

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

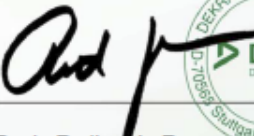
Revision status of the annex: 0 dated 2020-04-01

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

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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 Logic HD

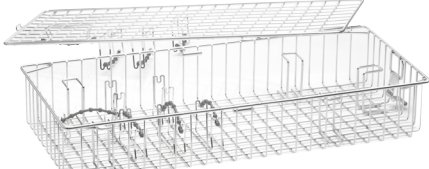
3-chip HD camera head



- Digital image processing and digital signal transmission
- 2 programmable camera head buttons with 4 available functions
- Universal C-Mount lens connection
- Cable outlet angled at 30°
- Camera head cable can be replaced in the hospital by technicians
- Steam-sterilizable
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Logic HD camera head **85525922**

3-chip type, cable length 3 m

Recommended accessories		Product no.
RIWO lens	C-Mount, f = 14 mm	85261144
	C-Mount, f = 24 mm	85261244
RIWO zoom lens	C-Mount, f = 13 - 29 mm	85261504
	Reprocessing basket for camera head (L x W x H) 445 x 200 x 73 mm	38047111

ENDOCAM Logic HD

Technical data of camera head

Camera head 85525922	
Device properties	
Sensor	3x 1/3" CCD
Operation	2 programmable head buttons with 4 functions
Operating conditions	+10°C to +30°C, 20% 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 and eyepiece snap-in coupling can be replaced on site
Dimensions and weight	
Camera head weight (without cable)	170 g
Housing dimensions (W x H) - without cable and anti-kink protection	43 x 53 mm
Camera head length (without cable)	105 mm
Cable length	3 m / 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.



AUTOCLAVE
134° C / 273° F

RIWO zoom lens
f = 21 - 36 mm

85261.501

RIWO zoom lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine



AUTOCLAVE
134° C / 273° F

RIWO zoom lens
f = 13 - 29 mm

85261504

RIWO zoom lens with snap-on mechanism and C-Mount thread, reprocessable by machine and suitable for low-temperature procedure



RIWO zoom lens
f = 13 - 29 mm

5261504

RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine



AUTOCLAVE
134° C / 273° F

RIWO lens
f = 14 mm

85261144

RIWO lens
f = 24 mm

85261244

RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine



AUTOCLAVE
134° C / 273° F

RIWO lens
f = 27 mm

85261.272

RIWO lens
f = 32 mm

85261.322

ENDOCAM Logic HD
Pendual camera head

ENDOCAM

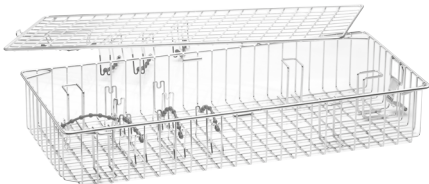
1



- Bendable housing for two operating modes:
1: pivoting camera head, 2: straight camera head
- Freely rotating snap-on mechanism with lock function
- Integrated lens f = 17 mm
- Digital image processing and signal transmission
- 2 programmable camera head buttons with 4 available functions
- Camera head cable can be replaced in the hospital by technicians
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Logic HD pendual camera head **5525933**

1-chip type, cable length 3 m

Recommended accessories		Product no.
	Reprocessing basket for camera head (L x W x H) 445 x 200 x 73 mm	38047111

ENDOCAM Logic HD

Technical data of pendul camera head

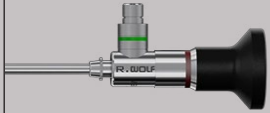
Camera head 5525933	
Device properties	
Sensor	1x 1/3" CCD
Operation	2 programmable head buttons with 4 functions
Focal length range with integrated lens	17 mm
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Equipment	
Degree of protection against the ingress of moisture	IPX7
Service	Cable and eyepiece snap-in coupling can be replaced on site
Handling	Pendulum housing can be converted into an axial camera head simply by rotating
Dimensions and weight	
Camera head weight (without cable)	175 g
Housing dimensions (W x H) - without cable and anti-kink protection	51 x 50 mm
Camera head length (without cable)	141 mm
Cable length	3 m
Cable outlet	0°

PANOVIEW Telescopes

Overview

PANOVIEW-Optiken

Übersicht

Blickrichtung Viewing direction	Farbkodierung Colour code	Anwendung Application	Ø mm	 HD High Definition AUTOCLAVE 134° C / 273° F
0°	 blau blue	Standard	4	8650.414
		PDD blue	4	8650.514**
		schwachkalibrig small calibre	3.3	8660.424
12°	 orange orange	Standard	4	8654.431
		PDD blue	4	8654.531**
30°	 rot red	Standard	4	8654.422
		PDD blue	4	8654.522**
		schwachkalibrig small calibre	3.3	8656.422
		Langschaft Long sheath	4	8668.433*
70°	 gelb yellow	Standard	4	8650.415
		PDD blue	4	8650.515**

* Only 25° available.

** Within the scope of our new, more powerful PDD system we have adapted our PANOVIEW telescopes to this blue PDD system. To distinguish them, the PANOVIEW telescopes are marked with the word **blue** and can of course also be used in conjunction with your previous PDD system.

* Nur in 25° erhältlich.

** Im Rahmen unseres neuen, leistungsstärkeren PDD-Systems, haben wir unsere PANOVIEW-Optiken an dieses blue PDD-System angepasst. Zur Unterscheidung sind die PANOVIEW-Optiken mit **blue** gekennzeichnet und können selbstverständlich auch mit Ihrem bisherigen PDD-System verwendet werden.