

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
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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

ENDOCAM Flex HD

Camera controller

ENDOCAM

1



- Small design – low space requirement
- Attractive price-performance ratio
- For universal use in urology and pneumology with the new, flexible sensor endoscopes
- Optional camera head when using rigid endoscopes
- Adaptation of various C-Mount lenses

- Integrated VESA 100 interface for mounting to the wall or on the side of a device cart
- Optional: Bracket for adaptation to a monitor
 - Please note the ordering details of the recommended mounting accessories
- Documentation on PC / laptop possible via ENDOCAM Flex documentation software

ENDOCAM Flex HD camera controller

bndl **555211011**

Comprising:

1x ENDOCAM Flex HD camera controller	5521101
1x HDMI/DVI-D cable, lockable, 3 m	103843
1x power cable	2440.03

ENDOCAM Flex HD

Technical data of camera controller

Camera controller		5521101
Device properties		
Max. native video signal resolution	1920 x 1080 pixels	
White balance, color temperature range	2300 K to 7000 K	
Noise level	Noiseless, as no fan installed	
Digital zoom	1.5x max.	
Brightness control	Rolling shutter	
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa	
Operating mode	Continuous operation	
Equipment		
IP rating	IP20	
Cooling method	Passive	
VESA mount	VESA 100 x 100 mm	
Power supply		
Mains + frequency	100-240 VAC, 50/60 Hz	
Power consumption	12 VA	
Current rating	0.1 - 0.05 A	
Regulatory standards		
Safety	US/ CA: UL 2601-1 / CSA C22.2 NO.601.1, EU: EN 60601	
EMC	EN 60601-1-2 / IEC 601-1-2	
Medical device class	Class 1	
Classification of applied part	BF	
Interfaces		
Video outputs	1x HDMI	
Resolution (HDMI output)	1920 x 1080 / 60p (16:9)	
USB port	USB 3.0	
Dimensions and weights		
Weight	1.5 kg	
Dimensions (W x H x D)	150 x 58 x 245 mm	

ENDOCAM Flex HD

Camera head

ENDOCAM



- Universally applicable in all endoscopic disciplines thanks to very high sensitivity
- C-Mount connection: universal application – even for easy adaptation to OR microscopes
- Small, weight-reduced camera head with two function buttons
- Ergonomic, stress-free handling
- Accurate color rendering thanks to sophisticated color calibration
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Flex HD camera head **5521902**

1-chip type, C-Mount, cable length 2.5 m

Recommended accessories		Product no.
RIWO zoom lens	f = 13 - 29 mm	85261504
Angular lens	f = 17 mm	5257171

ENDOCAM Flex HD

Technical data of CCD camera head

Camera head		5521902
Device properties		
Sensor	1x 1/3" CMOS	
Operation	2 head buttons with preprogrammed functions	
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa	
Equipment		
Thread for objective lens	C-Mount	
Degree of protection against the ingress of moisture	IPX7	
Service	Cable exchangeable	
Dimensions and weight		
Camera head weight (without cable)	125 g	
Housing dimensions (W x H) - without cable and anti-kink protection	34 x 34 mm	
Camera head length (without cable)	110 mm	
Cable length	2.5 m	
Cable outlet	30°	

RIWO lenses

RIWO zoom lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine		Product no.
 <p>AUTOCLAVE 134° C / 273° F</p>	<p>RIWO zoom lens f = 21 - 36 mm</p>	<p>85261.501</p>
RIWO zoom lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine		
 <p>AUTOCLAVE 134° C / 273° F</p>	<p>RIWO zoom lens f = 13 - 29 mm</p>	<p>85261504</p>
RIWO zoom lens with snap-on mechanism and C-Mount thread, reprocessable by machine and suitable for low-temperature procedure		
	<p>RIWO zoom lens f = 13 - 29 mm</p>	<p>5261504</p>
RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine		
 <p>AUTOCLAVE 134° C / 273° F</p>	<p>RIWO lens f = 14 mm</p>	<p>85261144</p>
	<p>RIWO lens f = 24 mm</p>	<p>85261244</p>
RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine		
 <p>AUTOCLAVE 134° C / 273° F</p>	<p>RIWO lens f = 27 mm</p>	<p>85261.272</p>
	<p>RIWO lens f = 32 mm</p>	<p>85261.322</p>

