Overview of the range

Lot : 30

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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*
			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
 **Set comprises:** Fiber Light Cable, adapter projector-light source-end (8095.07) and adapter endoscope-end (809509) *The fusion 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:

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

Wolf, Stryker.....**8095.07**			**Wolf**.....**809509**
Storz	no adapter necessary		**Storz, Stryker, Olympus**.....**807001**
Olympus.....**8096.811**			**ACMI, Circon, Henke-Sass-Wolf**.....**807002**

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen, Germany

Tel.: +49 7043 35-0
Fax: +49 7043 35-4300
info@richard-wolf.com

Co-CEOs:
Jürgen Pfab
Jürgen Steinbeck

Trade Register: Mannheim HRB 510031
VAT no.: DE144521586
Tax no.: 48020/00171

Lot :31

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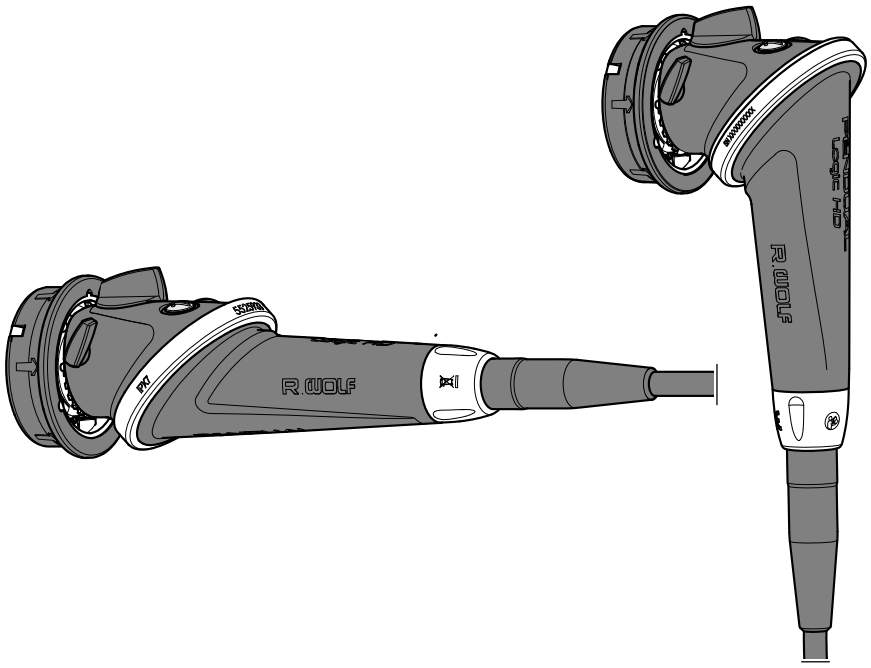
Instructions for use



Logic HD PENDUAL Camera Head

5525933

BB-A282-02 / en / EU / V3.0 / 2022-09 / PK20-0215 /

CE

14 Replacement parts

NOTE

For materials required for reprocessing the products please see section12 Re-processing and maintenance.

NOTE

As the camera cable with camera plug is a wear and tear part, any warranty is excluded.

Product no.	Designation
15135466	COVER PLATE
64300087	REPAIR SET SNAP-ON FASTENER
64300090	REPAIR SET CAMERA CABLE 3M
64300094	REPAIR SET FLAT PLUG

15 Disposal

⚠ CAUTION

- Reprocess the products before disposal in accordance with the instructions for use to protect the patient, user and third parties.

