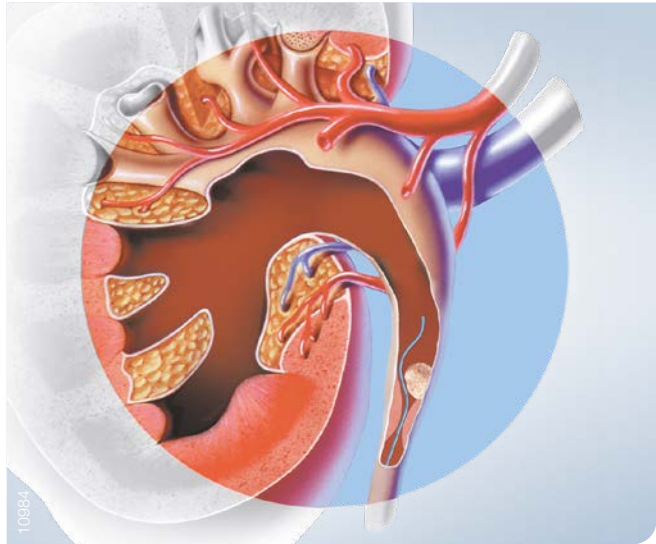


ACCESS



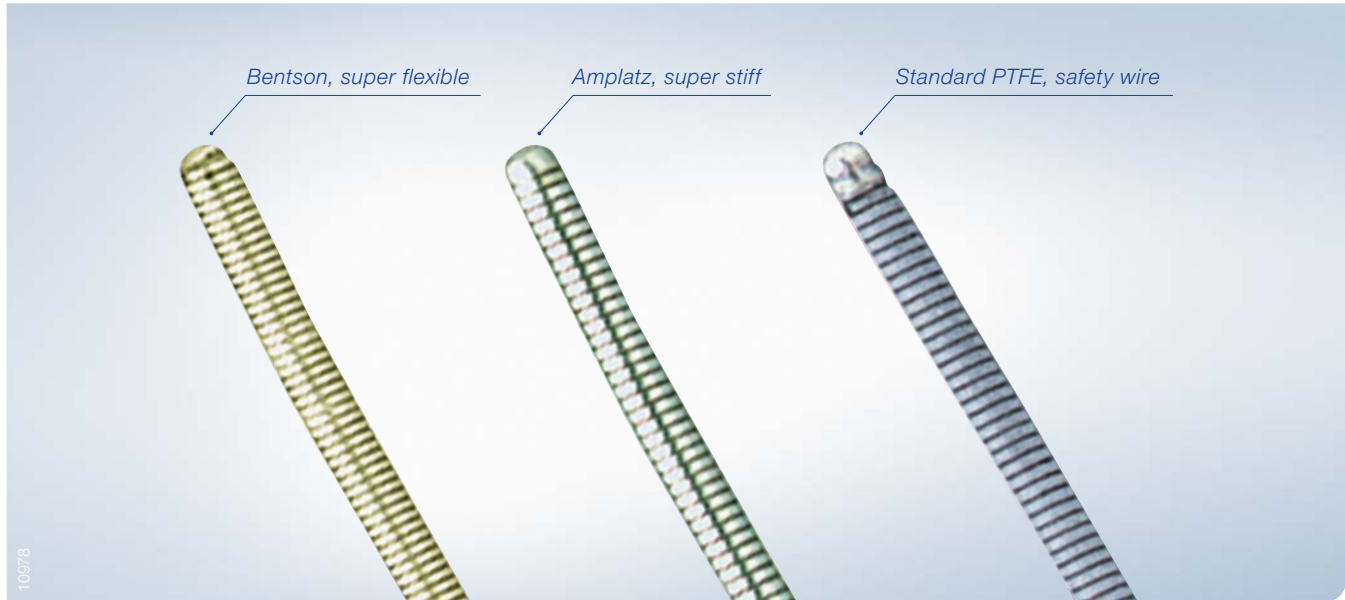
Getting access to the ureter or kidney is essential for every urologist treating stone burdens. Olympus recognizes the importance of achieving this access in a safe and time-efficient manner. Therefore, we provide a comprehensive lineup of nitinol and PTFE guidewires with various tip configurations to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

