxiliary instruments

**vision EF**  
flexibles Sensor-Cystoskop  
Zubehör und Hilfsinstrumente

	Außen - Ø Outer - Ø	NL WL	Typen Types
<b>Flexible Biopsiezange</b> <i>Flexible biopsy forceps</i> 	1.6 mm 5 Charr. / Fr.	550 mm	<b>829.051</b>
<b>Flexible Fasszange</b> <i>Flexible grasping forceps</i> 	1.6 mm 5 Charr. / Fr.	550 mm	<b>8735.685</b>
<b>Lasersfaser</b> für Nierensteine mit MegaPulse 30+ Laser, einzel steril verpackt, zum Einmalgebrauch <i>Laser fiber</i> for kidney stones with MegaPulse 30+ laser, packed singly, sterile, for single use	365 µm		<b>487501365</b>
	550 µm		<b>487501550</b>
<b>Ansatz</b> mit Instrumenten-Einführungshahn <i>Adapter</i> with instrument insertion tap 			<b>7305.782</b>
<b>Universal Dichtventil</b> (VE = 5 St.) zum Einführen von Hilfsinstrumenten von 1 – 6 Charr., steril, Einmalgebrauch <i>Universal sealing valve</i> (pack of 5) for inserting auxiliary instruments of 1 – 6 Fr., steril, for single use 			<b>4712348</b>
<b>Adapter</b> für maschinellen Dichtigkeitstest <i>Adapter</i> for automatic leak test 			<b>163.905</b>
Zum Verschließen des 2. Luer-Anschlusses: <b>Luer-Verschlusskappe</b> <i>For closing the 2nd luer connector: Luer sealing cap</i> 			<b>15023205</b>
<b>Spülset V</b> mit Doppel-Luer-Lock-Schlauchteil <i>Rinsing set V</i> with double luer lock tube connector 			<b>163910</b>











6

**Basic Set for TUR**

**Shark** Resectoscope, monopolar  
Telescope 4 mm, 12° / 30°  
26/24 Fr., active,  
continuous irrigation

**Basis Set zur TUR**

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

 <p>8675426      8675324</p>	<p>Außenschaft, 26 Charr. <i>Outer sheath, 26 Fr.</i></p>	<p>8675426</p>
	<p>Innenschaft, 24 Charr. <i>Inner sheath, 24 Fr.</i></p>	<p>8675324</p>
	<p>Dilatationsobturator <i>Dilation obturator</i></p>	<p>8673224</p>
<p>alternativ / alternative</p>	<p>Sicht-Obturator <i>Viewing obturator</i></p>	<p>8673124</p>
<p>alternativ / alternative</p>	<p>Obturator <i>Obturator</i></p>	<p>8673024</p>
	<p>Arbeitselement, aktiv <i>Working element, active</i></p>	<p>8674205</p>
	<p>PANOVIEW-Optik      12°</p>	<p>8654.431</p>
	<p>                                         12° PDD blue</p>	<p>8654.531</p>
	<p>PANOVIEW telescope      30°</p>	<p>8654.422</p>
	<p>                                         30° PDD blue</p>	<p>8654.522</p>
 <p>46782435      46782201</p>	<p>Schneide-Elektrode / <i>Cutting electrode</i></p>	<p>46782435</p>
	<p>Koag.-Elektrode / <i>Coag. electrode</i></p>	<p>46782201</p>
	<p>Sterilisations-Schutzhülse <i>Protective sterilisation sleeve</i></p>	<p>8428.901</p>
	<p>HF-Monopolar Anschlusskabel <i>HF monopolar connecting cable</i></p>	<p>siehe Seite <i>see page</i> D 259</p>
	<p>Urethrotom nach Otis <i>Otis knife</i></p>	<p>8517.00</p>
	<p>Ersatzmesser <i>Spare knife</i></p>	<p>8517.90</p>
	<p>FLUID CONTROL 2225 Spülpumpe <i>FLUID CONTROL 2225</i> <i>Irrigation Pump</i></p>	<p>22250011</p>
 <p>822.13      822.31</p>	<p>Blasenspritze <i>Bladder syringe</i></p>	<p>822.31</p>
	<p>Flexibler Ansatz <i>Flexible connector</i></p>	<p>822.13</p>









