

## Optical Urethrotome 8667

*E-line*

for telescope 4 mm, 0°


## Optisches Urethrotom 8667

*E-line*

für Optik 4 mm, 0°






cutting at 12 o'clock


auf 12 Uhr schneidend



Zur optisch kontrollierten Schlitzung von Harnröhrenstrikturen.  
For slitting urethral strictures under vision.

**AUTOCLAVE**  
**134° C / 273° F**

		Typen / Types
<b>Schaft für Urethrotom 20,5CH</b> mit Einführungshahn zur seitlichen Kathetereinführung (4 Charr.) <b>Sheath for urethrotome 20.5FR</b> with instrument port for lateral insertion of a catheter (4 Fr.)		<b>8667.011</b>
<b>Obturator für Urethrotom 20,5CH</b> oval, kanüliert, distales Ende abgerundet <b>Obturator for urethrotome 20.5FR</b> oval, cannulated, rounded distal end		<b>8667.111</b>
<b>Außenschaft für Urethrotom 20,5CH</b> , oval, seitlich offen zum Legen eines 16 Charr. Ballonkatheters <b>Outer sheath for urethrotome 20.5FR</b> , oval, lateral opening for inserting a 16 Fr. balloon catheter		<b>8667.161</b>
<b>Ansatz für Cystoskop</b> mit 1 Einführungshahn, Durchlass max. 10 Charr. <b>Adapter for cystoscope</b> with 1 instrument port capacity max. 10 Fr.		<b>8652.264</b>
<b>Arbeitselement Urethrotom passiv 0/12°</b> zur Aufnahme der Strikturskalpelle <b>Working element urethro passive 0/12°</b> for stricture scalpels		<b>8667.911</b>

Ø	Blickrichtung Viewing direction	Type Type	PANOVIEW-Optik PANOVIEW telescope
4 mm	0°	<b>8650.414</b>	 <div style="float: right; border: 1px solid black; padding: 2px; text-align: center;"><b>HD</b> <small>High Definition</small></div>

**Accessories:**

**Fiber light cable set**, Ø 2.5 mm, 2.3 m long consisting of:  
 Fiber light cable (80662523), adapter projector side (8095.07) and  
 adapter endoscope side (809509) ..... 806625231  
 For sterilising: **Perf. basket for standard telescope 2**,  
 capacity 1 telescope ..... 38016

**Zubehör:**

**Fiber Lichtleiter Set**, Ø 2,5 mm, 2,3 m lang bestehend aus:  
 Fiber Lichtleiter (80662523), Adapter projektorseitig (8095.07) und  
 Adapter endoskopseitig (809509) ..... 806625231  
 Zur Aufbereitung: **Siebkorb für Standardoptik 2**,  
 Aufnahmekapazität 1 Endoskop ..... 38016


