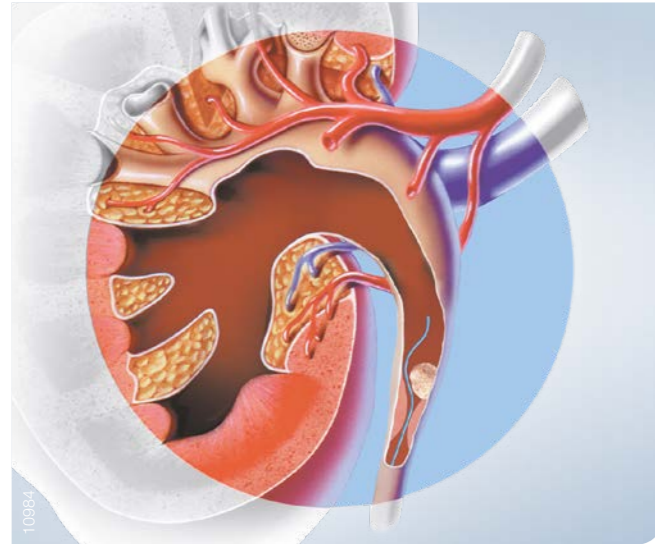


# ACCESS



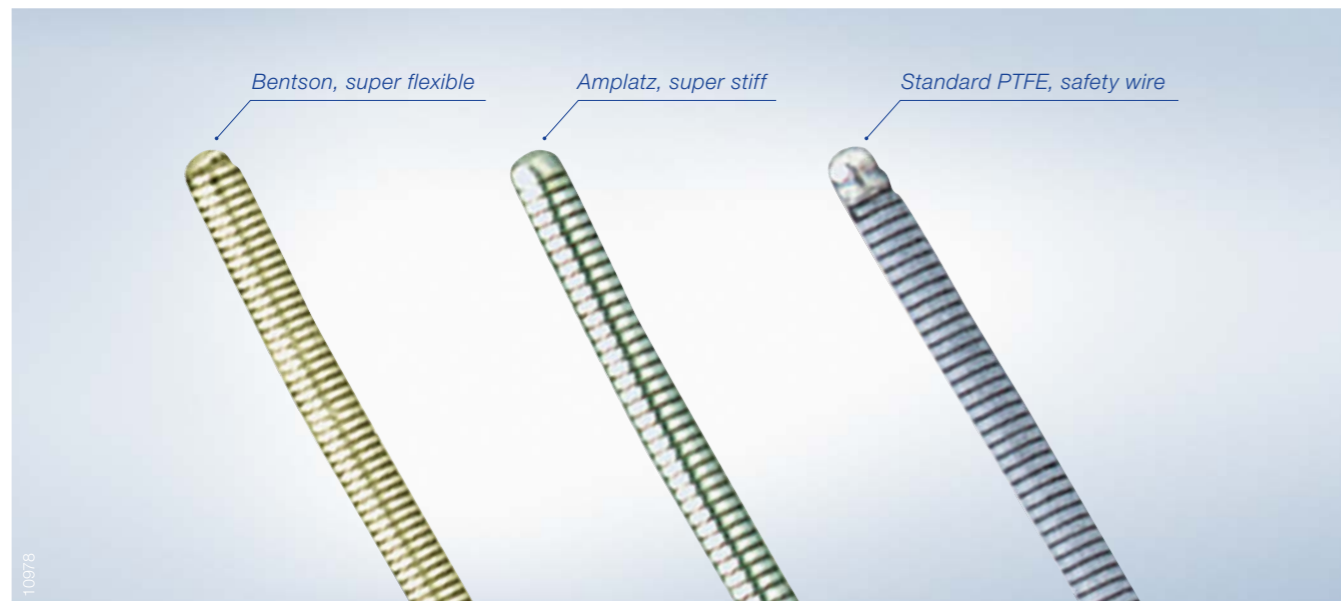
Getting access to the ureter or kidney is essential for every urologist treating stone burdens. Olympus recognizes the importance of achieving this access in a safe and time-efficient manner. Therefore, we provide a comprehensive lineup of nitinol and PTFE guidewires with various tip configurations to incorporate anatomical differences.



### E-Z Grip Torque Device

The E-Z Grip Torque Device is a little tool adding convenience to your procedures. When mounted on an angled guidewire, turning this to access the ureteral orifice becomes extremely comfortable.