### Monopolar Electrodes

for multiple use  
12°/30°



### Monopolare Elektroden

zum Mehrfachgebrauch  
12°/30°

für Dauerspül-Schaft for continuous-irrigation sheath	B_gel Loop	Stiel Stem	Für Schaftgrößen in Charr. / for sheath sizes in Fr.				
			Ds 22/24	iS 24	Ds 24/26	iS 26	
<b>Schneide-Elektrode</b> <i>Cutting electrode</i> 	Schlinge Loop 0.35 mm	Gabel Branches	grün / green	gelb / yellow	gelb / yellow	schwarz / black	
			86782235	86782435	86782435	86782635	
	Schlinge Loop 0.8 mm	Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	
		Gabel Branches	-	gelb / yellow	gelb / yellow	-	
				-	86782480	86782480	-
			Stiel Stem	-	dunkelgrau / dark gray	dunkelgrau / dark gray	-
<b>Koagulations-Elektrode</b> <i>Coagulating electrode</i> 	Rolle Roller	Gabel Branches	grün / green	gelb / yellow	gelb / yellow	schwarz / black	
			86782201	86782201	86782201	86782601	
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	
<b>Koagulations-Elektrode</b> <i>Coagulating electrode</i> 	Kugel Sphere	Gabel Branches	grün / green	grün / green	grün / green	-	
			86782202	86782202	86782202	-	
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	-	
<b>Koagulations-Elektrode</b> <i>Coagulating electrode</i> 	Knopf Button	Gabel Branches	grün / green	gelb / yellow	gelb / yellow	schwarz / black	
			86782203	86782203	86782203	86782603	
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	
<b>Messer-Elektrode</b> <i>Knife electrode</i> 	Messer Knife	Gabel Branches	grün / green	grün / green	grün / green	schwarz / black	
			86782204	86782204	86782204	86782604	
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	
<b>Haken-Elektrode</b> <i>Hook electrode</i> 	Haken Hook	Gabel Branches	grün / green	grün / green	grün / green	schwarz / black	
			86782205	86782205	86782205	86782605	
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	

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

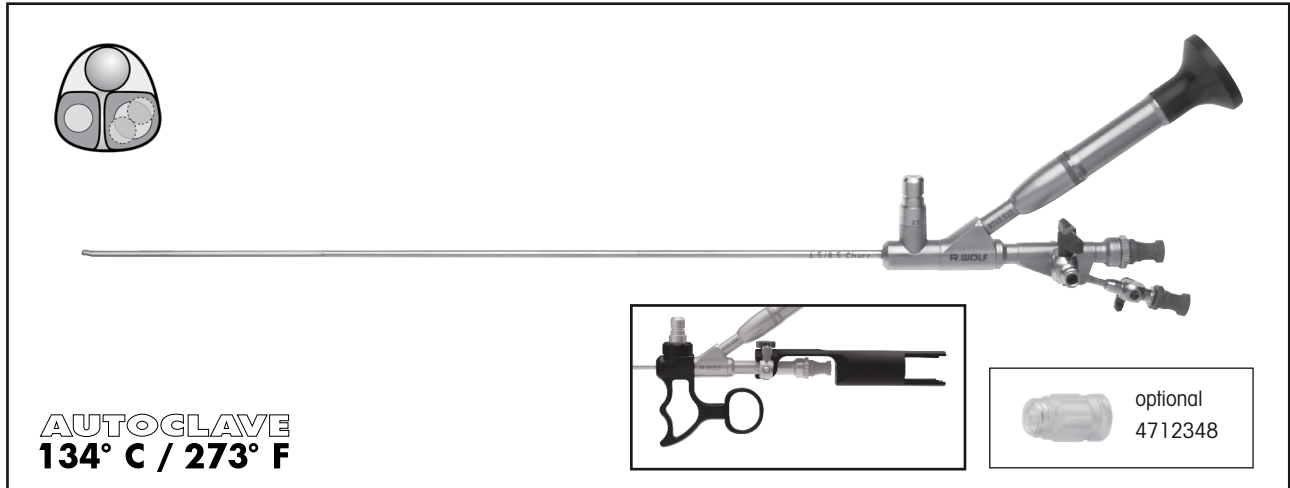


*E-line*

**Continuous-Irrigation Ureterorenoscope**  
with oblique eyepiece

*E-line*

**Dauerspül-Ureterorenoskop**  
mit seitlichem Einblick



- Optimum view
- Largest working channels – with smallest outer dimensions
- Simultaneous use of two accessory instruments
- No annoying "Flush-back" effect
- High-quality materials for maximum stability and long working life

- Optimale Sichtverhältnisse
- Größte Arbeitskanäle – bei kleinstem Außenmaß
- Gleichzeitiger Einsatz von zwei Hilfsinstrumenten
- Kein lästiger "Flush-back" Effekt
- Hochwertige Materialien für höchste Stabilität und Langlebigkeit

