

Guidewires

Quattro Guidewire

One Wire, Multiple Purposes

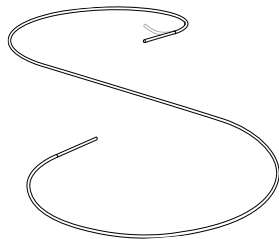
The PTFE coated, dual-flex, Nitinol Quattro guidewire provides smooth, reliable access for virtually every situation. It combines two guidewires in one: Silver tipped end of the guidewire has a stiff flex pattern similar to an Amplatz guidewire, the gold tipped end a softer flex pattern similar to a Bentson guidewire.

For Advancement

- Kink resistant Nitinol core for worry free insertion.
- Low friction PTFE coated main body for easy tracking through anatomy and effortless advancement of catheters, stents, etc.
- HydraSilk coated tips (ultra slippery silicone-based hydrophilic coating) for effortless passage around obstructions and through torturous anatomy.

For Safety

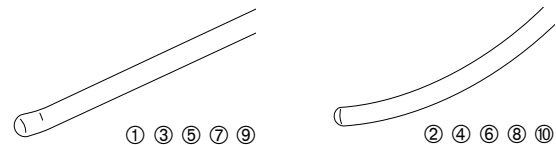
- Tungsten coiled tips provides unsurpassed radiopacity for clear fluoroscopic identification.
- Specially designed coiled tips and coating surface finish prevent inadvertent migration.



50BX	Quattro guidewire, 0.35" diameter, 150 cm length, tip length: 5 cm coil, straight tip, straight, stiff and regular body, sterile, single-use, 5 pcs.
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SureGlide Guidewires

The SureGlide guidewire combines a torque-stable and kink-resistant Nitinol core with a highly lubricious, hydrophilic-coated jacket to enable easy navigation through tortuous anatomy and smooth tracking of instruments. Scope-friendly rounded ends ease insertion.



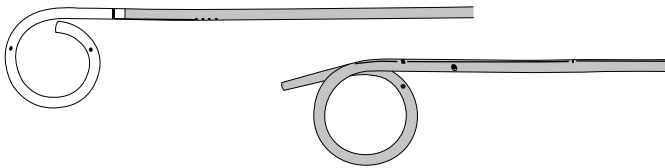
① 15BX	SureGlide guidewire, 0.025" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., straight tip, regular body
② 16BX	SureGlide guidewire, 0.025" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., angled tip, regular body
③ 35BX	SureGlide guidewire, 0.035" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., straight tip, regular body
④ 36BX	SureGlide guidewire, 0.035" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., angled tip, regular body
⑤ 41BX	SureGlide guidewire, 0.035" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., straight tip, stiff body
⑥ 43BX	SureGlide guidewire, 0.035" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., angled tip, stiff body
⑦ 37BX	SureGlide guidewire, 0.038" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., straight tip, regular body
⑧ 38BX	SureGlide guidewire, 0.038" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., angled tip, regular body
⑨ 42BX	SureGlide guidewire, 0.038" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., straight tip, stiff body
⑩ 44BX	SureGlide guidewire, 0.038" diameter, 150 cm length, tip length: 3 cm flex, sterile, single-use, 5 pcs., angled tip, stiff body
GWT	SureGlide grip guidewire torque device, sterile, single-use, 5 pcs. (not shown)

Ureteral Stents

Tecoflex

Sof-Curl

- Two durometers of unique Tecoflex provide firmness necessary for advancement and extra softness at body temperature for increased patient comfort.
- Unique soft bladder curl design reduces irritation to the trigone.
- Exclusive 360° kidney curl minimizes migration and reduces trauma during removal.
- Waxed, braided nylon tether: Soft, safe, comfortable, and removable
- Axial ring, medial line, trailing suture, and incremental markings aid in proper placement and orientation.
- Ultra slippery hydrophilic coating on inside and outside surfaces: Glides over any guidewire and through difficult anatomy.
- Spiral drainage hole design resists kinking and buckling.
- Radiopaque filler provides clear fluoroscopic visualization.