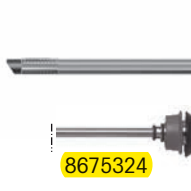













For stricture scalpels see overleaf Strikturskalpelle siehe Rückseite

## Basic Set for TUR

**Shark** Resectoscope, monopolar  
Telescope 4 mm, 12° / 30°  
26/24 Fr., active,  
continuous irrigation

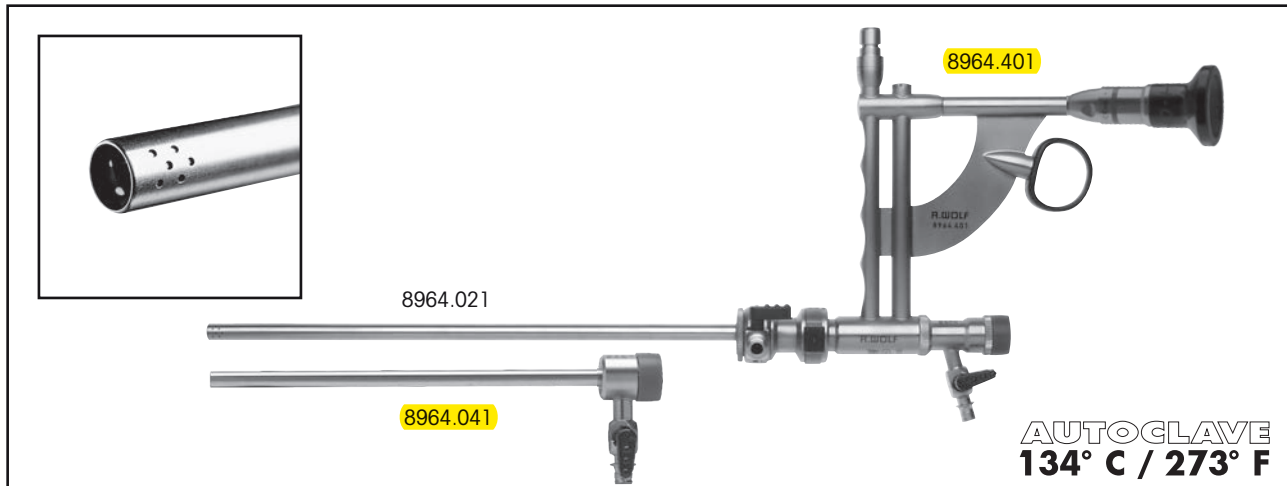
## Basis Set zur TUR

**Shark** Resektoskop, monopolar  
Optik 4 mm, 12° / 30°  
24/26 Charr., aktiv,  
Dauerspülung

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

## 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 Stablinnen-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, lancet 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

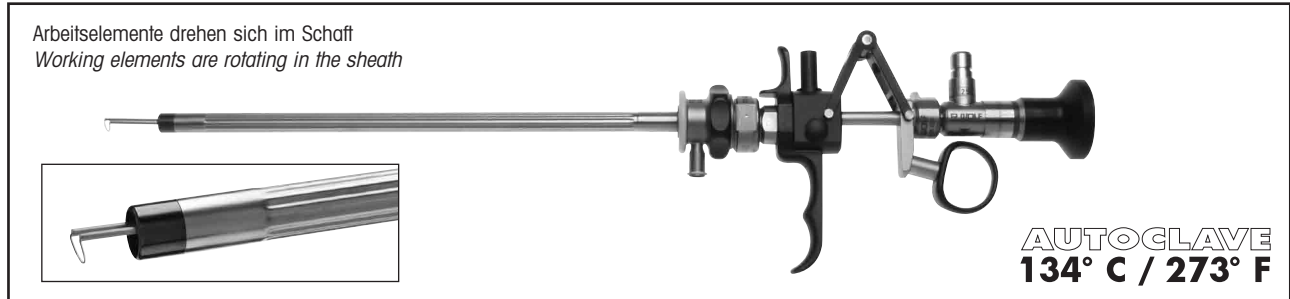
**PANOVIEW-Optik**, 0°, Ø 3,3 mm ..... 8660.424

**Strikturskalpell** mit Keramikschnede, lanzettenförmig ..... 8670.981

**Rotation Resectoscope E-line**  
 for 4 mm Telescope, 30°, 12°  
 with intermittent irrigation

**Rotations-Resektoskop E-line**  
 für Optik 4 mm, 30°, 12°  
 mit intermittierender Spülung

Resektoskope  
 Resectoscopes



3

Schäfte Sheaths	distales Ende Distal tip	Schäfte mit distaler Keramikisolation Sheaths with distal ceramic insulation			Dilatations-Obturator Dilatation obturator	Schneide-Elektrode Cutting electrode
		4 mm Lueranschuss 4 mm Luer connector	Luer-Hahn Luer tap	Zentralhahn central tap		
Charr., Kennfarbe Fr., colour code						
<b>24 Charr. / Fr.</b> gelb / yellow		<b>8654.374</b>	<b>8661.374</b>	<b>8663.374</b>	<b>8654.175</b>	<b>8424.131</b>
<b>26 Charr. / Fr.</b> schwarz / black		<b>8654.384</b>	<b>8661.384</b>	<b>8663.384</b>	<b>8654.185</b>	<b>8426.131</b>
<b>28 Charr. / Fr.</b> rot / red			<b>8661.394</b>		<b>8654.19*</b>	<b>8428.142</b>

\* Only as standard obturator available

\* Nur als Standard-Obturator lieferbar

**Rotatable connecting piece, singly, for**

24 Fr. capacity ..... **8654.3742**

26 Fr. capacity ..... **8654.3842**

**Drehbares Verbindungsteil, einzeln, für**

24 Charr. Durchlass ..... **8654.3742**

26 Charr. Durchlass ..... **8654.3842**



PANOVIEW-Optiken PANOVIEW telescopes	∅	Blickrichtung Viewing direction	mit gesteigerter Bildgröße und Objektivfeld with enlarged image and objective field	
	4 mm	30°	<b>8654.422</b>	
		12°	<b>8654.431</b>	