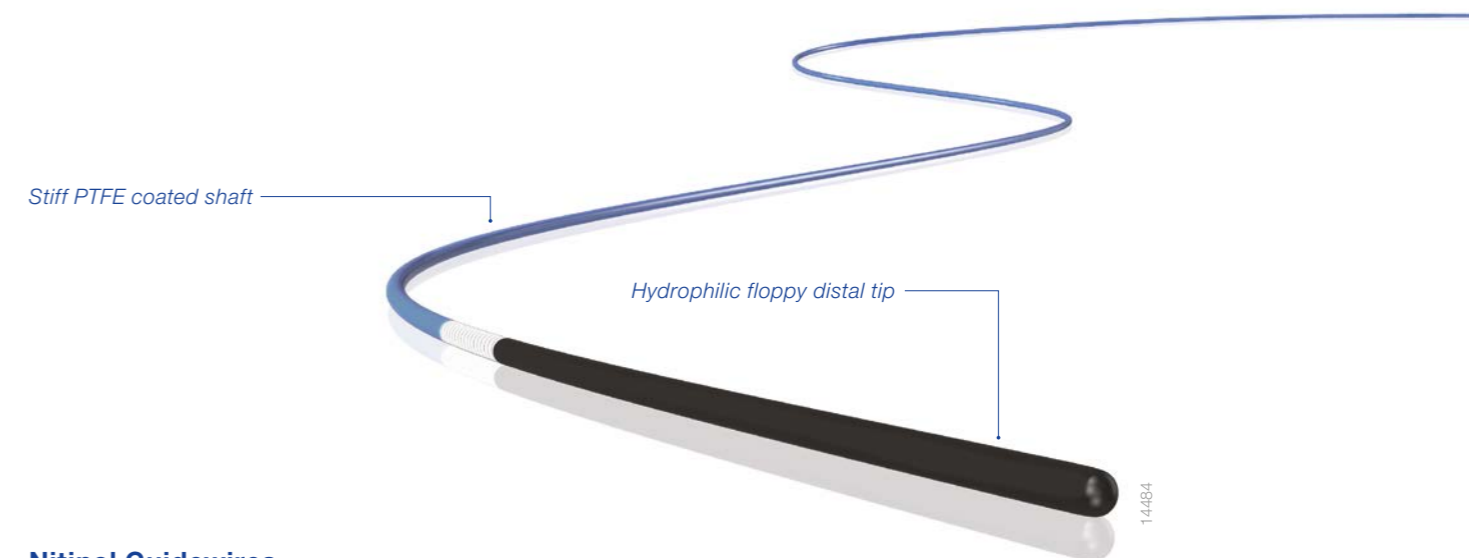
### PTFE Guidewires



### Hybrid Guidewires

#### UltraTrack – Hybrid Guidewire

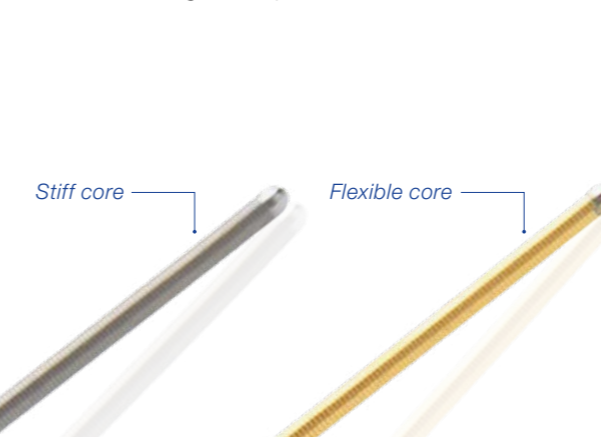
- Nitinol core with hydrophilic floppy tip and PTFE coated stiff shaft
- Hydrophilic floppy distal tip facilitates smooth and easy navigation through strictures and stone obstructions
- PTFE coated stainless steel coil optimizes grip and positioning
- Introducer coil allows for easy and safe surgeon controlled advancement of the wire
- Flexible proximal tip facilitates back loading of endoscopes



### Nitinol Guidewires

#### Quattro – Two-in-One Guidewire

- Two tip characteristics aimed at accommodating different patient anatomies in one guidewire
- Flexible golden tip for accessing challenging anatomies
- Stiff silver tip for fast and easy access
- Extremely well differentiated during fluoroscopy due to tungsten tips

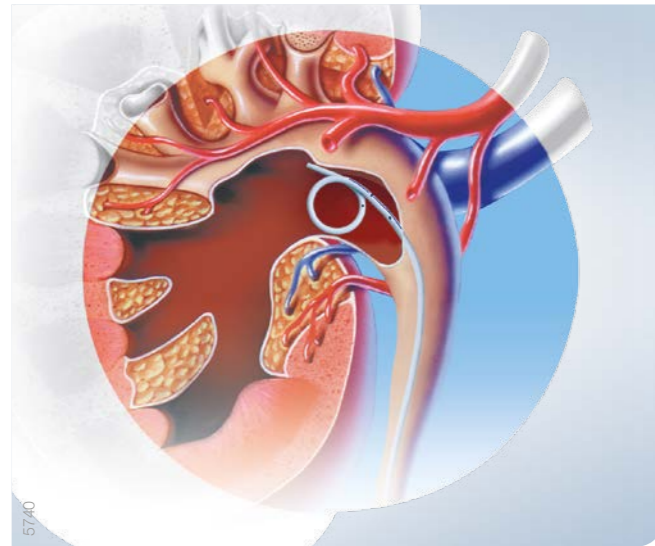


#### SureGlide – The Everyday Guidewire

- Smooth, easy tracking through tortuous anatomy
- Nitinol core with hydrophilic coating facilitates initial access
- Features radiopaque jacket for clear visibility and easy positioning



# DRAINAGE



We offer a broad selection of premium-quality stents from specialty to everyday usage. Our Single-J and Double-J as well as UroGuide stent minimize encrustation thanks to being made of silicone. Silicone is used in various medical applications because of its softness which allows easy insertion and removal of the stent.

Olympus understands your procedural needs and has pioneered advanced drainage technology without compromise. As an indication of the quality of the material, all TecoFlex stents are approved for 365 days of indwelling time.

