

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

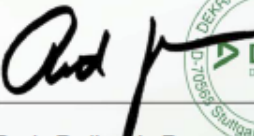
Revision status of the annex: 0 dated 2020-04-01

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

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

Overview of the range

Lot: 1

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:

	Wolf809509
	Storz, Stryker, Olympus.....807001
	ACMI, Circon, Henke-Sass-Wolf.....807002



Trocar Sleeves 5.5 mm

Trokarhülsen 5,5 mm

3

RIWO-ART-Trokarhülsen mit Magnet-Kugel-Ventil mit Insufflationshahn				Trokar, Spitze kegelig-stumpf	Trokar, Spitze kegelig-spitz	Trokar, Spitze dreikantig
						
<i>RIWO-ART trocar sleeves with magnetic-ball-valve with insufflation tap</i>		Durchlass / Capacity	Typen / Types	<i>Trocar, blunt conical tip</i>	<i>Trocar, conical tip</i>	<i>Trocar, pyramidal tip</i>
 <i>Metal sleeve, standard, straight distal tip</i>	NL / WL 100 mm	5.5 mm	8921.014	8921.103	8921.113	8921.123
	NL / WL 150 mm	5.5 mm	8921.016	8921.105	8921.115	8921.125
 <i>Metal sleeve, standard, oblique distal tip</i>	NL / WL 100 mm	5.5 mm	8921.013	8921.103	8921.113	8921.123
 <i>Metal with retaining thread, straight distal tip</i>	NL / WL 100 mm	5.5 mm	8921.024	8921.103	8921.113	8921.123
	NL / WL 150 mm	5.5 mm	8921.026	8921.105	8921.115	8921.125
 <i>Metal sleeve with retaining thread, oblique distal tip</i>	NL / WL 100 mm	5.5 mm	8921.023	8921.103	8921.113	8921.123
 <i>Plastic sleeve with retaining thread, straight distal tip</i>	NL / WL 100 mm	5.5 mm	8921.034	8921.103	8921.113	8921.123

Spare ball, 1 piece, capacity Ø 3.5 mm - 5.5 mm 8921.901
 Spare o-rings, PACK=10 PCS, capacity Ø 3.5 mm - 5.5 mm. 8921.951
 Spare sealing caps, PACK=10 PCS,
 capacity 5.5 mm, blue 89.02
 Spare plug 896.0002

Ersatzkugel, 1 Stück, Durchlass Ø 3,5 mm - 5,5 mm..... 8921.901
 Ersatz-O-Ringe, VE=10 ST, Durchlass Ø 3,5 mm - 5,5 mm.. 8921.951
 Ersatz-Dichtungskappen, VE=10 ST,
 Durchlass 5,5 mm, blau..... 89.02
 Ersatz-Hahnkükten 896.0002

Trocar Sleeves 10 mm

with insufflation tap

Trokarhülsen 10 mm

mit Insufflationshahn

RIWO-ART-Trokarhülsen mit Magnet-Kugel-Ventil				Trokar, Spitze kegelig-stumpf	Trokar, Spitze kegelig-spitz	Trokar, Spitze dreikantig
RIWO-ART trocar sleeves with magnetic-ball-valve		Durchlass / Capacity	Typen / Types	Trocar, blunt conical tip	Trocar, conical tip	Trocar, pyramidal tip
 Metallrohr, glatt, distal gerade	NL / WL 100 mm	10 mm	8923.014	8923.103	8923.113	8923.123
 Metal sleeve, standard, straight distal tip	NL / WL150 mm	10 mm	8923.016	-	8923.115	8923.125
 Metallrohr, glatt, distal abgeschrägt	NL / WL 100 mm	10 mm	8923.013	8923.103	8923.113	8923.123
 Metal sleeve, standard, oblique distal tip						
 Metallrohr mit Gewinde, distal gerade	NL / WL 100 mm	10 mm	8923.024	8923.103	8923.113	8923.123
 Metal with retaining thread, straight distal tip	NL / WL 150 mm	10 mm	8923.026	-	8923.115	8923.125
 Metallrohr mit Gewinde, distal abgeschrägt	NL / WL 100 mm	10 mm	8923.023	8923.103	8923.113	8923.123
 Metal sleeve with retaining thread, oblique distal tip						