5626022	Sof-Curl ureteral stent, 6 Fr. x 22 cm
5626024	Sof-Curl ureteral stent, 6 Fr. x 24 cm
5626026	Sof-Curl ureteral stent, 6 Fr. x 26 cm
5626028	Sof-Curl ureteral stent, 6 Fr. x 28 cm
5627022	Sof-Curl ureteral stent, 7 Fr. x 22 cm
5627024	Sof-Curl ureteral stent, 7 Fr. x 24 cm
5627026	Sof-Curl ureteral stent, 7 Fr. x 26 cm
5627028	Sof-Curl ureteral stent, 7 Fr. x 28 cm

sterile, single-use

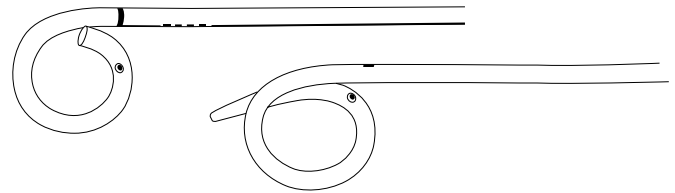
Delivery includes:

Stent, attached braided nylon tether, RAMROD metal tip push catheter

Classic Double PigTail

Classic Double PigTail Ureteral Stents have an exclusive balanced-curved double pigtail design that minimizes migration. They also feature unique Tecoflex construction for easy insertion and enhanced patient comfort.

- Advanced Tecoflex construction: Firm during placement for easier stent passage, then softens at body temperature for increased patient comfort.
- Exclusive bladder curl design provides balanced stability and comfort.
- Exclusive 360° kidney curl minimizes migration and reduces trauma during removal.
- Ultra slippery hydrophilic coating on inside and outside surfaces glides over any guidewire and through difficult anatomy.
- Axial ring, medial line, trailing suture, and incremental markings aid in proper placement and orientation.
- Spiral drainage hole design resists kinking and buckling.

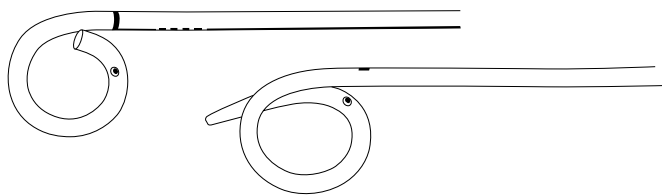


5604508	Classic Double PigTail stent, 4.5 Fr. x 8 cm
5604510	Classic Double PigTail stent, 4.5 Fr. x 10 cm
5604512	Classic Double PigTail stent, 4.5 Fr. x 12 cm
5604514	Classic Double PigTail stent, 4.5 Fr. x 14 cm
5604516	Classic Double PigTail stent, 4.5 Fr. x 16 cm
5604518	Classic Double PigTail stent, 4.5 Fr. x 18 cm
5604520	Classic Double PigTail stent, 4.5 Fr. x 20 cm
5604522	Classic Double PigTail stent, 4.5 Fr. x 22 cm
5604524	Classic Double PigTail stent, 4.5 Fr. x 24 cm
5604526	Classic Double PigTail stent, 4.5 Fr. x 26 cm
5604528	Classic Double PigTail stent, 4.5 Fr. x 28 cm
5606020	Classic Double PigTail stent, 6 Fr. x 20 cm
5606022	Classic Double PigTail stent, 6 Fr. x 22 cm
5606024	Classic Double PigTail stent, 6 Fr. x 24 cm
5606026	Classic Double PigTail stent, 6 Fr. x 26 cm

coated, sterile, single-use,

Delivery includes:

Stent, attached braided nylon tether, RAMROD metal tip push catheter

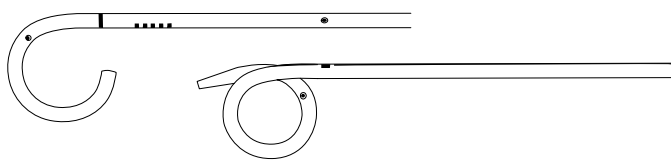
**Classic Double PigTail (cont.)**

5606028	Classic Double PigTail stent, coated, 6 Fr. x 28 cm
5606030	Classic Double PigTail stent, coated, 6 Fr. x 30 cm
5607020	Classic Double PigTail stent, coated, 7 Fr. x 20 cm
5607022	Classic Double PigTail stent, coated, 7 Fr. x 22 cm
5607024	Classic Double PigTail stent, coated, 7 Fr. x 24 cm
5607026	Classic Double PigTail stent, coated, 7 Fr. x 26 cm
5607028	Classic Double PigTail stent, coated, 7 Fr. x 28 cm
5607030	Classic Double PigTail stent, coated, 7 Fr. x 30 cm
5608520	Classic Double PigTail stent, coated, 8.5 Fr. x 20 cm
5608522	Classic Double PigTail stent, coated, 8.5 Fr. x 22 cm
5608524	Classic Double PigTail stent, coated, 8.5 Fr. x 24 cm
5608526	Classic Double PigTail stent, coated, 8.5 Fr. x 26 cm
5608528	Classic Double PigTail stent, coated, 8.5 Fr. x 28 cm
5608530	Classic Double PigTail stent, coated, 8.5 Fr. x 30 cm
5614508	Classic Double PigTail stent, uncoated, 4.5 Fr. x 8 cm
5614510	Classic Double PigTail stent, uncoated, 4.5 Fr. x 10 cm
5614512	Classic Double PigTail stent, uncoated, 4.5 Fr. x 12 cm
5614514	Classic Double PigTail stent, uncoated, 4.5 Fr. x 14 cm
5614516	Classic Double PigTail stent, uncoated, 4.5 Fr. x 16 cm
5614518	Classic Double PigTail stent, uncoated, 4.5 Fr. x 18 cm
5614520	Classic Double PigTail stent, uncoated, 4.5 Fr. x 20 cm
5614522	Classic Double PigTail stent, uncoated, 4.5 Fr. x 22 cm
5614524	Classic Double PigTail stent, uncoated, 4.5 Fr. x 24 cm
5614526	Classic Double PigTail stent, uncoated, 4.5 Fr. x 26 cm
5614528	Classic Double PigTail stent, uncoated, 4.5 Fr. x 28 cm
5616020	Classic Double PigTail stent, uncoated, 6 Fr. x 20 cm
5616022	Classic Double PigTail stent, uncoated, 6 Fr. x 22 cm
5616024	Classic Double PigTail stent, uncoated, 6 Fr. x 24 cm
5616026	Classic Double PigTail stent, uncoated, 6 Fr. x 26 cm
5616028	Classic Double PigTail stent, uncoated, 6 Fr. x 28 cm
5616030	Classic Double PigTail stent, uncoated, 6 Fr. x 30 cm
5617020	Classic Double PigTail stent, uncoated, 7 Fr. x 20 cm
5617022	Classic Double PigTail stent, uncoated, 7 Fr. x 22 cm
5617024	Classic Double PigTail stent, uncoated, 7 Fr. x 24 cm
5617026	Classic Double PigTail stent, uncoated, 7 Fr. x 26 cm
5617028	Classic Double PigTail stent, uncoated, 7 Fr. x 28 cm
5617030	Classic Double PigTail stent, uncoated, 7 Fr. x 30 cm
5618520	Classic Double PigTail stent, uncoated, 8.5 Fr. x 20 cm
5618522	Classic Double PigTail stent, uncoated, 8.5 Fr. x 22 cm
5618524	Classic Double PigTail stent, uncoated, 8.5 Fr. x 24 cm
5618526	Classic Double PigTail stent, uncoated, 8.5 Fr. x 26 cm
5618528	Classic Double PigTail stent, uncoated, 8.5 Fr. x 28 cm
5618530	Classic Double PigTail stent, uncoated, 8.5 Fr. x 30 cm

sterile, single-use

Lubri-Flex

- Advanced Tecoflex construction:
Firm during placement for easier stent passage, then softens at body temperature for increased patient comfort.
- Unique 270° bladder curl: Less material minimizes trigone irritation.
- Exclusive 360° kidney curl:
Minimizes migration and reduces trauma during removal.
- Ultra slippery hydrophilic coating on inside and outside surfaces:
Glides over any guidewire and through difficult anatomy.
- Axial ring, medial line, trailing suture, and incremental markings aid in proper placement and orientation.
- Spiral drainage hole design resists kinking and buckling.
- Radiopaque filler provides clear fluoroscopic visualization.