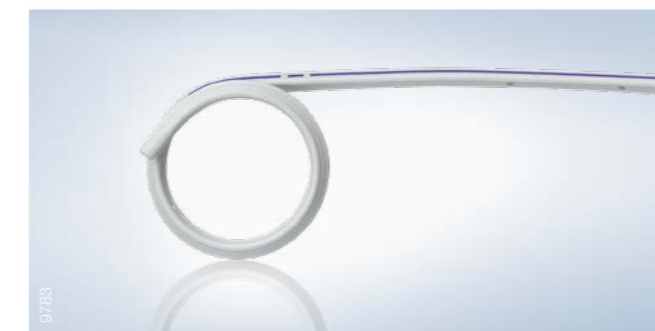
## Silicone Stents



- Single-J Stent**  
Single-J stent with 90 cm length for superior drainage.
- Double-J Stent**  
Silicone stent with closed tips for reliable drainage after stone treatment.
- UroGuide Stent**  
Silicone stent for easy insertion and high encrustation resistance with open ends.

## TecoFlex Stents

**LithoStent**  
TecoFlex stent with triangular shape to resist sidewall collapse and ensure optimized drainage.



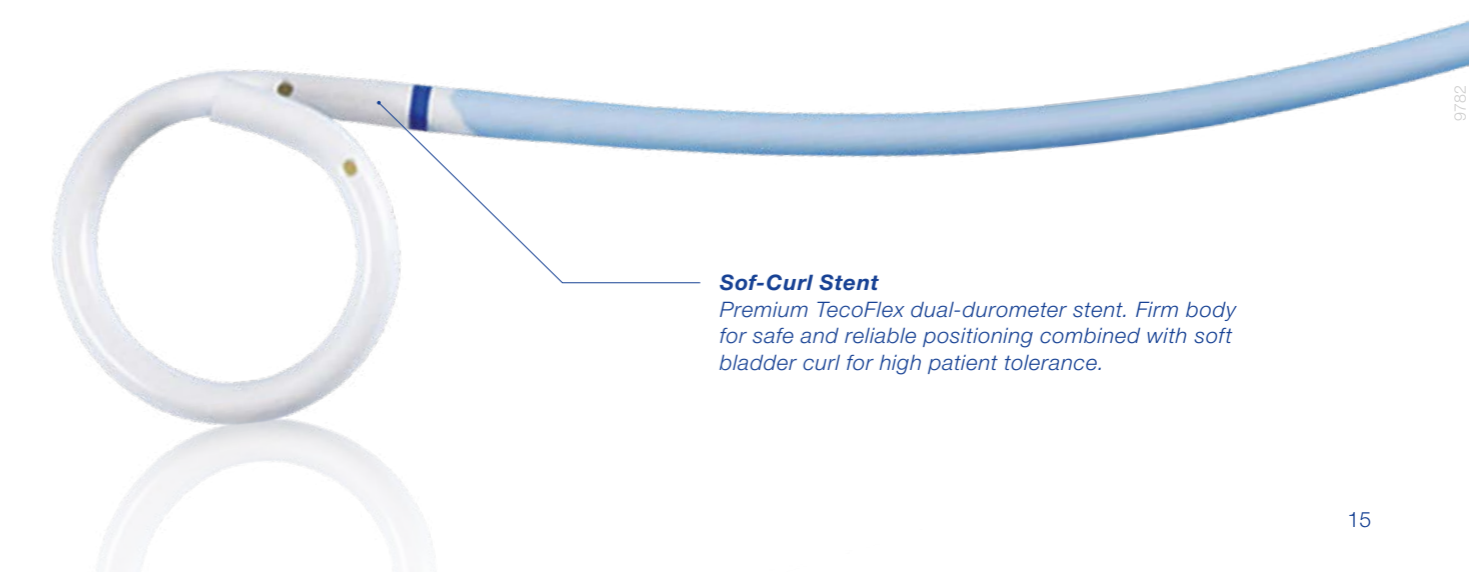
**Quadra-Coil Stent**  
Soft TecoFlex stent with specially designed bladder curl. The multilength concept allows for patient adjusted placement from 22–28 cm.



**Classic Double Pigtail Stent**  
Soft TecoFlex stent for high patient comfort due to the softness of the material.



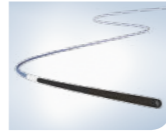
**Lubri-Flex**  
Firm TecoFlex stent for safe and reliable placement.



**Sof-Curl Stent**  
Premium TecoFlex dual-durometer stent. Firm body for safe and reliable positioning combined with soft bladder curl for high patient tolerance.

## ORDERING INFORMATION

### Hybrid Guidewires



#### UltraTrack

Catalogue No.	Size	Length	Tip	Quantity
EGGWH3505RA	0.035"	150 cm	5 cm, Angled	5/box
EGGWH3505R	0.035"	150 cm	5 cm, Straight	5/box
EGGWH3805RA	0.038"	150 cm	5 cm, Angled	5/box
EGGWH3805R	0.038"	150 cm	5 cm, Straight	5/box

### Nitinol Guidewires



#### SureGlide

Catalogue No.	Size	Length	Tip	Quantity
EG15BX	0.025"	150 cm	Straight	5/box
EG16BX	0.025"	150 cm	Angled	5/box
EG35BX	0.035"	150 cm	Straight	5/box
EG36BX	0.035"	150 cm	Angled	5/box
EG38BX	0.038"	150 cm	Straight	5/box
EG39BX	0.038"	150 cm	Angled	5/box