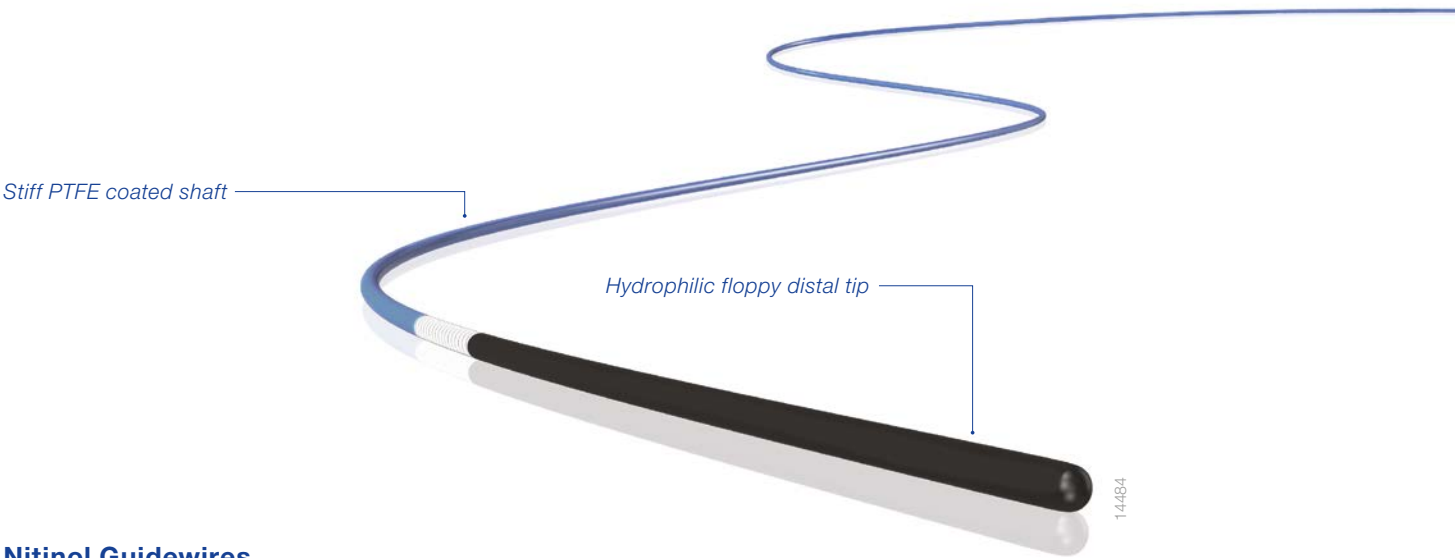
PTFE Guidewires



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

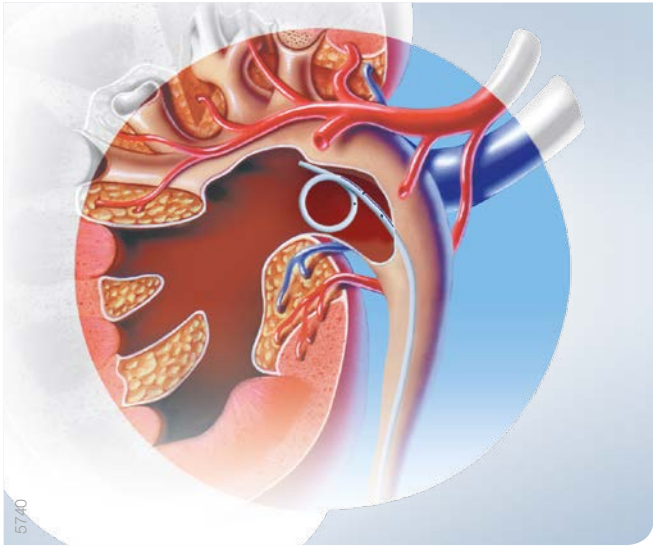
- Two tip characteristics aimed at accommodating different patient anatomies in one guidewire
- Flexible golden tip for accessing challenging anatomies
- Stiff silver tip for fast and easy access
- Extremely well differentiated during fluoroscopy due to tungsten tips