Weitere Elektroden siehe Seite / Further electrodes see page D 255 - D 259

Weitere Obturatoren siehe Seite / Further obturators see page D 271

HF-Anschlusskabel siehe Seite / HF connecting cable see page D 285




## Auxiliary Instruments

for percutaneous universal nephroscope  
model »Dresden«

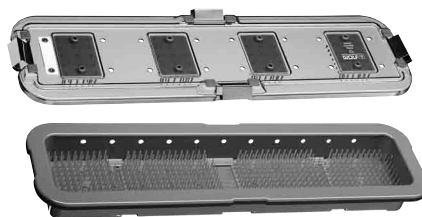
## Hilfsinstrumente

für perkutanes Universal-Nephroskop  
Modell »Dresden«

1

		Nutzlänge Working length	∅	Type Type
	<b>Steinfasszange</b> <i>Stone grasping forceps</i>	350 mm		<b>8964.601</b>
	<b>Steingreifer, dreiarmlig</b> <i>Stone grasper, 3-pronged</i>	350 mm	3.5 mm	<b>8964.671</b>
	<b>Ersatz-Steingreifer, dreiarmlig</b> <i>Spare stone grasper, 3-pronged</i>			<b>8964.675</b>
	<b>Steinfasszange,</b> fein gezahnt, für weiche Steine <i>Stone grasping forceps,</i> <i>finely serrated, for soft stones</i>	340 mm	3.5 mm	<b>8962.61</b>

Sterilisation - Storage - Transport



Sterilisation - Lagerung - Transport

**AUTOCLAVE**  
**134° C / 273° F**

### RIWO System Tray instrument container

consisting of:

instrument container with peg mat inlay, lid with fixed peg mat,  
2 coding plates (white) 1 for lid and 1 for base,  
1 marker pen (black)

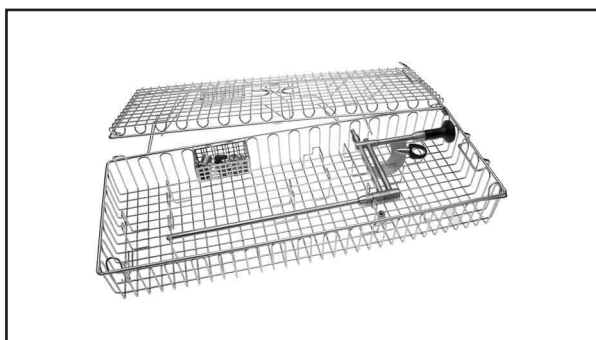
**500 x 200 x 60 mm** .....38 201.586

### RIWO-System-Tray Instrumentenbehälter

bestehend aus:

Instrumenten-Behälter mit eingelegten Noppenmatten, Deckel mit fixierten Noppenmatten, je 1 Codierschild (weiß) für Behälter und Deckel,  
1 Markierungsstift (schwarz)

**500 x 200 x 60 mm** .....38 201.586



### Aufbereitungskorb

für die maschinelle Aufbereitung und Sterilisation

**458 x 172 x 73 mm** .....38 042.311

hierzu:

**Spül-Adapter** .....64164.038

### Reprocessing basket

for mechanic reprocessing and sterilisation

**458 x 172 x 73 mm** .....38 042.311

also:






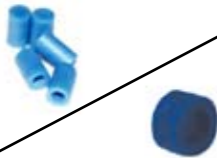

**Rinsing adapter** .....64164.038

**SYSTEM COMPONENTS & ACCESSORIES**

FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2

**PNEUMATIC HANDPIECE pn3**







	Ref. No.	Description
	<b>FR-089</b>	<b>Swiss LithoClast® pn3 Handpiece Set including:</b>
	EL-175	Pneumatic handpiece pn3
	EL-219	Adjustment interface
	AD-347	Probe cap for Ø 0.8-2.0 mm pneumatic probes
	EQ-062	Silicone probe guide set (two sets included)
	BE-028	Silicone seals (single use)
	DP-201	Transportation case
	EL-175	Pneumatic handpiece pn3 (only available within Set FR-089)
	EL-219	Adjustment Interface
	AD-347	Probe cap for connection of Ø 0.8 - Ø 2.0 mm probes with the pneumatic handpiece (EL-175)
	<b>EH-096</b>	Compressed air tube for handpiece with device connector
	EQ-062	Set of silicone guides for the pneumatic handpiece (Packing unit: 12 pieces)
	BE-028	Silicone seals, single use (packing unit: 20 pieces)
	DP-201	Transportation case for the pneumatic handpiece pn3 set