Spare ball, 1 piece, capacity Ø 7 mm - 12.5 mm 8923.901

Spare o-rings, PACK=10, capacity Ø 7 mm - 12.5 mm 8923.951

Spare sealing caps, PACK=10 PCS,

capacity 10 mm, red 89.08

Spare plug, PACK=5 PCS 896.0002

Ersatzkugel, 1 Stück, Durchlass Ø 7 mm - 12,5 mm 8923.901

Ersatz-O-Ringe, VE=10 ST, Durchlass Ø 7 mm - 12,5 mm ... 8923.951

Ersatz-Dichtungskappen, VE=10 ST,

Durchlass 10 mm, rot 89.08

Ersatz-Hahnkügen, VE=5 ST 896.0002

TROTEC protective trocars

TROTEC Schutztrokare

TROTEC-Trokar bestehend aus: TROTEC trocar consisting of:			TROTEC-Trokar komplett TROTEC trocar complete	Für RIWO ART-Trokarhülse mit: For RIWO ART trocar sleeves:	
					
Schaft mit Kanülen- spitze, kegelig / Sheath with conical cannula tip	Schaft mit Lanzetten- spitze, zweikantig / Sheath with two- edged lancet tip	Griff mit federndem Schutzstab / Handle with spring- mounted protective rod		NL WL	Ø
8923.132		8923.135	8923.131	100 mm	10 mm
	8923.134	8923.135	8923.133	100 mm	10 mm



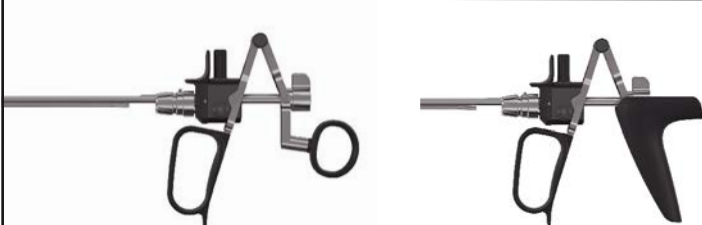
Working Elements

for resectoscope, monopolar
telescope 4 mm, 12°, 30°



Arbeits-Elemente

für Resektoskop, monopolar
Optik 4 mm, 12°, 30°

		Griff-Varianten Handle type	schneidend cutting action	Type Type
 Schnitt erfolgt gegen Federdruck Manual cutting action with spring-assisted release		geschlossen / closed	aktiv / active	8674205
		geschlossen mit Komfort-Daumenauflage closed with comfort thumb rest	aktiv / active	8674234
 Schnitt erfolgt durch Federdruck Spring-assisted cutting action		geschlossen / closed	passiv / passive	8674225
		offen / open	passiv / passive	8674224

Thumb ring with large inner diameter..... 15008.159

Rubber caps, pack of 5, red 8874
(for sealing the electrode clamping on the working element)

Daumenring mit größerem Innendurchmesser..... 15008.159

Gummikappe, VE=5 Stück, rot 8874
(zum Abdichten der Elektrodenklemmung am Arbeitselement)