Dauerspül-Ureterorenoskop mit Spül- und Sondenkanal <i>Continuous-irrigation ureterorenoscope with irrigation and instrument channel</i>	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
Dauerspül-Ureterorenoskop, seitlicher Einblick, mit 2-Kanal Dauerspül-System <i>Continuous-irrigation ureterorenoscope, oblique eyepiece, with 2-channel continuous-irrigation system</i>	430	563 mm	5°	6.5 / 8.5	1 x 4.2 und / and 1 x 2.55	1 x 4 und / and 1 x 2.4	<b>8708.534</b>

Accessories:

- Handle** ..... 8702.261
- Guide for Lithoclast handpiece** ..... 8702.251
- For inserting auxiliary 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:

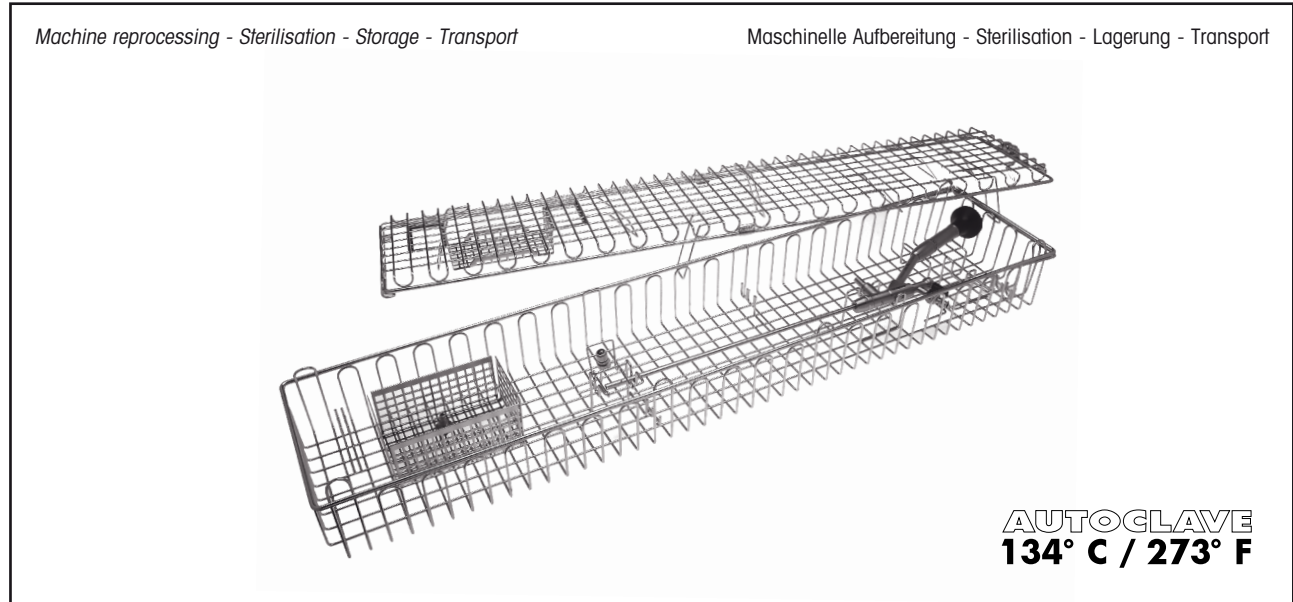
- Handgriff** ..... 8702.261
- Führungsteil für Lithoclast-Handstück** ..... 8702.251
- Zum Einführen von Hilfsinstrumenten von 1 – 6 Charr.:
- Universal Dichtventil, steril (VE = 5 St.)** ..... 4712348
- Membranaufnahme, Standard** ..... 15256.393
- Membranaufnahme mit Luer** ..... 15256.456
- Membrandichtung (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