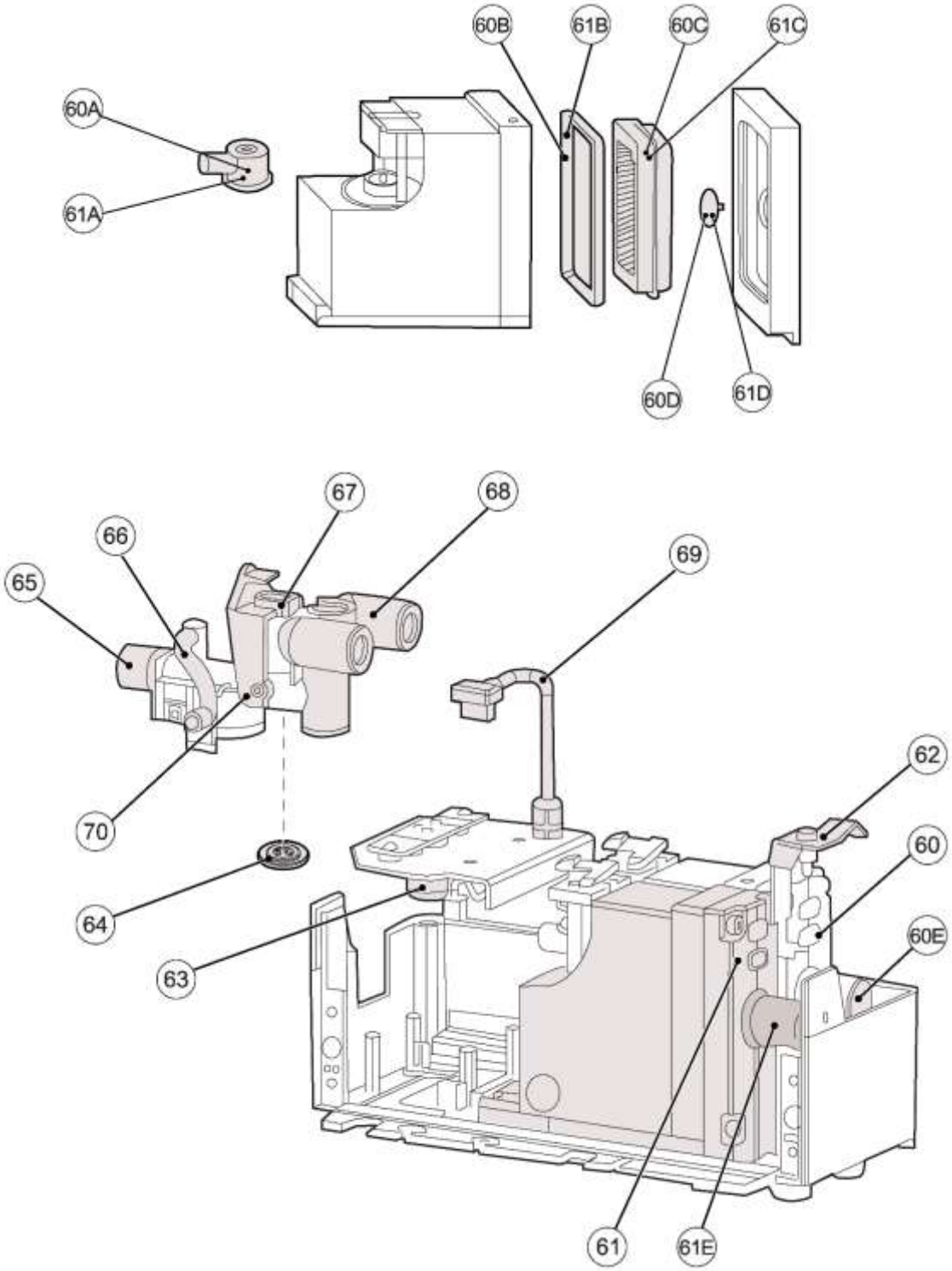
NOTE

For the disposal observe the relevant regulations and laws valid in your country.

- For further information please contact the manufacturer.

Lot : 160-161

Figure 3: Patient unit, Inspiratory section



Lot : 160-161

Table 3: Patient unit, Inspiratory section

ID	Part no.	Description	Comments
60	6671137	Gas module O2, Type III	
60A	6693792	Nozzle unit	
60B	6039528	Rubber seal for bacteria filter	
60C	6169416	Bacteria Filter for Gas Module	
60D	6169358	Non-return valve, 2 pcs	
60E	6532654	Module adapter O2, with O-rings	Fits only modules with 2 screws in end plate
61	6671135	Gas module Air, Type III	
61A	6693792	Nozzle unit	
61B	6039528	Rubber seal for bacteria filter	
61C	6169416	Bacteria Filter for Gas Module	
61D	6169358	Non-return valve, 2 pcs	
61E	6532647	Module adapter AIR, with O-rings	Fits only modules wit 2 screws in the end plate
62	6488113	Module bracket	
63	6670330	Pull magnet incl. bracket	
64	9303892	Filter for O2 cell, 25 pcs	
65	6532662	Inspiratory pipe	
66	6532977	Tube	
67	6640044	O2 cell	
68	6448612	Connector muff	
69	6487958	Cable for O2 cell	
70	6888750	O2 cell holder	