ENDOLIGHT Flex LED

LED light source



5 Light sources

- Extremely compact design
- The light output is comparable to a 180-watt xenon illuminant
- The LED illuminant exhibits only minimal power loss over the entire service life
- The LED service life is at least 30,000 hours
- The LED light source reduces power consumption by up to 80% compared to an equivalent xenon light source
- Extremely quiet ventilation concept at only 30 dB(A) noise level
- Connection option for Richard Wolf light cable
- Automatic dimming of the light cable socket if the light cable is removed
- Very homogenous illumination of the endoscopic surgical area. No drop in brightness in the peripheral area and no "black spot" in the center
- Very stable color temperature (6500 Kelvin) over the entire LED service life
- Very good price-performance ratio
- VESA 100 mount on the underside - versatile mounting options

Light source ENDOLIGHT Flex LED bndl 51660011

Comprising:

- 1x ENDOLIGHT Flex LED 5166001
- 1x power cable 2440.03

Recommended accessories	Product no.
Device mount VESA 100	32116452






For mounting a "Flex" series device on the side of the RIWomobil or on other vertical mounting surfaces
Dimensions (W x H x D):
190 x 138 x 100 mm

ENDOLIGHT Flex LED

Technical data

ENDOLIGHT Flex LED		5166001
Device properties		
Type and number of lamps	1x high-power LED	
Lamp service life	30,000 h	
Light output compared to xenon in W	180 W	
Color temperature	6500 K	
Brightness control	0 - 100%	
Noise level	30 dB(A)	
Operating mode	Continuous operation	
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa	
Equipment		
Supported light cables	Wolf	
IP rating	IP 20	
Cooling method	Fan	
Power supply		
Mains + frequency	100-240 VAC, 50/60 Hz	
Power consumption	110 VA - 145 VA	
Current rating	1.1-0.6 A	
Regulatory standards		
Safety	EU: EN 60601-1	
EMC	EN 60601-1-2 / IEC 601-1-2	
Medical device class	Class 1	
Classification	BF	
Dimensions and weight		
Weight	1.8 kg	
Dimensions (W x H x D)	150 x 58 x 245 mm	

Fiber light cable with color coding

Fiber light cable, complete	Color coding on endoscope side	Ø of fiber bundle and color code	Length	Fiber light cable without adapter Product no.	Complete Product no.
 <p>Fiber light cable, bndl Comprising: Fiber light cable, Adapter, projector side (8095.07), and adapter, endoscope side (809509)</p>		1.6 mm blue	1.8 m	80661618*	806616181
			2.3 m	80661623*	806616231
			3.0 m	80661630*	806616301
		2.5 mm green	1.8 m	80662518*	806625181
			2.3 m	80662523*	806625231
			3.0 m	80662530*	806625301
		3.5 mm orange	1.8 m	80663518*	806635181
			2.3 m	80663523*	806635231
			3.0 m	80663530*	806635301
			3.5 m	80663535*	806635351
		5.0 mm grey	2.3 m	80665023*	806650231
			3.0 m	80665030*	806650301
3.5 m			80665035*	806650351	

* The light cables can also be ordered without adapter.
Adapters for connecting products from other manufacturers are offered as separate items in our product range.

TO WHOM IT MAY CONCERN

spirit of excellence

Knittlingen, December 19th, 2022

AUTHORIZATION LETTER

We, **Richard Wolf GmbH, Pforzheimer Str. 32, 75438 Knittlingen, Germany**, a manufacturer and supplier of Medical Endoscopic Equipment, duly organized under the laws of Germany, hereby declare that the company

**Endo-Chirurgie LTD
9 Mesterul Manole str., MD-2023
Chisinau
REPUBLIC OF MOLDOVA**

is authorized to sell and distribute Richard Wolf Medical Endoscopic Equipment, except Spine Surgery Systems, in the territory of Moldova. The above company is also entitled to participate at related public tenders for the stated products.

Furthermore, the company is able to organize the commissioning, functional testing as well as warranty and post-warranty service procedure for the related products in cooperation with and on behalf of the Richard Wolf GmbH.


We hereby grant our full warranty for the Richard Wolf Medical Endoscopic Equipment offered by the above firm in accordance with our General Terms and Conditions of Business.

This authorization is effective immediately and valid until December 31, 2023.

Yours faithfully

RICHARD WOLF GMBH **RICHARD WOLF**
GmbH
75438 KNITTLINGEN


Jürgen Steinbeck
Co-CEO


Volker Maute
Vice President Sales, Service & Marketing