**SYSTEM COMPONENTS & ACCESSORIES**

FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2

**OPTIONAL HANDPIECE ACCESSORIES**






	Ref. No.	Description
	BF-121	Spare closing cap for the connector of the compressed air tube (EH-096)
	BG-075	Compressed air spare tube for the Swiss LithoClast® handpiece (EL-175) without connector
	<b>AD-425</b>	Probe cap for connection of the probe EL-092 (Ø 3.2 mm) with the Swiss LithoClast® handpiece (EL-175)
	<b>EQ-094</b>	O-ring set for the adjustment interface (EL-219) (Packing unit: 6 pieces)

SYSTEM COMPONENTS & ACCESSORIES

FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2

SWISS LITHOCLAST® PROBES









	Ref. No.	Description
 Ø 2.0 mm	EL-044	Swiss LithoClast® probe Ø 2.0 mm (6.0 Fr.), length 425 mm* also used in combination with the LithoVac® suction probe (EL-211) Indications: kidney, bladder
 Ø 1.0 mm	EL-045	Swiss LithoClast® probe Ø 1.0 mm (3.0 Fr.), length 605 mm* Indication: ureter
 Ø 0.8 mm	EL-046	Swiss LithoClast® probe Ø 0.8 mm (2.4 Fr.), length 605 mm* Indication: ureter
 Ø 1.6 mm	EL-058	Swiss LithoClast® probe Ø 1.6 mm (4.8 Fr.), length 605 mm* (for ureteroscopes with a working channel > 5.0 Fr.) Indication: ureter
 Ø 3.2 mm	EL-092	Swiss LithoClast® probe Ø 3.2 mm (9.6 Fr.), length 425 mm* <b>Note: Probe cap (AD-425) for the Swiss LithoClast® handpiece pn3 is also required</b> Indications: bladder, kidney

\* Indicated is the nominal length. To calculate the effective pneumatic probe length (the introduction length into the endoscope), subtract 43 mm of the indicated length of each probe.








SYSTEM COMPONENTS & ACCESSORIES

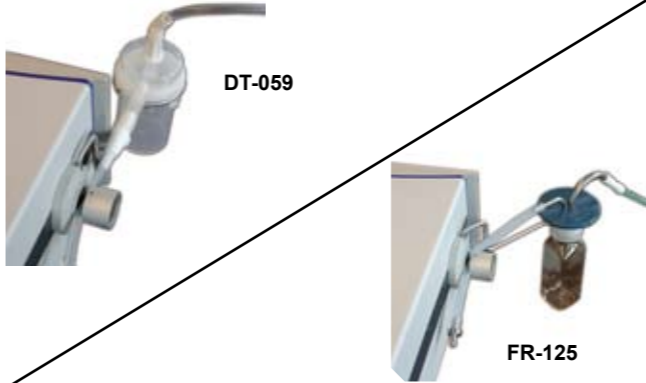







FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2

SWISS LITHOCLAST® PROBES

 Ø 0.8 mm	EL-080	Length adapted Swiss LithoClast® probe Ø 0.8 (2.4 Fr.), length 668 mm* for use with LithoVac® suction probe EL-213 Indication: ureter
 Ø 1.6 mm	EL-081	Length adapted Swiss LithoClast® probe Ø 1.6 mm (4.8 Fr.), length 453 mm* for use with LithoVac® suction probe EL-212 Indications: bladder, kidney
 Ø 0.89 mm / 940 mm	EL-254B	flexible Swiss LithoClast® probe set (3 probes) Ø 0.89 mm, Länge 940 mm*, for flexible ureteroreno- scopes to be used with the pneumatic handpiece pn3 EL-175
 Ø 0.89 mm / 600 mm	EL-304B	flexible Swiss LithoClast® probe set (3 probes) Ø 0.89 mm, length 600 mm*, for flexible nephroscopes to be used with the pneumatic handpiece pn3 EL-175
 Ø 0.89 mm / 940 mm	EL-298B	flexible Swiss LithoClast® probe set (3 probes) Ø 0.89 mm, length 940 mm*, for flexible ureteroreno- scopes to be used with the Swiss LithoClast® handpiece EL-043
 Ø 0.89 mm / 940 mm	EL-299B	flexible Swiss LithoClast® probe set (3 pieces) Ø 0.89 mm, length 940 mm* for flexible ureteroreno- scopes to be used with the Swiss LithoClast® Master handpiece EL-103

\* Indicated is the nominal length. To calculate the effective pneumatic probe length (the introduction length into the endoscope), subtract 43 mm of the indicated length of each probe.