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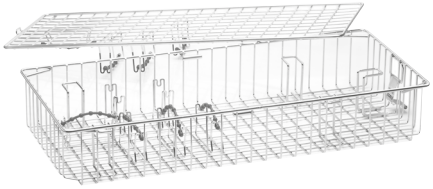
ENDOCAM Logic HD
Pendual camera head

- 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**

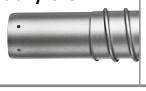
ENDOCAM Logic HD

Technical data of pendual 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°

TROCAR SLEEVES 5.5 MM

RIWO-ART trocar sleeves
with magnetic ball valve
with insufflation stopcock

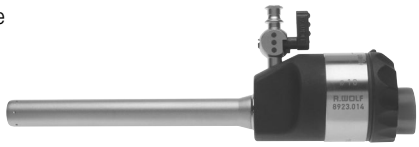
				Tip tapered/blunt 	Tip tapered/ pointed 	Tip triangular 
				Trocar tip blunt Size 5.5 mm	Trocar tip pointed Size 5.5 mm	Trocar tip triangular Size 5.5 mm
Stainless steel sheath tube	**WL**	**Capacity**	**Product no.**	**WL 169 mm**	**WL 169 mm**	**WL 169 mm**
Trocar sleeve straight capacity 5.5 mm **WL 100 mm** smooth 	100 mm	5.5 mm	**8921.014**	**8921.103**	**8921.113**	**8921.123**
Trocar sleeve slanted capacity 5.5 mm **WL 100 mm** smooth 	100 mm	5.5 mm	**8921.013**	**8921.103**	**8921.113**	**8921.123**
Trocar sleeve straight capacity 5.5 mm **WL 100 mm** with thread 	100 mm	5.5 mm	**8921.024**	**8921.103**	**8921.113**	**8921.123**
Trocar sleeve slanted capacity 5.5 mm **WL 100 mm** with thread 	100 mm	5.5 mm	**8921.023**	**8921.103**	**8921.113**	**8921.123**
Plastic tube **Trocar sleeve straight capacity 5.5 mm** **WL 100 mm** with thread 	100 mm	5.5 mm	**8921.034**	**8921.103**	**8921.113**	**8921.123**
				WL 219 mm	WL 219 mm	WL 219 mm
Trocar sleeve straight capacity 5.5 mm **WL 150 mm** smooth 	150 mm	5.5 mm	**8921.016**	**8921.105**	**8921.115**	**8921.125**
Trocar sleeve straight capacity 5.5 mm **WL 150 mm** with thread 	150 mm	5.5 mm	**8921.026**	**8921.105**	**8921.115**	**8921.125**

Accessories	Product no.
Spare ball capacity 5.5 mm	**8921.901**
Spare O rings capacity 3.5 mm (PACK= 10 PCS), capacity Ø 3.5–5.5 mm	**8921.951**
Sealing cap capacity 3.4–5.1 mm (PACK= 10 PCS) blue	**89.02**
Stopcock insert bndl cap. 3.0 mm (PACK= 5 PCS)	**896.0002**

TROCAR SLEEVE 10 MM

WITH INSUFFLATION STOPCOCK

RIWO-ART trocar sleeves with magnetic ball valve



				Tip tapered/blunt 	Tip tapered/pointed 	Tip triangular 
				Trocar tip blunt Size 10 mm	Trocar tip pointed Size 10 mm	Trocar tip triangular Size 10 mm
Stainless steel sheath tube	WL	Capacity	Product no.	WL 164 mm	WL 164 mm	WL 164 mm
Trocar sleeve straight capacity 10 mm WL 100 mm 	100 mm	10 mm	**8923.014**	**8923.103**	**8923.113**	**8923.123**
Trocar sleeve slanted capacity 10 mm WL 100 mm 	100 mm	10 mm	**8923.013**	**8923.103**	**8923.113**	**8923.123**
Trocar sleeve straight capacity 10 mm WL 100 mm with thread 	100 mm	10 mm	**8923.024**	**8923.103**	**8923.113**	**8923.123**
Trocar sleeve slanted capacity 10 mm WL 100 mm with thread 	100 mm	10 mm	**8923.023**	**8923.103**	**8923.113**	**8923.123**
				WL 214 mm	WL 214 mm	WL 214 mm
Trocar sleeve straight capacity 10 mm WL 150 mm 	150 mm	10 mm	**8923.016**	-	**8923.115**	**8923.125**
Trocar sleeve straight capacity 10 mm WL 150 mm with thread 	150 mm	10 mm	**8923.026**	-	**8923.115**	**8923.125**