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

P^{MORCE}POWER PLUS

Electronic Morcellator 2307

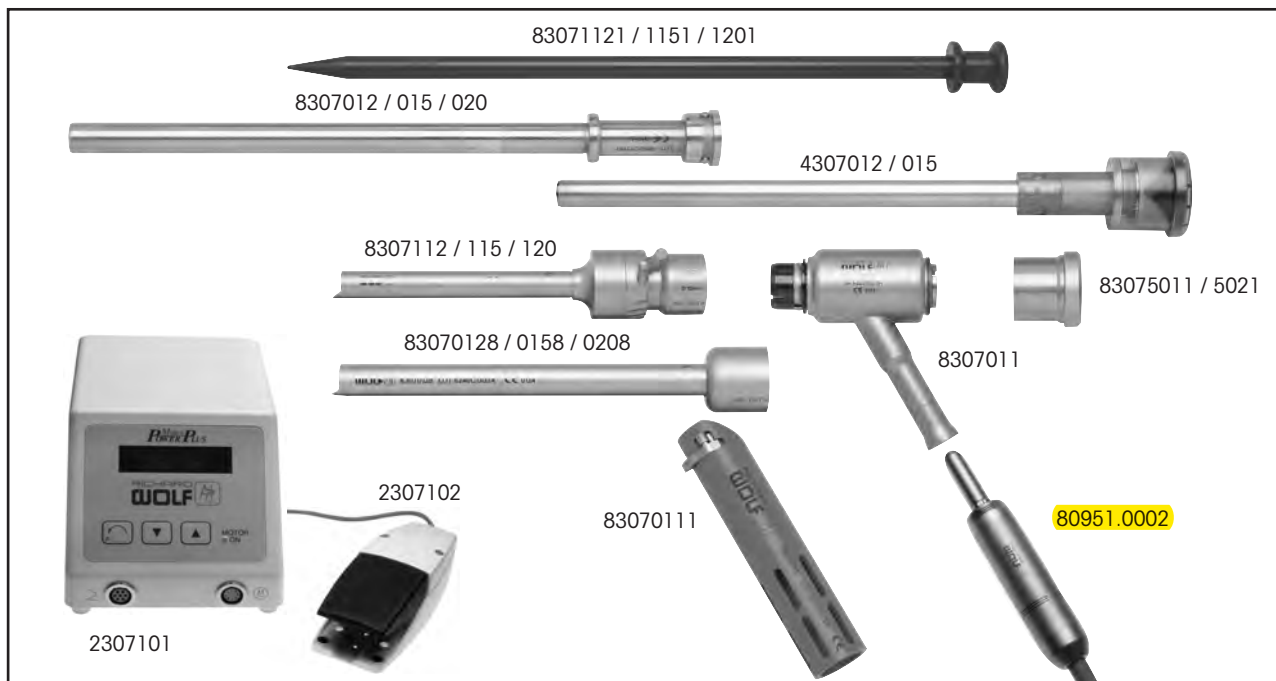
Accessories

P^{MORCE}POWER PLUS

Elektronischer Morcellator 2307

Zubehör

 Hysterektomie
Hysterectomy



Control unit 230 / 100 / 115 V a.c.

for Morce Power Plus 100-1000 rpm, clockwise or anticlockwise

120 x 180 x 110 mm2307101

Footswitch (ON/OFF) IP 68 for Morce Power Plus2307102

Electronic motor for control unit

230 / 115 / 100 V a.c.80951.0002

Morcellator handpiece for Morce Power Plus8307011

also:

Ergonomic handle83070111

Sealing unit complete with tissue and instrument seal for

12 / 15 mm83075011

20 mm83075021

Trocar sleeve with automatic flap valve and tissue positioner

12 mm8307112

15 mm8307115

20 mm8307120

Protection sleeve

12 mm83070128

15 mm83070158

20 mm83070208

Morcellator cutting tube

12 mm8307012

15 mm8307015

20 mm8307020

Cutting tube, sterile with sealing unit for Morce Power Plus,
individually packed, sterile (pack of 5)

12 mm4307012

15 mm4307015

Trocar for morcellator, long

12 mm83071121

15 mm83071151

20 mm83071201

Steuergerät 230 / 115 / 100 V~

für Morce Power Plus 100-1000 U/Min, Links- oder Rechtslauf

120 x 180 x 110 mm2307101

Fußpedal (ON/OFF) IP 68 für Morce Power Plus2307102

Elektronikmotor für Steuergerät

230 / 115 / 100 V~80951.0002

Morcellator-Handstück für Morce Power Plus8307011

hierzu:

Ergonomischer Handgriff83070111

Dichtungseinheit kpl. mit Gewebe- und Instrumentendichtung für

12 / 15 mm83075011

20 mm83075021

Trokarhülse mit automatischer Klappendichtung und Gewebepositionierer

12 mm8307112

15 mm8307115

20 mm8307120

Schutzhülse

12 mm83070128

15 mm83070158

20 mm83070208

Morcellator Schneidrohr

12 mm8307012

15 mm8307015

20 mm8307020

Schneidrohr, steril mit Dichtungseinheit für Morce Power Plus,
einzeln steril verpackt (VE = 5 Stück),