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



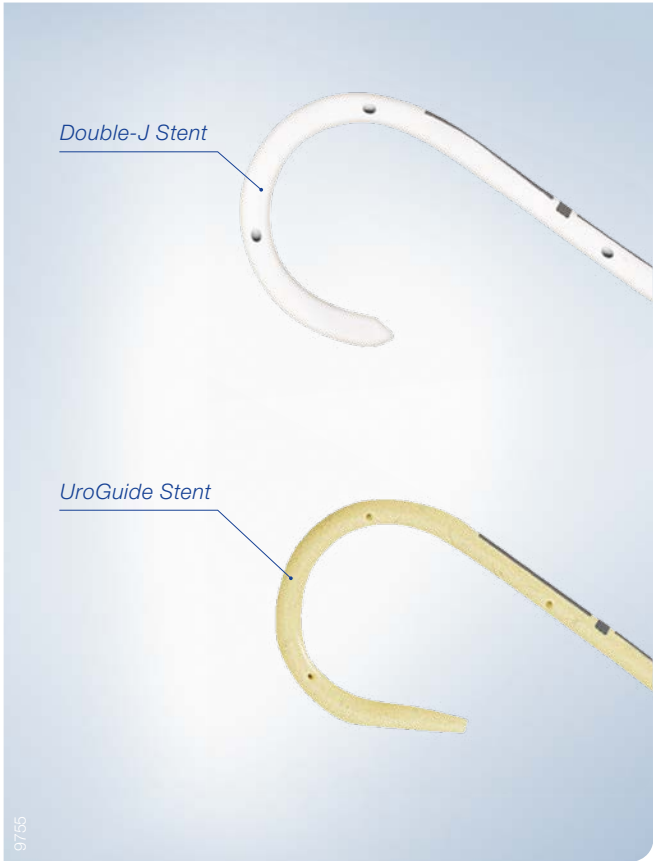
DRAINAGE



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



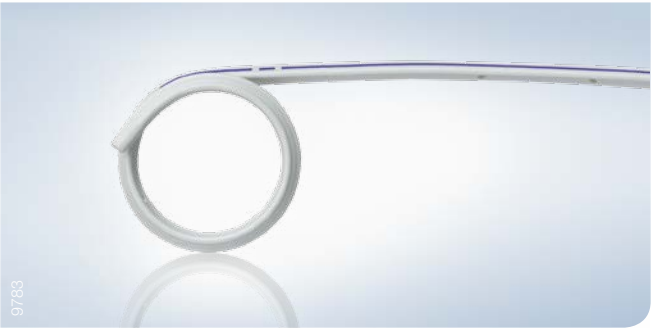
Single-J Stent
Single-J stent with 90 cm length for superior drainage.

Double-J Stent
Silicone stent with closed tips for reliable drainage after stone treatment.

UroGuide Stent
Silicone stent for easy insertion and high incrustation resistance with open ends.

TecoFlex Stents

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



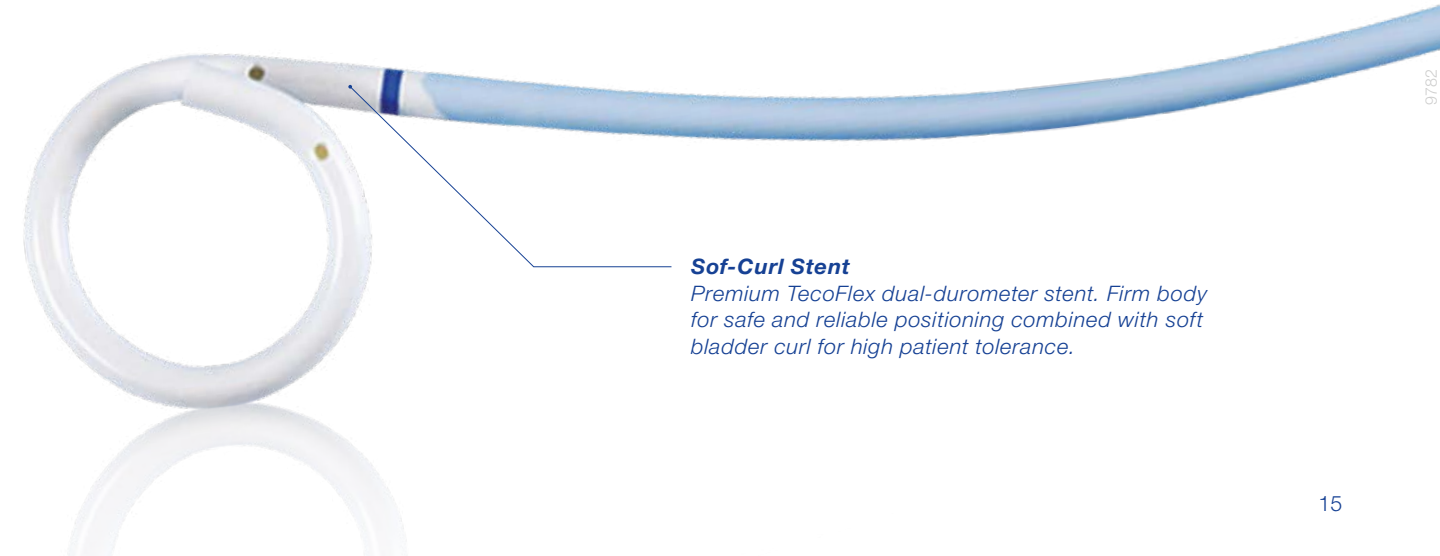
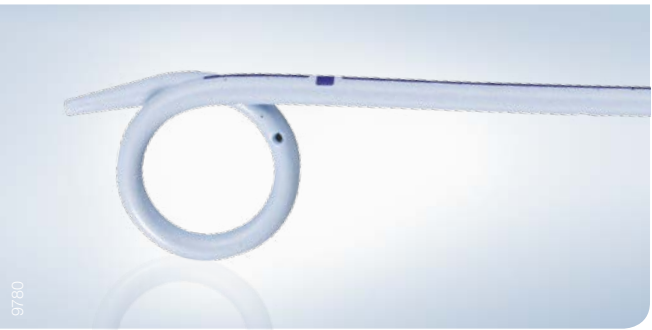
Quadra-Coil Stent
Soft TecoFlex stent with specially designed bladder curl. The multilength concept allows for patient adjusted placement from 22–28 cm.