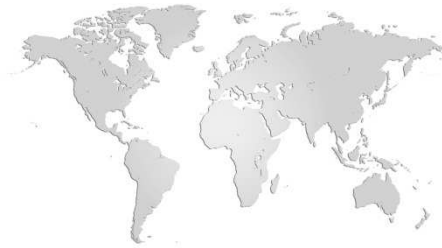
SYSTEM COMPONENTS & ACCESSORIES		
FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2		
<b>LITHOVAC® lv3</b>		
		
	Ref. No.	Description
	<b>FR-127</b>	<b>Lithovac lv3 Set including:</b>
	EL-182	LithoVac® body
	EL-237	(shown here with adjustment interface EL-219) Suction set
	EL-182	LithoVac® body (shown here with adjustment interface EL-219)
	EL-237	Suction set for LithoVac® (silicone tube for LithoVac® tube valve with connecting piece)
 Ø 4.0 mm	EL-211	Suction probe for LithoVac® Ø 4.0 mm (12.0 Fr.), sheath length 355 mm* for applications with nephroscopes with a working channel > 12.0 Fr.
 Ø 3.5 mm	<b>EL-212</b>	Suction probe for LithoVac® Ø 3.5 mm (10.5 Fr.), sheath length 380 mm* for applications with cysto-/nephroscopes with a working channel > 10.5 Fr.
 Ø 1.6 mm	<b>EL-213</b>	Suction probe for LithoVac® Ø 1.6 mm (4.8 Fr.), sheath length 595 mm* for applications with ureterorenoscopes with a working channel > 5 Fr.
* Indicated is the nominal length of the LithoVac® suction probe. To calculate the effective probe length (introduction length into the endoscope), subtract 18 mm of the indicated length of each probe.		

SYSTEM COMPONENTS & ACCESSORIES		
FOR SWISS LITHOCLAST® MASTER & LITHOCLAST® 2		
<b>STONE CATCHER</b>		
SWISS LITHOCLAST® MASTER		SWISS LITHOCLAST® 2
		
	DT-059	FR-126
	FR-125	
	Ref. No.	Description
	EL-225	Stone fragment catcher holder for Swiss LithoClast® Master
	FR-126	Stone fragment catcher holder for the Swiss LithoClast® 2 for the use with Stone fragment catcher set DT-059 (including mounting kit for Swiss LithoClast® 2)
	FR-125	Stone fragment catcher for the Swiss LithoClast® Master autoclavable, reusable in combination with single use suction tubes, sterile, with conical fitting (such as FR-091/4)
	FR-091/4	Suction tube, sterile, length 3 m for the Stone catcher set (FR-125) Packing unit: 10 pieces
	DT-059	Stone fragment catcher set sterile, single use for the Swiss LithoClast® Master/Swiss LithoClast® 2 Packing unit: 10 pieces
	FR-113	Roller clamp (set of 2) for precise adjustment of suction flow in connection with FR-125 or DT-059



# 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  
**E.M.S. Electro Medical Systems S.A.**

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland

**Certified location:**

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland  
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 2, 1260 Nyon, Switzerland  
E.M.S. Electro Medical Systems S.A., Rte. de Champ-Colin 18, 1260 Nyon, Switzerland  
E.M.S. Foncine S.A.S., Rte. de Pontarlier 32, 39460 Foncine-le-Haut, France

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. 50081-Z7-00, the decision dated 2020-06-15 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-06-15 to 2024-05-26

Registration No.: 50081-16-09



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2020-06-15  
Notified Body ID-number: 0124



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)  
**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 50081-16-09

Valid from 2020-06-15 to 2024-05-26

Revision status of the annex: 0 dated 2020-06-15

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.