#### SureGlide TC

Catalogue No.	Size	Length	Tip	Quantity
EG41BX	0.035"	150 cm	Straight	5/box
EG42BX	0.038"	150 cm	Straight	5/box
EG43BX	0.035"	150 cm	Angled	5/box
EG44BX	0.038"	150 cm	Angled	5/box

#### Quattro

Catalogue No.	Size	Length	Tip	Quantity
EG50BX	0.035"	150 cm	Straight	5/box

#### E-Z Grip Torque Device

Catalogue No.	Description
EGGWT	E-Z Grip Guidewire Torque Device, 5/box

### PTFE Guidewires



#### Bentson

Catalogue No.	Size	Length	Tip	Quantity
EG10BX	0.035"	150 cm	15 cm	5/box
EG12BX	0.038"	150 cm	15 cm	5/box

#### Amplatz

Catalogue No.	Size	Length	Tip	Quantity
EG13BX	0.035"	150 cm	9 cm	5/box
EG14BX	0.038"	150 cm	9 cm	5/box

#### PTFE-coated

Catalogue No.	Size	Length	Tip	Quantity
EG22BX	0.025"	150 cm	3 cm flex	5/box
EG25BX	0.035"	150 cm	3 cm flex	5/box
EG26BX	0.035"	150 cm	Moveable	5/box
EG28BX	0.038"	150 cm	3 cm flex	5/box
EG29BX	0.038"	150 cm	Moveable	5/box

#### PTFE extra-firm TC

Catalogue No.	Size	Length	Tip	Quantity
EG24BX	0.038"	150 cm	3 cm flex	5/box

### Catheter



#### Ureteral Catheter

Catalogue No.	Description
EG608BX	Dual Lumen ureteral catheter, 6/10 Fr, 57 cm, 5/box

### Uropass Ureteral Access Sheath

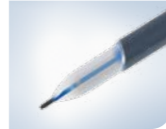


#### UroPass Ureteral Access Sheath

Catalogue No.	Description
EG61024BX	UroPass 10/12 Fr x 24 cm, (5/Bx)
EG61038BX	UroPass 10/12 Fr x 38 cm, (5/Bx)
EG61046BX	UroPass 10/12 Fr x 46 cm, (5/Bx)
EG61054BX	UroPass 10/12 Fr x 54 cm, (5/Bx)
EG61124BX	UroPass 11/13 Fr x 24 cm, (5/Bx)
EG61138BX	UroPass 11/13 Fr x 38 cm, (5/Bx)
EG61146BX	UroPass 11/13 Fr x 46 cm, (5/Bx)
EG61154BX	UroPass 11/13 Fr x 54 cm, (5/Bx)
EG61224BX	UroPass 12/14 Fr x 24 cm, (5/Bx)
EG61238BX	UroPass 12/14 Fr x 38 cm, (5/Bx)
EG61246BX	UroPass 12/14 Fr x 46 cm, (5/Bx)
EG61254BX	UroPass 12/14 Fr x 54 cm, (5/Bx)
EG61324BX	UroPass 13/15 Fr x 24 cm, (5/Bx)
EG61338BX	UroPass 13/15 Fr x 38 cm, (5/Bx)
EG61346BX	UroPass 13/15 Fr x 46 cm, (5/Bx)
EG61354BX	UroPass 13/15 Fr x 54 cm, (5/Bx)

## ORDERING INFORMATION

### Nephro-EZDilate Balloon Dilator



Kit: Balloon Dilator with 25 cc Inflation Device

Catalogue No.	Description
EGBPCN0815K	PCNL Balloon + Inflation Device kit 8 mm (24 Fr) × 15 cm
EGBPCN1015K	PCNL Balloon + Inflation Device kit 10 mm (30 Fr) × 15 cm

#### Individual Balloon Dilators

Catalogue No.	Description
EGBPCN0815	PCNL Balloon, 8mm (24 Fr) × 15 cm
EGBPCN1015	PCNL Balloon, 10mm (30 Fr) × 15 cm
EGBINF2530	Balloon Inflation Device

### Uro-EZDilate Balloon Dilator

Kit: Balloon Dilator with 25 cc Inflation Device

Catalogue No.	Description
EGBURS0404K	URS Balloon + Inflation Device kit 4 mm (12 Fr) × 4 cm
EGBURS0410K	URS Balloon + Inflation Device kit 4 mm (12 Fr) × 10 cm
EGBURS0504K	URS Balloon + Inflation Device kit 5 mm (15 Fr) × 4 cm
EGBURS0510K	URS Balloon + Inflation Device kit 5 mm (15 Fr) × 10 cm
EGBURS0604K	URS Balloon + Inflation Device kit 6 mm (18 Fr) × 4 cm
EGBURS0610K	URS Balloon + Inflation Device kit 6 mm (18 Fr) × 10 cm

#### Individual Balloon Dilators

Catalogue No.	Description
EGBURS0404	URS Balloon, 4 mm (12 Fr) × 4 cm
EGBURS0410	URS Balloon, 4 mm (12 Fr) × 10 cm
EGBURS0504	URS Balloon, 5 mm (15 Fr) × 4 cm
EGBURS0510	URS Balloon, 5 mm (15 Fr) × 10 cm
EGBURS0604	URS Balloon, 6 mm (18 Fr) × 4 cm
EGBURS0610	URS Balloon, 6 mm (18 Fr) × 10 cm
EGBINF2530	Balloon Inflation Device