Accessories	Product no.
Spare ball capacity 7 mm	**8923901**
Spare O rings capacity 7 mm (PACK= 10 PCS), capacity Ø 7–12.5 mm	**8923951**
Sealing cap capacity 9.5–10.1 mm (PACK= 10 PCS) red	**8908**
Stopcock insert bndl cap. 3.0 mm (PACK= 5 PCS)	**896.0002**

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INSUFFLATOR HIGHFLOW 45 BASIC

		Product no.
Insufflator 45 BASIC bndl consisting of: Insufflator 45 BASIC FR 45 l/min (2235001), Insufflation tube set L 2.5 m (8170.101), Hygiene filter, sterile, disposable (PACK= 10 PCS) (4171.111) and power cable 3 m long (2440.03)		**22350011**
Accessories: Tube sets for insufflation		
Insufflation tube set L 2.5 m, High Flow, D = 8 mm, autoclavable		**8170.232**
Insufflation tube set L 2.5 m, autoclavable		**8170.101**
Insufflation tube set L 2.7 m, with integrated hygiene filter, disposable, (PACK= 10 PCS) in individual sterile packaging		**4170.501**
Hygiene filter, sterile, disposable (PACK= 10 PCS) in individual sterile packaging		**4171.111**
Accessories for gas supply		
CO_2 connection tube 1.5 m NIST-NIST		**74021038**
with		
Pressure reducer for CO_2 connector DIN 477-1	DIN 477-1	**74007054**
Pressure reducer for CO_2 connector DIN EN ISO 407	DIN EN ISO 407	**74007055**
Pressure reducer for CO_2 connector ISO 5145	ISO 5145	**74007056**
or		
Connection tube for CO_2 5.0 m DIN for centralized CO_2 gas supply (Dräger)		**74021039**
Connection tube for CO_2 5.0 m NF for centralized CO_2 gas supply (Liquid Air)		**74021040**
Software modules (optional)		
Software module CAN bus CAN bus interface for integration in CORE		**2235101**
Software module BABY MODE BABY MODE for special use in pediatrics		**2235102**
Software module VIDEO DISPLAY: video display using DIALOG via CAN bus		**2235103**

Lot : 34

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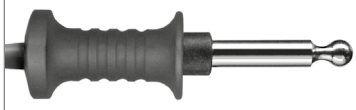
HF CONNECTION CABLE MONO
815xxx

Instrument connector	Device connector		Product no.
WOLF resectoscope 	 Erbe (ACC/ICC)/BOWA (EU) R. Wolf HF surgical generator 400 kHz 2260002	**HF connection cable mono L 3 m**	**815.032**
		HF connection cable mono L 5 m	**815.052**
	 Erbe (T series)	**HF connection cable mono L 3 m**	**815.132**
		HF connection cable mono L 5 m	**815.152**
HF electrodes, monopolar 	 Martin (M-version)/Berchtold/ Aesculap	**HF connection cable mono L 3 m**	**815.031**
		HF connection cable mono L 5 m	**815.051**
	 Bovie/Valleylab/Erbe (Int.)/ BOWA (Int.) R. Wolf HF surgical generator 400 kHz 2260001	**HF connection cable mono L 3 m**	**815.033**
		HF connection cable mono L 5 m	**815.053**
	 BOWA (Int./EU) Eschmann and other devices with 4 mm plugs R. Wolf HF surgical generator 400 kHz 2260001	**HF connection cable mono L 3 m**	**815.034**
		HF connection cable mono L 5 m	**815.054**

Lot : 35

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HF CONNECTION CABLE MONO
8106xxx