IntraCorporal Lithotripters systems  
- Stone Catcher

## Class II a:

IntraCorporal Lithotripters systems  
- Swiss LITHOPUMP  
- Probes (pneumatic, ultrasound and combined)  
- Probes Sets (pneumatic, ultrasound and combined)

Piezo-ceramic systems for dentistry - Piezon  
- PIEZON product group  
- PIEZON Surgery product group  
- PIEZON Handpieces, PIEZON instruments

Air abrasion / air polisher devices for dental prophylaxis  
- AIRFLOW product group  
- PERIOFLOW nozzles  
- AIRFLOW, PERIOFLOW Handpieces

Air abrasion / air polisher devices for dental prophylaxis with Piezo-ceramic systems for dentistry  
- AIRFLOW / PIEZON product group

Surgical HO\_YAG laser systems  
- SmartFibers product group

## Class II b:

IntraCorporal Lithotripters systems  
- LITHOCLAST product group  
- LITHOCLAST handpieces (pneumatic, ultrasound and combined)  
- Handpiece Sets (pneumatic, ultrasound and combined)

ExtraCorporal shock wave therapy systems  
- DOLORCLAST product group  
- DOLORCLAST Handpieces, DOLORCLAST applicators

Surgical HO\_YAG laser-system  
- Swiss LASERCLAST product group

  
Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2020-06-15  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

# CERTIFICATE



## EN ISO 13485:2016 + AC:2018 + A11:2021

DEKRA Certification GmbH hereby certifies that the organization

### **E.M.S. Electro Medical Systems S.A.**

#### **Scope of certification:**

Design, manufacturing, distribution and servicing of medical devices and accessories for dentistry, urology and orthopedics

#### **Certified location:**

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland  
(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. 50081-R3-00.

Certificate registration no.: 50081-21-00

Certificate valid from: 2024-04-23

Validity of previous certificate: 2024-04-22

Certificate valid to: 2026-06-14



*K. Leicht*

Karin Leicht  
DEKRA Certification GmbH, Stuttgart, 2024-04-23



Deutsche  
Akkreditierungsstelle  
D-ZM-16029-08-00

# Annex to the Certificate No. 50081-21-00

valid from 2024-04-23 to 2026-06-14

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	E.M.S. Electro Medical Systems S.A.	Chemin de la Vuarpillière 31 1260 Nyon Switzerland	see page 1
	<b>at the following locations/at the companies at the following locations</b>		<b>Scopes of certification</b>
1.		Rte. de Champ-Colin 2 1260 Nyon Switzerland	Manufacturing of medical devices and accessories for dentistry, urology and orthopedics.
2.		Rte. de Champ-Colin 18 1260 Nyon Switzerland	Manufacturing and logistic activities of medical devices and accessories for dentistry, urology and orthopedics.
3.		Rte. de Pontarlier 32 39460 Foncine-le-Haut France	Manufacturing of medical devices and accessories for dentistry, urology and orthopedics



Karin Leicht  
DEKRA Certification GmbH, Stuttgart, 2024-04-23



**EC DECLARATION OF CONFORMITY  
DECLARATION CE DE CONFORMITE  
EG-KONFORMITÄTSERKLÄRUNG**

Nous,

We,

Wir,

**E.M.S. Electro Medical Systems S.A.,  
Chemin de la Vuarpillière 31,  
1260 Nyon, Switzerland**déclarons sous notre seule  
responsabilité que les références du  
produit :declare under our sole responsibility  
that the references of the product :erklären in alleiniger Verantwortung,  
daß die Referenzen des Produkts:**Swiss LithoClast Master, LCM21 and Accessories**de satisfont aux dispositions  
applicables des directives relatives aux  
dispositifs médicaux 93/42/CEE &  
2007/47/CEE, Annexe II (Système  
complet d'assurance de qualité), hors  
point (4),are conforming to the relevant  
provisions of the Medical Device  
Directives 93/42/EEC &  
2007/47/EEC, Annex II (Full quality  
assurance system), excluding  
section (4),den einschlägigen Bestimmungen  
der richtlinien 93/42/EWG &  
2007/47/EWG Medizinprodukte,  
Anhang II (Vollständiges  
Qualitätssicherungssystem), ausser  
Nummer (4), entsprechen,**sous le numéro de certificat CE :****Under the EC Certificate No. :**  
50081-16-09**EG Zertifikat-Nr. :****Date de la dernière recertification :****Date of last recertification :**  
2020-06-15**Datum der letzten Rezertifizierung:****Nom, adresse et numéro  
d'identification de l'organisme notifié:****Name, address and identification  
number of Notified Body:**  
DEKRA Certification GmbH  
Handwerkstrasse 15,  
70565 Stuttgart, Germany **CE**<sub>0124</sub>**Name, Adresse und Kenn-  
nummer der Benannten Stelle:**La documentation technique est  
disponible auprès d'E.M.S. Electro  
Medical Systems S.A.Technical documentation is kept  
available by E.M.S. Electro Medical  
Systems S.A.Die technische Dokumentation wird  
durch E.M.S. Electro Medical  
Systems S.A. gehalten.**Nom et adresse du Mandataire:****Name and address of the  
Authorized Representative:****Name und anschrift des  
Bevollmächtigter:**E.M.S. Electro Medical Systems FRANCE SARL  
32, Route de Pontarlier  
39460 Foncine-Le-Haut – France**Lieu, date****Place, date****Ort, Datum**