12 mm4307012

15 mm4307015

Trokar für Morcellator, lang

12 mm83071121

15 mm83071151

20 mm83071201

ERAGON *bipolar*

modular bipolar instruments, 5.5 mm,
rotatable

ERAGON *bipolar*

modulare Bipolar-Instrumente, 5,5 mm,
drehbar



Innenteil Jaw insert	Schaftrohr Sheath tube		Handgriff, drehbar Handle, rotatable	Komplett • Innenteil • Schaftrohr • Handgriff Complete • Jaw insert • Sheath • Handle	
		NL / WL 330 mm	NL / WL 460 mm		
	Typen / Types	83930921	82340024	839300102	Typen / Types
 Greif- und Präparierzange, MTL= 21 mm Grasping and preparation forceps, JL= 21 mm	83930031	●		●	839300312
	839400310		●	●	839400312
 Greif- und Dissektionszange "Maryland-Dissektor", MTL= 23 mm Grasping and dissecting forceps "Maryland-Dissector", JL= 23 mm	83930032	●		●	839300322
	839400320		●	●	839400322
 Greif- und Dissektionszange "Dolphin", MTL= 21 mm Grasping and dissecting forceps "Dolphin", JL= 21 mm	83930033	●		●	839300332
	839400330		●	●	839400332
 Fasszange, gefenstert, MTL= 23 mm Grasping forceps, fenestrated, JL= 23 mm	83930034	●		●	839300342
	839400340		●	●	839400342
 Präparierzange "Hasskamp", MTL= 19 mm Dissecting forceps "Hasskamp", JL= 19 mm	83930035	●		●	839300352
	839400350		●	●	839400352
 Sterilisationszange "Hasskamp", MTL= 19 mm Sterilisation forceps "Hasskamp", JL= 19 mm	83930036	●		●	839300362
	839400360		●	●	839400362

* JL = Jaw length when jaws closed (approximate measurements)

* MTL = Maulteillänge bei geschlossenem Maulteil (gerundete Angaben)

Bipolar cable see page BDE 164.

Bipolar Anschlusskabel siehe Blatt BDE 164.

ERAGON bipolar

modular bipolar instruments, 5.5 mm,
rotatable

ERAGON bipolar

modulare Bipolar-Instrumente, 5,5 mm,
drehbar

					
Innenteil Jaw insert  MTL / JL*	Schaftrohr Sheath NL / WL 330 mm	Handgriff, drehbar Handle, rotatable  NL / WL 460 mm	Komplett • Innenteil • Schaftrohr • Handgriff Complete • Jaw insert • Sheath • Handle		
	Typen / Types	83930921	82340024	839300102	Typen / Types
Greif- und Dissektionszange "Münster", MTL= 22 mm Grasping and dissecting forceps "Münster" JL= 22 mm	83930037	•		•	839300372
Greif- und Dissektionszange "Maryland", kurz MTL= 15 mm Grasping and dissecting forceps "Maryland", short, JL= 15 mm	83930038	•		•	839300382
	839400380		•	•	839400382
 83930041	•		•	•	839300412
Metzenbaumschere, MTL= 22 mm Metzenbaum scissors, JL= 22 mm	839400410		•	•	839400412

* JL = Jaw length when jaws closed (approximate measurements)

* MTL = Maulteillänge bei geschlossenem Maulteil (gerundete Angaben)

INSUFFLATOR Highflow 45 BASIC

INSUFFLATOR Highflow 45 BASIC



- ☐ 6,5" Color display
- ☐ Touchscreen
- ☐ Max. flow rate 45 l / min
- ☐ Functional and user-friendly design
- ☐ Optional configurable software modules

INSUFFLATOR Highflow 45 BASIC Set

consisting of:

INSUFFLATOR Highflow 45 Basic (2235001),
insufflation tube, Ø 5 mm, 2.5 m long (8170.101),
hygiene filter, sterile PACK=10 PCS (4171.111),
power cable 3 m long (2440.03) 22350011