Instrument connector	Device connector		Product no.
WOLF Instruments/surgical generator 	 Erbe (ACC/ICC)/BOWA (EU) R. Wolf HF surgical generator 400 kHz 2260002	**HF connection cable mono L 3 m**	**8106.032**
		HF connection cable mono L 5 m	**8106.052**
	 Erbe (T series)	**HF connection cable mono L 3 m**	**8106.132**
		HF connection cable mono L 5 m	**8106.152**
HF electrodes, monopolar 	 Martin (M-version)/Berchtold/ Aesculap	**HF connection cable mono L 3 m**	**8106.031**
		HF connection cable mono L 5 m	**8106.051**
	 Bovie/Valleylab/Erbe (Int.)/ BOWA (Int.) R. Wolf HF surgical generator 400 kHz 2260001	**HF connection cable mono L 3 m**	**8106.033**
		HF connection cable mono L 5 m	**8106.053**
	 BOWA (Int./EU) Eschmann and other devices with 4 mm plugs R. Wolf HF surgical generator 400 kHz 2260001/2260002	**HF connection cable mono L 3 m**	**8106.034**
		HF connection cable mono L 5 m	**8106.054**

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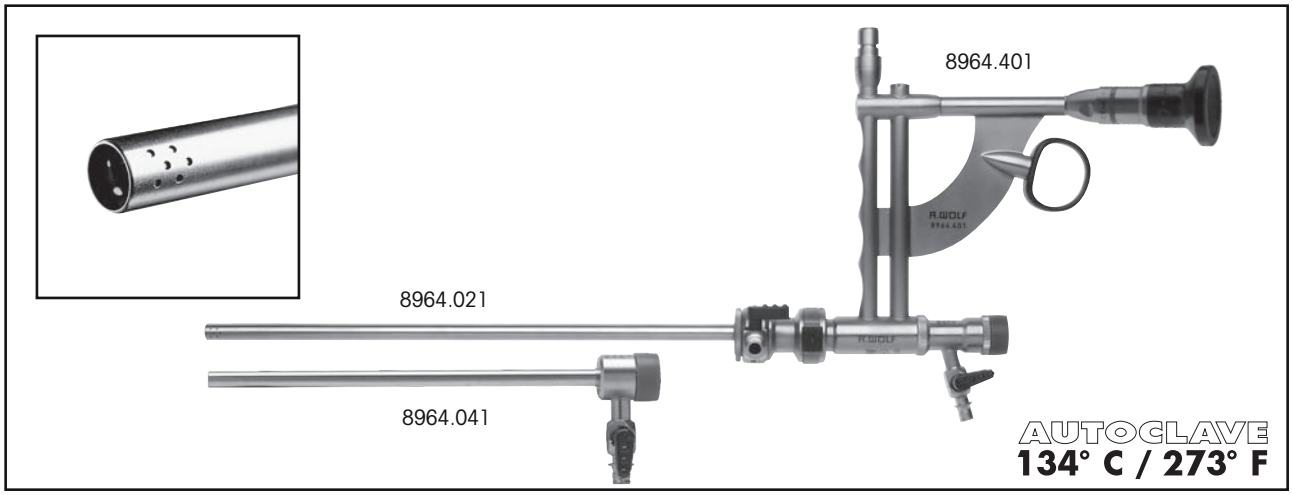
Percutaneous Universal Nephroscope Model "Dresden"

Perkutanes Universal-Nephroskop Modell "Dresden"



- *Extremely small sheath circumference – but the same sturdy construction*
- *Large oval working channel, 14 Fr., for accessory instruments up to Ø 3.5 mm such as the standard ultrasound sonotrodes – with effective irrigation*
- *PANOVIEW rod lens system – for optimum image quality*
- *Ergonomic design and user-friendly automatic valve – for fatigue-free operation and optimum handling*

- Besonders kleiner Schaftumfang – bei gleichzeitig robuster Bauweise
- Großer ovaler Arbeitskanal, 14 Charr., für Hilfsinstrumente bis Ø 3,5 mm wie Standard-Ultraschall-Sonotroden – bei effektiver Spülung
- PANOVIEW Stablinsen-System – für optimale Bildqualität
- Ergonomisches Design und anwenderfreundlich durch automatisches Ventil – für ermüdungsfreies Arbeiten und optimales Handling

PANOVIEW operating telescope
with parallel eyepiece, 12°, capacity 3.5 mm, oval instrument channel, WL 224 mm (8964.401), automatic valve (8964.711) with sealing membrane (pack of 5, 89.102), sealing cap blue (89.02), cleaning brush (6.05) 8964.401
recommended light cable:
***Fiber light cable set,** Ø 3.5 mm, 2300 mm long consisting of:*
Fiber light cable (80663523), adapter projector-side (8095.07) and adapter endoscope-side (809509) 806635231

