

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

[illegible]

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

- 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

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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).

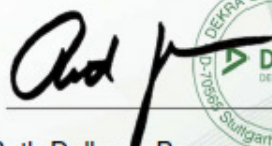
Certified location:

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-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



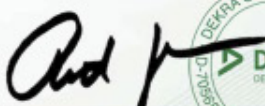
Annex to the Certificate No. 50593-14-01

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



Certificate



spirit of excellence

This is to certify that

Mr. Artiom Pascal
of Endo-Chirurgie Ltd

has successfully attended an **advanced service training** at the premises of the
Richard Wolf Prima Vista Academy in Knittlingen from
11th of November, 2015 up to 13th of November, 2015.

The following contents were conveyed:
Operating, handling, checking and troubleshooting
of following electro medical devices:

LED Light Source 1.1 (5160), 1.2 (5161), 1.3 (5162), 2.1 (5163)
Xenon Light Source Highlight 5132 and X300 (5142)

Basics of Video Technology
1 CCD Endocam Performance HD (5514)
3 CCD Endocam 5550 and Logic HD (5525)

Monitors LCD with software update NDS

Basics of Image & Archiving
Core Docu HD, Mediacapture USB300 and Victor

Core Control and Core Nova

Insufflators 2232 and HighFlow 2235 (software update)
Laparo Pump 2216 (software update)
Fluid Control (2204) with software update
Power Drive Art 1 (2304) with software update
and change of motor handle cable

Video Cart/Wiring

This certificate is only valid for participants in an employment relationship with the above named company.

Marek Rast
Head of Technical Support and Training

Donald Smolin
Technical Support and Training

Knittlingen, 11/13/2015

Richard Wolf GmbH

Service Department

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

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



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
Schneide-Elektrode Cutting electrode 	Schlinge Loop 0.35 mm	Gabel Branches	grün / green	gelb / yellow	gelb / yellow	schwarz / black
			86782235	86782435	86782435	86782635
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray
	Schlinge Loop 0.8 mm	Gabel Branches	-	gelb / yellow	gelb / yellow	-
			-	86782480	86782480	-
		Stiel Stem	-	dunkelgrau / dark gray	dunkelgrau / dark gray	-
Koagulations-Elektrode Coagulating electrode 	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
Koagulations-Elektrode Coagulating electrode 	Kugel Sphere	Gabel Branches	grün / green	grün / green	grün / green	-
			86782202	86782202	86782202	-
		Stiel Stem	dunkelgrau / dark gray	dunkelgrau / dark gray	dunkelgrau / dark gray	-
Koagulations-Elektrode Coagulating electrode 	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
Messer-Elektrode Knife electrode 	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
Haken-Elektrode Hook electrode 	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

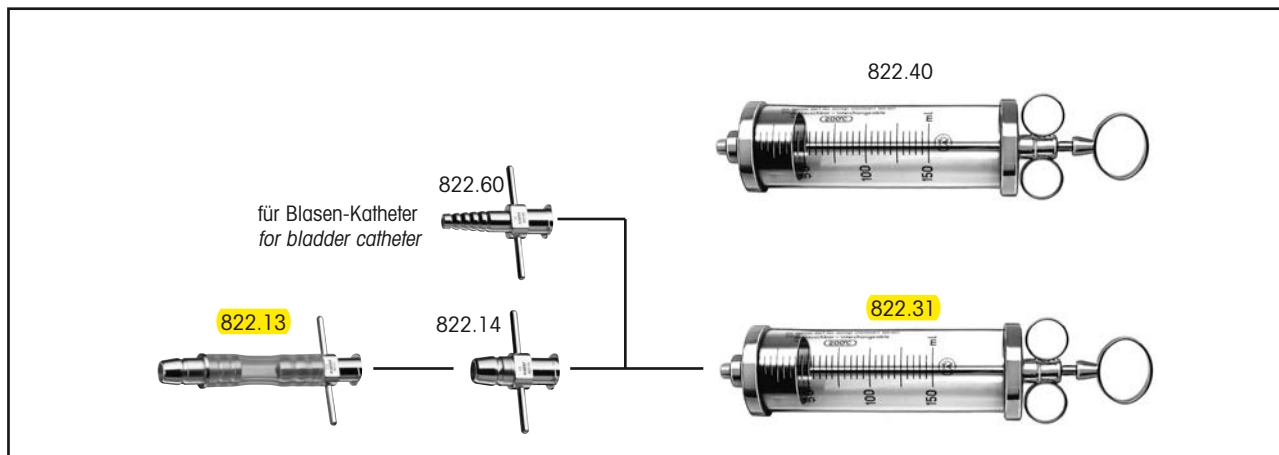
8428.901

Sterilisations-Schutzhülse zur Aufnahme von
max. 5 Resektions- oder Vaporisations-Elektroden
oder Urethrotommesser,

Außen-Ø 20 mm, Länge 328 mm

Bladder Syringe

Blasenspritzen



	Ø	ml	Ersatz-Zylinder Spare barrel	Typen Types
Blasenspritze für flexible und starre Ansätze Bladder syringe for flexible or rigid adapters	54 mm	150	82295	822.31
Ansatz zum flexiblen Ansetzen der Spritze Adapter for flexible connection of syringe				822.13
Ansatz zum starren Ansetzen der Spritze Adapter for rigid connection of syringe				822.14
Ansatz starr für Blasenspritze Rigid adapter for bladder syringe				822.60
Blasenspritze Bladder syringe	54 mm	150	82295	822.40
Adapter für Toomey-Spritze, mit Kegel Adapter for Toomey syringes, with cone				845.11

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
 Set bestehend aus: Fiber Lichtleiter, Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509) * Die Lichtleiter können auch ohne Adapter bestellt werden. Adapter zum Anschluss an Fremdprodukte bieten wir separat an (siehe unten).		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*
		5,0 mm	3,5 m	806635351	80663535*
			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
 Set comprises: Fiber Light Cable, adapter projector-light source-end (8095.07) and adapter endoscope-end (809509) *The <i>fusion</i> light cables can also be ordered without adapters and they are compatible with the same adapters.		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