### Nitinol Devices



Ultra-Catch 4-Wire No-Tip Nitinol Basket

Catalogue No.	Diameter	Cage size
EGNT4W18115	1.8 Fr	11 mm
EGNT4W22115	2.2 Fr	14 mm
EGNT4W30115	3.0 Fr	18 mm

X-Catch 6-Wire No-Tip Nitinol Basket

Catalogue No.	Diameter	Cage size
EGNTCP18115	1.8 Fr	11 mm
EGNTCP22115	2.2 Fr	14 mm
EGNTCP30115	3.0 Fr	17 mm

### Stainless Steel Devices



SurLok Flat-Wire Stone Baskets

Catalogue No.	Diameter	Wires	Length
EG5710002	2.4 Fr	4	120 cm
EG5710005	3.0 Fr	4	120 cm
EG5710009	4.5 Fr	4	70 cm

SurLok Helical Stone Baskets

Catalogue No.	Diameter	Wires	Length
EG5700002	1.9 Fr	3	120 cm
EG5700005	3.0 Fr	4	90 cm
EG5700014	4.5 Fr	6	70 cm

SurLok Stone Grasping Forceps

Catalogue No.	Diameter	Wires	Length
EG5720001	2.4 Fr	3	120 cm
EG5720004	3.0 Fr	3	120 cm

### Silicone Ureteral Stents



Double-J Ureteral Stents (closed ends)

Catalogue No.	Diameter	Length
EG5201800	6.0 Fr	12 cm
EG5202000	6.0 Fr	16 cm
EG5202600	6.0 Fr	20 cm
EG5202700	6.0 Fr	22 cm
EG5202800	6.0 Fr	24 cm
EG5202100	6.0 Fr	26 cm
EG5202200	6.0 Fr	28 cm
EG5202400	6.0 Fr	30 cm
EG5203600	7.0 Fr	12 cm
EG5204000	7.0 Fr	16 cm
EG5204600	7.0 Fr	20 cm
EG5204700	7.0 Fr	22 cm
EG5204800	7.0 Fr	24 cm
EG5204100	7.0 Fr	26 cm
EG5204200	7.0 Fr	28 cm
EG5204400	7.0 Fr	30 cm
EG5208600	8.5 Fr	12 cm
EG5209000	8.5 Fr	16 cm
EG5209600	8.5 Fr	20 cm
EG5209050	8.5 Fr	22 cm
EG5209800	8.5 Fr	24 cm
EG5209100	8.5 Fr	26 cm
EG5209200	8.5 Fr	28 cm
EG5209400	8.5 Fr	30 cm

Each Double-J Ureteral Stent supplied with attached braided nylon tether, one 0.028" × 100 cm PTFE-coated guidewire, and one push catheter.

Single-J Urinary Diversion Stents (open ends)

Catalogue No.	Diameter	Length
EG5230600	7.0 Fr	90 cm
EG5230800	8.5 Fr	90 cm

Each Single-J Urinary Diversion Stent supplied with two urinary diversion stents and one 0.028" × 120 cm PTFE-coated guidewire.

UroGuide Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EG5496022	6.0 Fr	22 cm
EG5496024	6.0 Fr	24 cm
EG5496026	6.0 Fr	26 cm
EG5496028	6.0 Fr	28 cm
EG5496030	6.0 Fr	30 cm
EG5497022	7.0 Fr	22 cm
EG5497024	7.0 Fr	24 cm
EG5497026	7.0 Fr	26 cm
EG5497028	7.0 Fr	28 cm
EG5497030	7.0 Fr	30 cm
EG5498522	8.5 Fr	22 cm
EG5498524	8.5 Fr	24 cm
EG5498526	8.5 Fr	26 cm
EG5498528	8.5 Fr	28 cm
EG5498530	8.5 Fr	30 cm

Each UroGuide Ureteral Stent supplied with attached braided nylon tether and one push catheter.

## ORDERING INFORMATION

### TecoFlex Ureteral Stents



#### Lubri-Flex Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EG5554508	4.5 Fr	8 cm
EG5554510	4.5 Fr	10 cm
EG5554512	4.5 Fr	12 cm
EG5554514	4.5 Fr	14 cm
EG5554516	4.5 Fr	16 cm
EG5554518	4.5 Fr	18 cm
EG5554520	4.5 Fr	20 cm
EG5554522	4.5 Fr	22 cm
EG5554524	4.5 Fr	24 cm
EG5554526	4.5 Fr	26 cm
EG5554528	4.5 Fr	28 cm
EG5556022	6.0 Fr	22 cm
EG5556024	6.0 Fr	24 cm
EG5556026	6.0 Fr	26 cm
EG5556028	6.0 Fr	28 cm
EG5556030	6.0 Fr	30 cm
EG5557022	7.0 Fr	22 cm
EG5557024	7.0 Fr	24 cm
EG5557026	7.0 Fr	26 cm
EG5557028	7.0 Fr	28 cm
EG5557030	7.0 Fr	30 cm
EG5558522	8.5 Fr	22 cm
EG5558524	8.5 Fr	24 cm
EG5558526	8.5 Fr	26 cm
EG5558528	8.5 Fr	28 cm
EG5558530	8.5 Fr	30 cm