Necessary accessories:

Connecting hose CO₂ 1,5m NIST-NIST 74021038
with

Pressure reducer CO₂

DIN 477-1 74007.054

DIN EN ISO 407 74007.055

ISO 5145 74007.056

or

Connecting hose CO₂ 5,0m DIN

for central CO₂ gas supply (Air Liquide) 74021039

Connecting hose CO₂ 5,0m NF

for central CO₂ gas supply (Air Liquide) 74021040

Optional accessories:

Insufflation tube, disposable

with integrated hygiene filter,

PACK=10 PCS, in individual sterile packs 4170.501

High-flow insufflation tube*,

Ø 8 mm, autoclavable 8170.232

*recommended in conjunction with high-flow trocar sleeves

Optional software module:

Software module CAN-BUS, integrated core 2235101

Software module BABY-MODE 2235102

Software module VIDEO-DISPLAY 2235103

- ☐ 6,5" Farbdisplay
- ☐ Touchscreen
- ☐ Max. Flowrate 45 l / min
- ☐ Funktionelles und anwenderfreundliches Design
- ☐ Optional konfigurierbare Software-Module

INSUFFLATOR Highflow 45 BASIC Set

bestehend aus:

INSUFFLATOR Highflow 45 Basic (2235001),
Insufflationsschlauch, Ø 5 mm, 2,5 m lang (8170.101),
Hygiene-Filter, VE=10 ST, steril verpackt (4171.111),
Netzkabel 3 m lang (2440.03) 22350011

Erforderliches Zubehör:

Verbindungsschlauch CO₂ 1,5m NIST-NIST 74021038
mit

Druckminderer CO₂

DIN 477-1 74007.054

DIN EN ISO 407 74007.055

ISO 5145 74007.056

oder

Verbindungsschlauch CO₂ 5,0m DIN

für zentrale CO₂-Gasversorgung (Dräger) 74021039

Verbindungsschlauch CO₂ 5,0m NF

für zentrale CO₂-Gasversorgung (Air Liquide) 74021040

Optionales Zubehör:

Insufflationsschlauch, zum Einmalgebrauch

mit integriertem Hygienefilter,

VE=10 ST, einzeln steril verpackt 4170.501

High-Flow-Insufflationsschlauch*,

Ø 8 mm, autoklavierbar 8170.232

*in Verbindung mit High-Flow-Trokarhülsen empfohlen

Optionale Software-Module:

Softwaremodul CAN-BUS, Integration in core 2235101

Softwaremodul BABY-MODE 2235102

Softwaremodul VIDEOEINBLENDUNG 2235103



AGENTIA MEDICAMENTULUI
SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr.	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
0M000186450	Endoscop	Richard Wolf	3,3mm 70°, 305mm	8660.412	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186446	Endoscop	Richard Wolf	4 mm 30°, 305mm	8755.411	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186443	Endoscop	Richard Wolf	4.0 mm 5° Cystoscope	8755.401	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186449	Endoscop	Richard Wolf	4 mm 12°, 305mm	8654.412	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186448	Endoscop	Richard Wolf	3,3 mm 0°, 330 mm	8660.411	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186447	Endoscop	Richard Wolf	4 mm 12°, 305mm	8654.411	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186439	Endoscop	Richard Wolf	4.0 mm 12°, 303,5mm	8654.511	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186444	Endoscop	Richard Wolf	4.0 mm 70° 310,5mm	8650.505	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186445	Endoscop	Richard Wolf	3,3 mm 30° 307mm	8656.414	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
0M000186442	Endoscop	Richard Wolf	3 mm 25°, histeroscop	8656.411	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018

трианица 1 из 2 (Всего элементов: 14)

1 2

✓ Содержит([Producatorul], 'wolf')