5554508	Lubri-Flex ureteral stent, 4.5 Fr. x 8 cm
5554510	Lubri-Flex ureteral stent, 4.5 Fr. x 10 cm
5554512	Lubri-Flex ureteral stent, 4.5 Fr. x 12 cm
5554514	Lubri-Flex ureteral stent, 4.5 Fr. x 14 cm
5554516	Lubri-Flex ureteral stent, 4.5 Fr. x 16 cm
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5554520	Lubri-Flex ureteral stent, 4.5 Fr. x 20 cm
5554522	Lubri-Flex ureteral stent, 4.5 Fr. x 22 cm
5554524	Lubri-Flex ureteral stent, 4.5 Fr. x 24 cm
5554526	Lubri-Flex ureteral stent, 4.5 Fr. x 26 cm
5554528	Lubri-Flex ureteral stent, 4.5 Fr. x 28 cm
5556022	Lubri-Flex ureteral stent, 6 Fr. x 22 cm
5556024	Lubri-Flex ureteral stent, 6 Fr. x 24 cm
5556026	Lubri-Flex ureteral stent, 6 Fr. x 26 cm
5556028	Lubri-Flex ureteral stent, 6 Fr. x 28 cm
5556030	Lubri-Flex ureteral stent, 6 Fr. x 30 cm
5557022	Lubri-Flex ureteral stent, 7 Fr. x 22 cm
5557024	Lubri-Flex ureteral stent, 7 Fr. x 24 cm
5557026	Lubri-Flex ureteral stent, 7 Fr. x 26 cm
5557028	Lubri-Flex ureteral stent, 7 Fr. x 28 cm
5557030	Lubri-Flex ureteral stent, 7 Fr. x 30 cm
5558522	Lubri-Flex ureteral stent, 8.5 Fr. x 22 cm
5558524	Lubri-Flex ureteral stent, 8.5 Fr. x 24 cm
5558526	Lubri-Flex ureteral stent, 8.5 Fr. x 26 cm
5558528	Lubri-Flex ureteral stent, 8.5 Fr. x 28 cm
5558530	Lubri-Flex ureteral stent, 8.5 Fr. x 30 cm

sterile, single-use

Delivery includes:

Stent, attached braided nylon tether, 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

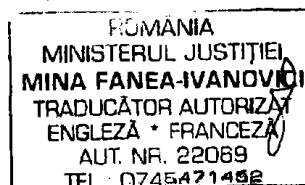
Șampilă:

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

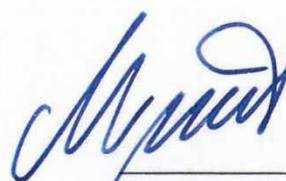
are fulfilled. The quality management system is subject to yearly surveillance.

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

**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

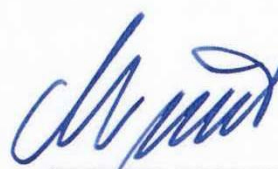
Scope:

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

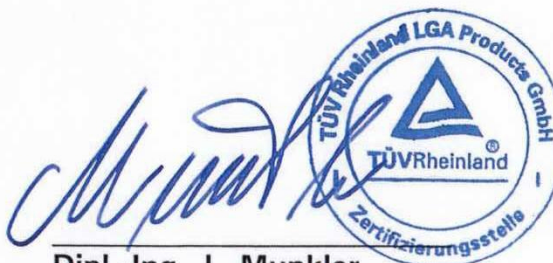
Scope:

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

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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>





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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



**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
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Dipl.-Ing. I. Munkler





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**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
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Dipl.-Ing. I. Munkler





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**TÜV Rheinland
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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





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**



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 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

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Tillystraße 2, 90431 Nürnberg**

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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

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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:

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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

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