#### LithoStent Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EG5637008	7.0 Fr	8 cm
EG5637010	7.0 Fr	10 cm
EG5637012	7.0 Fr	12 cm
EG5637016	7.0 Fr	16 cm
EG5637022	7.0 Fr	22 cm
EG5637024	7.0 Fr	24 cm
EG5637026	7.0 Fr	26 cm
EG5637028	7.0 Fr	28 cm

#### Quadra-Coil Multi-Length Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EG5001945	4.5 Fr	22-28 cm
EG5001960	6.0 Fr	22-28 cm
EG5001970	7.0 Fr	22-28 cm
EG5001985	8.5 Fr	22-28 cm

#### Classic Double-Pigtail Stents, coated (open ends)

Catalogue No.	Diameter	Length
EG5604508	4.5 Fr	8 cm
EG5604510	4.5 Fr	10 cm
EG5604512	4.5 Fr	12 cm
EG5604514	4.5 Fr	14 cm
EG5604516	4.5 Fr	16 cm
EG5604518	4.5 Fr	18 cm
EG5604520	4.5 Fr	20 cm
EG5604522	4.5 Fr	22 cm
EG5604524	4.5 Fr	24 cm
EG5604526	4.5 Fr	26 cm
EG5604528	4.5 Fr	28 cm
EG5606020	6.0 Fr	20 cm
EG5606022	6.0 Fr	22 cm

#### Classic Double-Pigtail Stents, coated (open ends)

Catalogue No.	Diameter	Length
EG5606024	6.0 Fr	24 cm
EG5606026	6.0 Fr	26 cm
EG5606028	6.0 Fr	28 cm
EG5606030	6.0 Fr	30 cm
EG5607020	7.0 Fr	20 cm
EG5607022	7.0 Fr	22 cm
EG5607024	7.0 Fr	24 cm
EG5607026	7.0 Fr	26 cm
EG5607028	7.0 Fr	28 cm
EG5607030	7.0 Fr	30 cm
EG5608520	8.5 Fr	20 cm
EG5608522	8.5 Fr	22 cm
EG5608524	8.5 Fr	24 cm
EG5608526	8.5 Fr	26 cm
EG5608528	8.5 Fr	28 cm
EG5608530	8.5 Fr	30 cm

#### Sof-Curl Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EGSSC4508	4.5 Fr	8 cm
EGSSC4510	4.5 Fr	10 cm
EGSSC4512	4.5 Fr	12 cm
EGSSC4514	4.5 Fr	14 cm
EGSSC4516	4.5 Fr	16 cm
EGSSC4518	4.5 Fr	18 cm
EGSSC4520	4.5 Fr	20 cm
EGSSC4522	4.5 Fr	22 cm
EGSSC4524	4.5 Fr	24 cm
EGSSC4526	4.5 Fr	26 cm
EGSSC4528	4.5 Fr	28 cm

#### Sof-Curl Ureteral Stents (open ends)

Catalogue No.	Diameter	Length
EGSSC4530	4.5 Fr	30 cm
EGSSC4532	4.5 Fr	32 cm
EGSSC6020	6.0 Fr	20 cm
EGSSC6022	6.0 Fr	22 cm
EGSSC6024	6.0 Fr	24 cm
EGSSC6026	6.0 Fr	26 cm
EGSSC6028	6.0 Fr	28 cm
EGSSC6030	6.0 Fr	30 cm
EGSSC6032	6.0 Fr	32 cm
EGSSC7020	7.0 Fr	20 cm
EGSSC7022	7.0 Fr	22 cm
EGSSC7024	7.0 Fr	24 cm
EGSSC7026	7.0 Fr	26 cm
EGSSC7028	7.0 Fr	28 cm
EGSSC7030	7.0 Fr	30 cm
EGSSC7032	7.0 Fr	32 cm
EGSSC8520	8.5 Fr	20 cm
EGSSC8522	8.5 Fr	22 cm
EGSSC8524	8.5 Fr	24 cm
EGSSC8526	8.5 Fr	26 cm
EGSSC8528	8.5 Fr	28 cm
EGSSC8530	8.5 Fr	30 cm
EGSSC8532	8.5 Fr	32 cm

Each TecoFlex Ureteral Stent supplied with attached braided nylon tether and one RAMROD Metal Tip Push Catheter.

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Olympus Europa SE & Co. KG**  
**Amsinckstr. 63**  
**20097 Hamburg**  
**Deutschland**

has established and applies a quality management system for medical devices  
for the following scope:

**Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of  
endoscopy and microscopy**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**



are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-06-21  
Certificate Registration No.: SX 60148788 0001  
An audit was performed. Report No.: 60319405 001  
This Certificate is valid until: 2023-06-20

Certification Body



Date 2020-04-29



Dipl.-Ing. I. Munkler

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
Olympus Europa SE & Co. KG  
Albert-Schweitzer-Ring 24-26  
22045 Hamburg  
Germany

Scope:  
Servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories  
in the field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:

Olympus Deutschland GmbH  
Albert-Schweitzer-Ring 35  
22045 Hamburg  
Germany

Scope:

Servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories  
in the field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
Olympus Deutschland GmbH  
Amsinckstr. 63  
20097 Hamburg  
Germany

Scope:  
Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**TÜVRheinland LGA Products GmbH**  
**TÜVRheinland**<sup>®</sup>  
Zertifizierungsstelle