AGENTIA MEDICAMENTULUI
SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr.	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
DM000186451	Endoscop	Richard Wolf	3,3 mm 0°, Cystoscope	8660.414	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
DM000186440	Endoscop	Richard Wolf	3.3 mm 70°, 303,5mm	8660.415	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
DM000186438	Endoscop	Richard Wolf	4.0 mm 110° Cystoscope	8650.409	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018
DM000186441	Endoscop	Richard Wolf	4 mm 0°, 305mm	8650.504	Germania	RICHARD WOLF GMBH	S.C. ENDO-CHIRURGIE S.R.L.	A07.PS-01.Rg04-337	19-11-2018

pagina 2 из 2 (Всего элементов: 14) < 1 2 >

✓ Содержит([Producatorul], 'wolf')

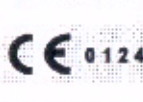
**EG-Konformitätserklärung nach
EG-Richtlinie 93/42/EWG für Medizinprodukte
EC-Conformity Declaration according to
Medical Device Directive 93/42/EEC**

Die
RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Deutschland

RICHARD WOLF GMBH
Pforzheimer Straße 32
75438 Knittlingen
Germany

erklärt hiermit, daß das Produkt mit der

herewith declare that the product with

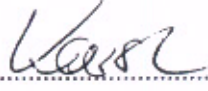
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Typ:				type:			
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	8654.511	8656.411	8656.414	8660.411	8660.412	8660.414	
	8660.415	8755.401	8755.411	8755.451	8755.461	8880.404	
ab Produkthauptakte:				from Device Master Record:			
	28.07.97	04.11.97	04.11.97	28.07.97	28.07.97	04.11.97	
	04.11.97	28.07.97	28.07.97	28.07.97	28.07.97	28.07.97	
	28.07.97	28.07.97	28.07.97	28.07.97	28.07.97	28.07.97	
den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht und dies durch ein Konformitätsbewertungsverfahren nach				is conforming to the relevant provisions of Medical Device Directive 93/42/EEC, and that this was proved by a conformity assessment procedure according to			
Anhang:				Annex:			
☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII							
nachgewiesen wurde.				This is visible by one of the following			
Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.				CE markings on the product and / or the enclosed information.			
☐ 				☐ 			
☐ 				☒ 			

Datum / Name / Unterschrift
Date / Name / Signature

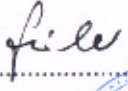
Bereichsleitung
Forschung und Entwicklung
Director
Research and Development

26.11.97 / Dr. H. U. Obbarius / 

Bereichsleitung Produktion
Director Production

3.12.97 / S. Karst / 

Leiter des
Qualitätswesen
Quality Assurance Manager

3.12.97 / H. Fischer / 

**EG-Konformitätserklärung nach
EG-Richtlinie 93/42/EWG für Medizinprodukte
EC-Conformity Declaration according to
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Die
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RICHARD WOLF GMBH
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Germany

erklärt hiermit, daß das Produkt mit der

herewith declare that the product with

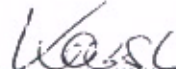
Bezeichnung:	Endoskope					designation:	Endoscopes				
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	8930.452	8933.411	8933.412	8933.413	8935.411	8935.412					
	8935.413	8974.401	8989.403								
ab Produkthauptakte:						from Device Master Record:					
	28.07.97	04.11.97	04.11.97	04.11.97	04.11.97	04.11.97					
	04.11.97	04.11.97	04.11.97	04.11.97	04.11.97	04.11.97					
	04.11.97	28.07.97	28.07.97								
den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte entspricht und dies durch ein Konformitätsbewertungsverfahren nach						is conforming to the relevant provisions of Medical Device Directive 93/42/EEC, and that this was proved by a conformity assessment procedure according to					
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☒ II, ☐ III, ☐ IV, ☐ V, ☐ VI, ☐ VII											
nachgewiesen wurde.						This is visible by one of the following					
Dies ist erkennbar an der nachfolgend aufgeführten CE Kennzeichnung des Produkts und / oder der dem Produkt beigefügten Informationen.						CE markings on the product and / or the enclosed information.					
☐ 						☐ 					
☐ 						☒ 					

Datum / Name / Unterschrift
Date / Name / Signature

Bereichsleitung
Forschung und Entwicklung
Director
Research and Development

: 26.11.97 / Dr. H. U. Obbarius / 

Bereichsleitung Produktion
Director Production

: 3.12.97 / S. Karst / 

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