Sheath, 20.8 Fr.
round, with swivel irrigation connector, distal tip
straight, automatic locking mechanism, WL 204 mm 8964.021
also:
***Obturator,** hollow 8964.121*
alternative:
Sheath, 24 Fr.
round, with swivel irrigation connector, distal tip
straight, automatic locking mechanism, WL 204 mm 8965.041
***Obturator,** hollow 8965.141*

***Amplatz sheath, 24.3 Fr.**, WL 150 mm 8964.041*

***Sealing membrane retainer** 15176.100*

Option for optical percutaneous ureterotomy:
***Working element**, passive 8670.911*
***PANOVIEW telescope**, 0°, Ø 3.3 mm 8660.424*
***Stricture scalpel** with ceramic blade,*
lanzet blade 8670.981

PANOVIEW Operations-Optik
mit Paralleleinblick, 12°, Durchlass 3,5 mm, ovaler Sondenkanal, NL 224 mm (8964.401), automatisches Ventil (8964.711) mit Dichtmembran (VE = 5 Stück, 89.102), Dichtungskappe blau (89.02), Reinigungsbürste (6.05) 8964.401
empfohlenes Lichtleitkabel:
Fiber Lichtleiter Set, Ø 3,5 mm, 2300 mm lang bestehend aus:
Fiber Lichtleiter (80663523), Adapter projektorseitig (8095.07) und Adapter endoskopseitig (809509) 806635231

Schaft, 20,8 Charr.
rund, mit drehbarer Spülung, distales Ende
gerade, automatischer Verschluss, NL 204 mm 8964.021
hierzu:
Obturator, zentral hohl 8964.121
alternativ:
Schaft, 24 Charr.
rund, mit drehbarer Spülung, distales Ende
gerade, automatischer Verschluss, NL 204 mm 8965.041
Obturator, zentral hohl 8965.141

Amplatz-Schaft, 24,3 Charr., NL 150 mm 8964.041

Dichtmembran-Aufnahme 15176.100

Möglichkeit zur optischen perkutanen Ureterotomie:
Arbeits-Element, passiv 8670.911
PANOVIEW-Optik, 0°, Ø 3,3 mm 8660.424
Strikturskalpell mit Keramikschneide,
lanzettenförmig 8670.981

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: 713170827

Preceding certificate No.: This certificate is issued for the first time

Valid from: 2020-02-17
Valid until: 2025-02-16

Date of initial issuance / Rev.00: 2020-02-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-02-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 072017 0015 Rev. 00

Device(s):	Risk classification	CND Code	Intended Purpose
INSTRUMENTS FOR ANESTHESIA AND PULMONARY VENTILATION SUPPORT	IIb	Z120301	Intended for respiratory support, administration of anesthetic and treatment of neonatal, pediatric and adult patients.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History including Changes:

Revision / Issue Date / Report
Rev. 00 / 2020-02-17 / 713170827

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 072017 0014 Rev. 01

Manufacturer:

MAQUET CRITICAL CARE AB
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):

MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

Product Category(ies): **Anaesthesia, Monitoring, Ventilator and Perfusion Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713161324

Valid from: 2020-01-22
Valid until: 2024-05-26

Date, 2020-01-22

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 072017 0013 Rev. 01

Holder of Certificate: **MAQUET CRITICAL CARE AB**
Röntgenvägen 2
171 54 Solna
SWEDEN

Facility(ies):
MAQUET CRITICAL CARE AB
Röntgenvägen 2, 171 54 Solna, SWEDEN

See Scope of Certificate

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design, development and manufacturing of Anaesthesia, Monitoring, Ventilator Systems and Perfusion Systems**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 072017 0013 Rev. 01

Report No.: 713193727

Valid from: 2020-12-30

Valid until: 2023-12-29

Date, 2020-12-28

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

DEKRA Certification GmbH * Stuttgart * Handwerkstraße 15

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

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

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

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 • D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

34460

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

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15 DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex V

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 V 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.: 50593-17-04

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15, D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

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Annex to the EC Certificate No. 50593-17-04

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.

- Endoscope inflation bulb
- Proctoscope, single-use
- Rectoscope, single-use

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124