**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
Olympus France S.A.S.  
65 Rue de Monthléry  
94533 Rungis  
France

**Scope:**  
Servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories in  
the field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**TÜVRheinland LGA Products GmbH**  
**TÜVRheinland**<sup>®</sup>  
Zertifizierungsstelle

**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
OLYMPUS IBERIA S.A.U.  
PL. Europa 29-31  
08908 L'Hospitalet de Llobregat  
Barcelona  
Spain

**Scope:**  
Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
microscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus France S.A.S.  
19 rue d'Arcueil  
94150 Rungis  
France

Scope:

Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
Olympus Czech Group, s.r.o.  
Evropská ul. 176/16  
160 41 Praha 6  
Czech Republic

**Scope:**  
Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus Czech Group, s. r.o.  
clen koncernu  
Telickova 457/29  
751 24 Prerov-Predmosti  
Czech Republic

Scope:

Servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories  
in the field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus Service Facility Portugal  
Tecnologias Opticas e Digitais, Lda.  
Rua de Alcorredores 43 A  
3020-923 Torre de Vilela (Coimbra)  
Portugal

Scope:

In-house servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories in the  
field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:** Subsidiary:  
  
Olympus Austria GmbH  
Shuttleworthstr. 25  
1210 Vienna  
Austria

**Scope:**  
Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**TÜVRheinland LGA Products GmbH**  
**TÜVRheinland**  
Zertifizierungsstelle

**Dipl.-Ing. I. Munkler**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus Nederland B.V.  
Simon Smitweg 18  
2353 GA Leiderdorp  
Netherlands



Scope:

Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus Schweiz AG  
Chriesbaumstr. 6  
8604 Volketswil  
Switzerland

Scope:

Servicing of optical, opto-digital, electronic and  
mechanical systems as well as associated accessories  
in the field of endoscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60148788 0001  
**Report No.:** 60319405 001

**Organization:** Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Deutschland

**Scope:**

Subsidiary:

Olympus Schweiz AG  
Richtiring 30  
8304 Wallisellen  
Switzerland

Scope:

Marketing, sales and servicing of optical, opto-digital,  
electronic and mechanical systems as well as associated  
accessories and consumables in the field of endoscopy  
and microscopy

**Certification Body**



**Date:** 2020-04-29



**Dipl.-Ing. I. Munkler**



# Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

**OLYMPUS EUROPA SE & Co. KG**  
**Amsinckstr. 63**  
**20097 Hamburg**  
**Germania**

a implementat și aplică un sistem de management al calității pentru dispozitive medicale pentru următoarele domenii:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei**

S-a furnizat dovada faptului că au fost îndeplinite cerințele specificate în

**EN ISO 13485:2016**

Sistemul de management al calității este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020

Nr. înregistrare certificat: SX 60148788 0001

A fost efectuat auditul, raport nr. 60319405 001

Acest certificat este valabil până la 20.06.2023.



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl. Ing. I. Munkler

**TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg**  
Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com <http://www.tuv.com/safety>





TÜVRheinland®

Doc. 1/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Europa SE & Co. KG  
Albert-Schweitzer-Ring 24-26  
22045 Hamburg  
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,  
precum și pentru accesoriile corespunzătoare și consumabilele din  
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 2/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Deutschland GmbH  
Albert-Schweitzer-Ring 35  
22045 Hamburg  
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,  
precum și pentru accesoriile corespunzătoare și consumabilele din  
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și stampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 3/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Deutschland GmbH  
Amsinckstr. 63  
20097 Hamburg  
Germania

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 4/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.  
65 Rue de Monthléry  
94533 Rungis  
Franța

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,  
precum și pentru accesoriile corespunzătoare și consumabilele din  
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler







TÜVRheinland®

Doc. 5/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Iberia S.A.U.  
PL. Europa, 29-31  
08908 L'Hospitalet de Llobregat  
Barcelona  
Spania

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,  
electronice și mecanice, precum și pentru accesoriile corespunzătoare și  
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.  
19 rue d'Arcueil  
94150 Rungis  
Franța

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





Doc. 7/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Czech Group, s.r.o.  
Evropská ul. 176/16  
160 41, Praga 6  
Republica Cehă

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,  
electronice și mecanice, precum și pentru accesoriile corespunzătoare și  
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 8/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Czech Group, s.r.o.  
clen koncernu  
Telickova 457/29  
751 24 Prerov-Predmosti  
Republica Cehă

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,  
precum și pentru accesoriile corespunzătoare și consumabilele din  
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 9/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Service Facility Portugal  
Tecnologias Optica e Digitais, Lda.  
Rua de Alcorredores, 43 A  
3020-923 Torre de Vilela (Coimbra)  
Portugalia

Domeniul de aplicabilitate:

**Service intern pentru sisteme optice, opto-digitale, electronice și mecanice precum și accesorii corespunzătoare din domeniul endoscopiei.**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat  
Nr. de înregistrare: SX 60148788 0001  
Nr. raport: 60319405 001

Organizație:  
**Olympus Europa SE & Co. KG**  
**Amsinckstr. 63**  
**20097 Hamburg**  
**Germania**

Domeniu de aplicabilitate: Filială  
  
Olympus Austria GmbH  
Shuttleworthstr. 25  
1210 Viena  
Austria

Domeniul de aplicabilitate:  
**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 11/13 Rev. 0