Nyon, 2021-05-25

Valid until : 2024-05-26

**Fonction, nom et signature****Function, name and signature****Funktion, Name und Unterschrift**

Marketing Manager, Urology

Jérôme Blondeau

Head of Quality

Timothée Deblock

References of all classes except class I, are compliant with Annex II (Full Quality Assurance System), excluding section (4):



References	SET/DEV/ACC	Product name	Class 93/42	Rules	CE market release date
FT-207#	SET	Swiss LithoClast LCM21	IIb	9 part 2	2010-07-29
FT-128#	SET	Swiss LithoClast Master	IIb	9, part 2	2007-04-10
FR-159#	SET	Upgrade kit Vario Ultrasound handpiece	IIb	9, part 2	N/A
FR-159	SET	Upgrade kit Vario Ultrasound handpiece	IIb	9, part 2	N/A
FR-127#	SET	Lithovac Iv3 Set	IIb	9, part 2	N/A
FR-127	SET	LithoVac Iv3 Set	IIb	9, part 2	N/A
FR-089	ACC	Pneumatic handpiece kit pn3	IIb	9, part 2	N/A
FR-089#	ACC	Pneumatic handpiece pn3 set	IIb	9, part 2	N/A
EN-055#	ACC	Vario Ultrasound handpiece	IIb	9, part 2	N/A
EN-055	ACC	Vario Ultrasound handpiece	IIb	9, part 2	N/A
EL-237	ACC	Suction set for Lithovac	IIb	9, part 2	N/A
EL-182	ACC	LithoVac Iv3	IIb	9, part 2	N/A
FR-142#	ACC	Vario Ultrasound handpiece Set	IIb	9, part 2	N/A
FR-142	ACC	Vario Ultrasound handpiece kit	IIb	9, part 2	N/A
FR-106	ACC	Ultrasound Probe Ø 3.8 X 330 mm	IIa	5 & 7	N/A
FR-105	ACC	Ultrasound Probe Ø 3.3 X 330 mm	IIa	5 & 7	N/A
FR-103	ACC	Ultrasound Probe Ø 1.9 X 360 mm	IIa	5 & 7	N/A
FR-102	ACC	Ultrasound Probe Ø 1.5 X 573 mm	IIa	5 & 7	N/A
FR-084	ACC	Ultrasound Probe Ø 3.3 X 403 mm	IIa	5 & 7	N/A
FR-083	ACC	Ultrasound Probe Ø 3.8 X 403 mm	IIa	5 & 7	N/A
EL-552#	ACC	LithoClast Probe Ø0.8 x 410mm (2,4 Ch.)	IIa	5 & 7	N/A
EL-535#	ACC	Probe LithoClast Ø 1.3 X 410 mm	IIa	5 & 7	N/A
EL-535	ACC	LithoClast Probe Ø 1.3 x 410 mm	IIa	5 & 7	N/A
EL-304B	SET	3 x LithoClast FlexProbe®	IIa	5 & 7	N/A
EL-293#	ACC	Probe Ø1 x 636 mm	IIa	5 & 7	N/A
EL-293	ACC	Probe Ø1 x 636 mm	IIa	5 & 7	N/A
EL-276#	ACC	Probe Ø 1 X 497 mm	IIa	5 & 7	N/A
EL-276	ACC	LithoClast Probe Ø 1.0 X 497 mm	IIa	5 & 7	N/A
EL-264#	ACC	Probe Ø 1 x 482 mm	IIa	5 & 7	N/A
EL-264	ACC	Probe Ø 1 x 482 mm	IIa	5 & 7	N/A
EL-261#	ACC	Probe Ø 1.6 X 380 mm	IIa	5 & 7	N/A
EL-261	ACC	Probe Ø 1.6 x 380 mm	IIa	5 & 7	N/A
EL-255#	ACC	Probe Ø 1.3 x 570 mm	IIa	5 & 7	N/A
EL-255	ACC	Probe Ø 1.3 x 570 mm	IIa	5 & 7	N/A