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



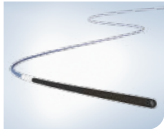
Lubri-Flex
Firm TecoFlex stent for safe and reliable placement.



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

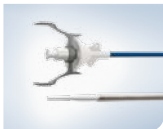
Catheter



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



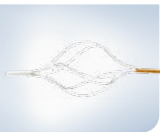
Ultra-Catch 4-Wire No-Tip Nitinol Basket

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.

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

Registration No.: HD 60149405 0001

Report No.: 12018179 053

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 included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

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: 2020-05-12

Date: 2020-05-12



Notified Body

M. Aihara
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

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60149405 0001
Report No.: 12018179 053

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

Ultrasonic Surgical System generator

Ultrasonic Surgical System transducer

Hard-tissue ultrasonic surgical system holder/tip

Disinfecting Units

Capsule Endoscopes and Systems

Ultrasound Diagnostic Imaging Systems

Notified Body

M. Aihara

M.Sc. M. Aihara



Date: 2020-05-12

Traducere din limba engleza



CERTIFICAT CE
Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4
Sistem complet de asigurare a calității
Echipamente medicale

Nr. Înregistrare: HD 60149405 0001

Nr. Raport: 12018179 053

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 produsele incluse)
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60144066 0001

Data expirării: 26.05.2024

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: 12-05-2020

Data: 12.05.2020

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





Doc. 1/1 Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. Înregistrare: HD 60149405 0001

Nr. Raport: 12018179 053

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
- Generator sistem chirurgical cu ultrasunete
- Traductor sistem chirurgical cu ultrasunete
- Suport/varf sistem chirurgical cu ultrasunete pentru tesut tare
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.05.2020

Organism notificat

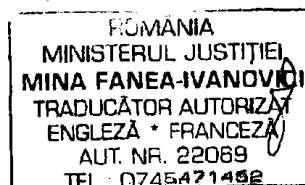
Șampilă:

TUV Rheinland LGA Products GmbH

Zertifizierungsstelle

M.Sc. M. Aihara

(semnătură indescifrabilă)



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

Doc. 1/13, Rev.0

**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



TÜV Rheinland 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 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



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/13, Rev.0

**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

Doc. 10/13, Rev.0

**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

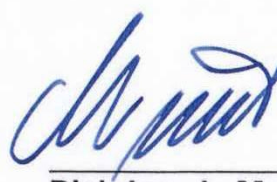
Scope:

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



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

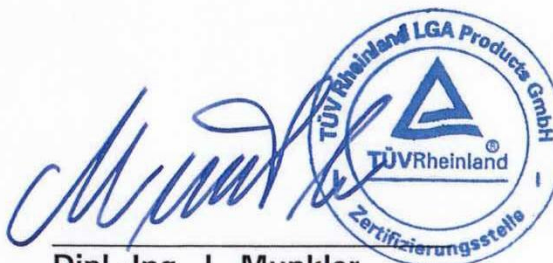
Scope:

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

Doc. 13/13, Rev.0

**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>



**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



**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 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
Germany**

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

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





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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**



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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 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





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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**



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

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





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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**



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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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 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



**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