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Nederland B.V.  
Simon Smitweg 18  
2353 GA Leiderdorp  
Țările de Jos

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG  
Chriesbaumstr. 6  
8604 Volketswil  
Elveția

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,  
precum și pentru accesoriile corespunzătoare și consumabilele din  
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG  
Amsinckstr. 63  
20097 Hamburg  
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG  
Richtiring 30  
8304 Wallisellen  
Elveția

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,  
electronice și mecanice, precum și pentru accesoriile corespunzătoare și  
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare  
(Semnătură indescifrabilă și ștampilă TÜV  
Rheinland LGA Products GmbH)  
Dipl.-Ing. I. Munkler





**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60123878 0001

**Report No.:** 12018179 022

**Manufacturer:** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho,  
Hachioji-shi, Tokyo 192-8507  
Japan

**Products:** Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products  
  
(see attachments for products and additional sites included)  
  
Replaces Approval, Registration No.: HD 60078827 0001

**Expiry Date:** 2022-11-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-11-03

**Date:** 2017-10-12



Notified Body

M.Sc. M. Aihara

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60123878 0001

**Report No.:** 12018179 022

**Manufacturer:** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho,  
Hachioji-shi, Tokyo 192-8507  
Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units

Electrosurgical Equipment

Probes and Transducers for Ultrasonic Lithotriptors

Laparoscopic Insufflators

Ultrasound Surgical Equipment

Disinfecting Units

Capsule Endoscopes and Systems

Ultrasound Diagnostic Imaging Systems



Notified Body

*M. Aihara*

M.Sc. M. Aihara

**Date:** 2017-10-12

Traducere din limba engleza



**APROBARE**  
**Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4**  
**Sistem complet de asigurare a calității**  
**Echipeamente medicale**

Nr. Înregistrare: HD 60123878 0001  
Nr. Raport: 12018179 022

**Producător:** Olympus Medical Systems Corp.  
2951 Ishikawa-cho  
HACHIOJI-SHI, TOKIO 192-8507  
JAPONIA

**Produse:** Proiectare și dezvoltare, producție de sisteme de endoscopie medicală, produse de diagnostic, operație și tratament.  
(a se vedea atasamentele pentru produse și locații suplimentare incluse)  
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirării: 02.11.2022

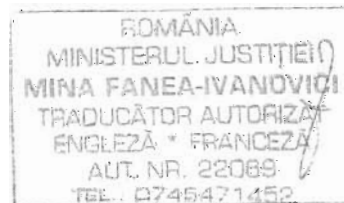
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa II, secțiunea 5 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate cu Anexa II, secțiunea 4.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat  
Ștampilă:  
TUV Rheinland LGA Products GmbH  
Zertifizierungsstelle  
M.Sc. M. Aihara  
(semnătură indescifrabilă)

**TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva  
93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Atasament la  
Certificat

Nr. de înregistrare: HD 60123878 0001  
Nr. raport: 12018179 022

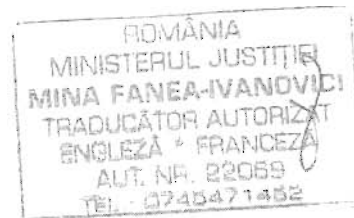
**Producător:** Olympus Medical Systems Corp.  
2951 Ishikawa-cho  
HACHIOJI-SHI, TOKIO 192-8507  
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
  - Endoscoape
  - Echipamente endoterapie
  - Procesoare de imagine
  - Pompe pentru endoscopie
  - Surse de lumină
  - Unități de detectare poziție
  - Unități de cauterizare electrotermică
  - Sisteme endochirurgicale integrate
  - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde și traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.10.2012

Organism notificat  
Ștampilă:  
TUV Rheinland LGA Products GmbH  
Zertifizierungsstelle  
M.Sc. M. Aihara  
(semnătură indescifrabilă)





**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60123877 0001

**Report No.:** 12018179 022

**Manufacturer:** OLYMPUS MEDICAL SYSTEMS CORP.  
2951 Ishikawa-cho,  
Hachioji-shi, Tokyo 192-8507  
Japan

**Products:** Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Instruments used in conjunction with Endoscopes and Sterile Non Active Instruments used in conjunction with Medical Ultrasound Diagnostic Imaging Systems  
Replaces Approval, Registration No.: DD 60116725 0001

**Expiry Date:** 2022-11-02

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2017-11-03

**Date:** 2017-10-12



Notified Body

M.Sc. M. Aihara

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Traducere din limba engleza



**CERTIFICAT CE**  
**Directiva CE 93/42/CEE Anexa V**  
**Asigurarea calității producției**  
**Echipeamente medicale**

Nr. Înregistrare: DD 60123877 0001  
Nr. Raport: 12018179 022

**Producător:** Olympus Medical Systems Corp.  
2951 Ishikawa-cho  
HACHIOJI-SHI, TOKIO 192-8507  
JAPONIA

**Produse:** Echipamentelor sterile pentru endoterapie, utilizate împreună cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape și instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.  
Înlocuiește Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirării: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea 4 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa IIb și clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate cu Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat  
Ștampilă:  
TUV Rheinland LGA Products GmbH  
Zertifizierungsstelle  
M.Sc. M. Aihara  
(semnătură indescifrabilă)

**TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197