EL-254	ACC	Flex Probe	Ila	5 6 7	N/A
EL-254B	SET	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
EL-220#	ACC	Probe Ø 1.0 X 570 mm	Ila	5 & 7	N/A
EL-220	ACC	LithoClast Probe Ø 1.0 X 570 mm	Ila	5 & 7	N/A
EL-213#	ACC	Suction tube Ø1,6x595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-213	ACC	Suction tube Ø1,6x595 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-212#	ACC	Suction tube Ø3,5x380 mm (10,5 Ch.)	Ila	5 & 7	N/A
EL-212	ACC	Suction tube Ø3,5x380 mm (10,5 Ch.)	Ila	5 & 7	N/A
EL-211#	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	Ila	5 & 7	N/A
EL-211	ACC	Suction tube Ø4,0 x 353 mm (12 Ch.)	Ila	5 & 7	N/A
EL-175	ACC	Pneumatic handpiece pn3	Ila	5 & 7	N/A
EL-101#	ACC	Probe Ø 1.6 x 490 mm	Ila	5 & 7	N/A
EL-101	ACC	Probe Ø 1.6 x 490 mm	Ila	5 & 7	N/A
EL-099#	ACC	Probe Ø 0.8 x 490 mm	Ila	5 & 7	N/A
EL-099	ACC	Probe Ø 0.8 x 490 mm	Ila	5 & 7	N/A
EL-092#	ACC	Probe Ø 3.2 x 425 mm (9,6 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-092	ACC	Probe Ø 3.2 x 425 mm (9,6 Ch.)	Ila	5 & 7	N/A
EL-081#	ACC	Probe Ø 1,6 x 453 mm (4,8 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-081	ACC	LithoClast Probe Ø 1.6 X 453 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-081/A	ACC	LithoBreaker Probe Ø 1,6 x 453 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-080#	ACC	Probe Ø 0,8 x 668 mm (2,4 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-080	ACC	LithoClast Probe Ø 0.8 X 668 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-080/A	ACC	LithoBreaker Probe Ø 0,8 x 668 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-079#	ACC	Probe Ø 0.8 x 558 mm	Ila	5 & 7	N/A
EL-079	ACC	Probe Ø 0.8 x 558 mm	Ila	5 & 7	N/A
EL-058#	ACC	Probe Ø 1,6 x 605 mm (4,8 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-058	ACC	LithoClast Probe Ø 1.6 X 605 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-058/A	ACC	LithoBreaker probe Ø 1,6 x 605 mm (4,8 Ch.)	Ila	5 & 7	N/A
EL-046#	ACC	Probe Ø 0.8 x 605 mm (2,4 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-046	ACC	LithoClast Probe Ø 0.8 X 605 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-046/A	ACC	LithoBreaker probe Ø 0,8 x 605 mm (2,4 Ch.)	Ila	5 & 7	N/A
EL-045#	ACC	Probe Ø 1 x 605 mm (3,0 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A
EL-045	ACC	LithoClast probe Ø 1,0 x 605 mm (3,0 Ch.)	Ila	5 & 7	N/A
EL-045/A	ACC	LithoBreaker probe Ø 1 x 605 mm (3,0 Ch.)	Ila	5 & 7	N/A
EL-044#	ACC	Probe Ø 2 x 425 mm (6,0 Ch.) for LithoClast or LithoBreaker	Ila	5 & 7	N/A

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EL-044	ACC	LithoClast probe Ø 2,0 x 425 mm (6,0 Ch.)	Ila	5 & 7	N/A
EL-044/A	ACC	LithoBreaker probe Ø 2,0 x 425 mm (6,0 Ch.)	Ila	5 & 7	N/A
EL-298B	ACC	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A
EL-299B	ACC	3 x LithoClast FlexProbe®	Ila	5 & 7	N/A

Note: the # symbol indicates that the product is available as a configurable item with various combinations of optional items.