### Instrument Care Systems

for miniature nephroscope  
15 / 18 Fr. by Lahme

### Aufbereitungs-Systeme

für Miniatur-Nephroskop  
15 / 18 Charr. nach Lahme



1

Reprocess basket ..... **38045.111**










Aufber. Korb ..... 38045.111

Marker pen ..... 38201.948

Markierungsstift ..... 38201.948

Forceps and Scissors,  
flexible





Zangen und Scheren,  
flexibel

		Einsatzgebiete <i>Fields of application</i>	Nutzlänge <i>Working length</i>	Charr. <i>Fr.</i>	Typen <i>Types</i>
	Biopsiezeange <i>Biopsy forceps</i>	Cystoskopie <i>Cystoscopy</i>	230 mm	3	<b>829.03</b>
			315 mm	5	<b>829.05</b>
			375 mm	7	<b>829.07</b>
			325 mm	10	<b>829.10</b>
	Biopsiezeange <i>Biopsy forceps</i>	Ureterorenoskopie, Nephroskopie <i>Ureterorenoscopy, nephroscopy</i>	550 mm	5	<b>829.051</b>
	Biopsiezeange <i>Biopsy forceps</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	530 mm	3	<b>829.603</b>
			920 mm	3	<b>829.601</b>
	Biopsiezeange <i>Biopsy forceps</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	550 mm	3.5	<b>8953.60</b>
	Fremdkörper-Fasszange <i>Foreign body forceps</i>	Cystoskopie <i>Cystoscopy</i>	230 mm	3	<b>828.03</b>
			315 mm	5	<b>828.05</b>
			365 mm	7	<b>828.07</b>
			325 mm	10	<b>828.10</b>
	Fremdkörper-Fasszange <i>Foreign body forceps</i>	Ureterorenoskopie, Nephroskopie <i>Ureterorenoscopy, nephroscopy</i>	530 mm	3	<b>828.605</b>
			550 mm	5	<b>828.051</b>
	Fremdkörper-Fasszange <i>Foreign body forceps</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	920 mm	3	<b>828.651</b>
	Schere, mit Wellengriff <i>Scissors, wave shaped</i>	Cystoskopie <i>Cystoscopy</i>	375 mm	7	<b>830.07</b>
	Mauszahn-Fasszange <i>Mouse-tooth grasping forceps</i>	Cystoskopie <i>Cystoscopy</i>	550 mm	5	<b>8735.685</b>
			550 mm	6.6	<b>8736.685</b>

*Injection Cannulas and  
Electrodes*






Injektionskanülen und  
Elektroden

5



		Einsatzgebiete <i>Fields of application</i>	Nutzlänge <i>Working length</i>	Charr. <i>Fr.</i>	Type <i>Type</i>
	<b>Koagulations-Elektrode</b> <i>Coagulation electrode</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	600 mm	5	<b>8599.80</b>
	<b>Koagulations-Elektrode</b> <i>Coagulation electrode</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	920 mm	3	<b>8741.80</b>
	<b>Koagulations-Elektrode</b> unipolar <i>Button electrode</i> unipolar	Cystoskopie <i>Cystoscopy</i>	400 mm	4	<b>823.04</b>
				5	<b>823.05</b>
				6	<b>823.06</b>
				10	<b>823.10</b>
		Ureterorenoskopie <i>Ureterorenoscopy</i>	580 mm	3	<b>823.031</b>
	<b>Haken-Elektrode</b> <i>Hook electrode</i>	Ureterorenoskopie <i>Ureterorenoscopy</i>	600 mm	2.4	<b>823.221</b>

# Overview of the range

## Light Cables in new design

Fiber Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 <p><b>Set bestehend aus:</b> Fiber Lichtleiter, Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509)</p> <p>* Die Lichtleiter können auch ohne Adapter bestellt werden. Adapter zum Anschluss an Fremdprodukte bieten wir separat an (siehe unten).</p>		1,6 mm	1,8 m	806616181	80661618*
			2,3 m	806616231	80661623*
			3,0 m	806616301	80661630*
		2,5 mm	1,8 m	806625181	80662518*
			2,3 m	806625231	80662523*
			3,0 m	806625301	80662530*
		3,5 mm	1,8 m	806635181	80663518*
			2,3 m	806635231	80663523*
			3,0 m	806635301	80663530*
			3,5 m	806635351	80663535*
		5,0 mm	2,3 m	806650231	80665023*
			3,0 m	806650301	80665030*
3,5 m			806650351	80665035*	

## Fused *fusion* light cables, resistant to high temperatures

fusion Light Cable Set	Color identification, endoscope-side	Ø Fiber bundle and color code	Length	Order number	Order number without adapter
 <p><b>Set comprises:</b> Fiber Light Cable, adapter projector-light source-end (8095.07) and adapter endoscope-end (809509)</p> <p>*The <i>fusion</i> light cables can also be ordered without adapters and they are compatible with the same adapters.</p>		5,0 mm	2,3 m	806550231	80655023*
			3,0 m	806550301	80655030*
			3,5 m	806550351	80655035*

## Adapters for light cables

for connection to **light sources** from the following manufacturers:

Wolf, Stryker..... 8095.07	
Storz	no adapter necessary
Olympus..... 8096.811	



for connection to **endoscopes** from the following manufacturers:

Wolf..... 809509	
Storz, Stryker, Olympus..... 807001	
ACMI, Circon, Henke-Sass-Wolf..... 807002	

