

Mechanical lithotriptors



Single Use
Mechanical
Lithotripter



Handle for
LithoCrush V



Reusable
emergency
Lithotripter

V-System single-use mechanical lithotriptors



- Pre-assembled for easy handling
- Unique double sheath to aid cannulation
- Quick and effective crushing
- Available in different basket specifications
- Rotatable basket
- Wire-guided version (BML-V442QR-30) enables easier passage beyond the stone
- To combine with a V-BML handle (MAJ-441)
- Compatible with emergency lithotripter (BML-110A-1)

LithoCrush[™]

2

STERILE

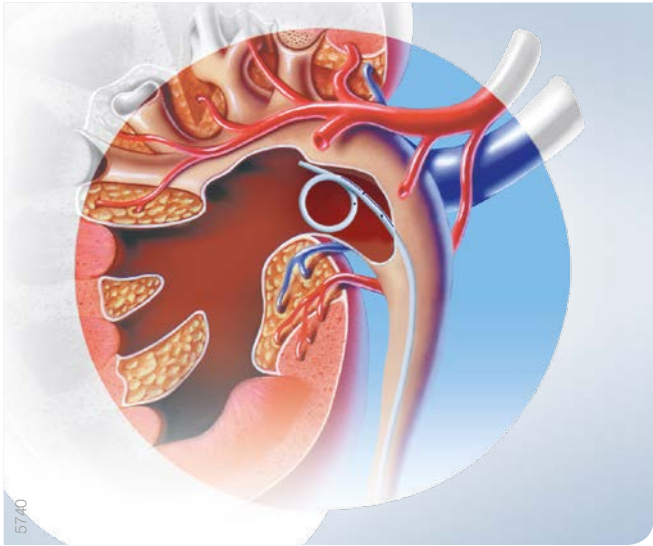
X-ray



Article name	Article number	Quantity	Min. working channel ø	Working length	Basket ø	Features	Compatible guidewire	Area compatibility
BML-V242QR-30	N2303030	1	● 4.2 mm	1950 mm	30 mm	Rotatable type	-	
BML-V232QR-30	N2302830	1	● 3.2 mm	1950 mm	30 mm	Rotatable type	-	
BML-V232QR-26	N2302730	1	● 3.2 mm	1950 mm	26 mm	Rotatable type	-	
BML-V442QR-30	N2303230	1	● 4.2 mm	1950 mm	30 mm	Rotatable type	0.035"	



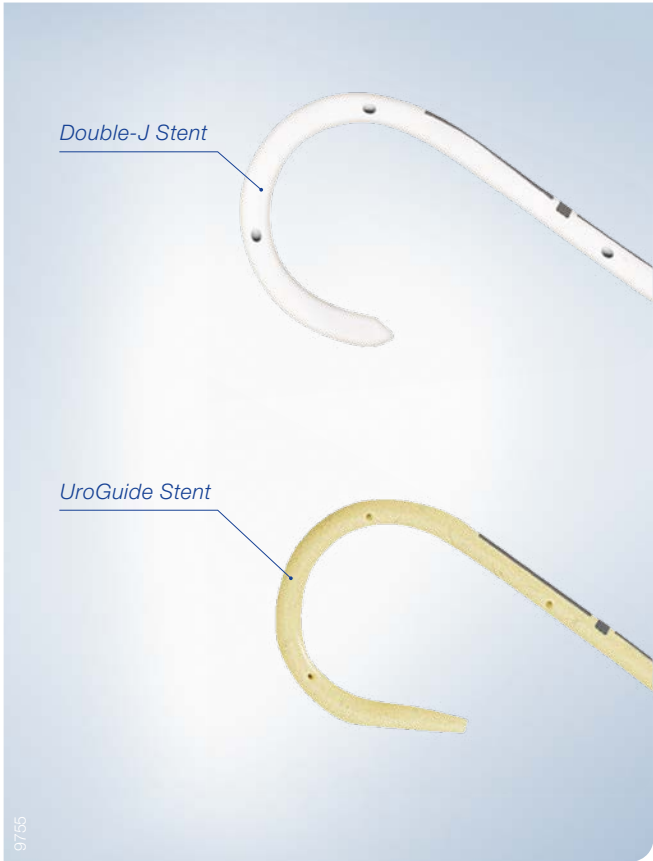
DRAINAGE



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



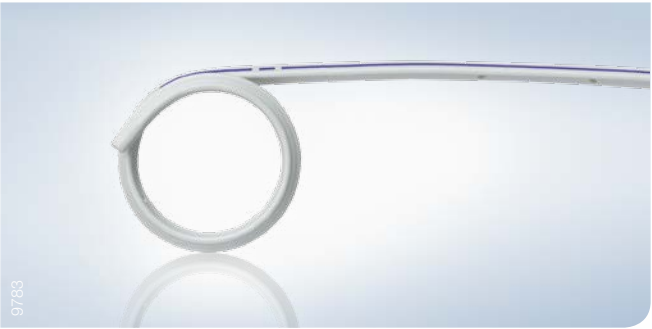
Single-J Stent
Single-J stent with 90 cm length for superior drainage.

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.



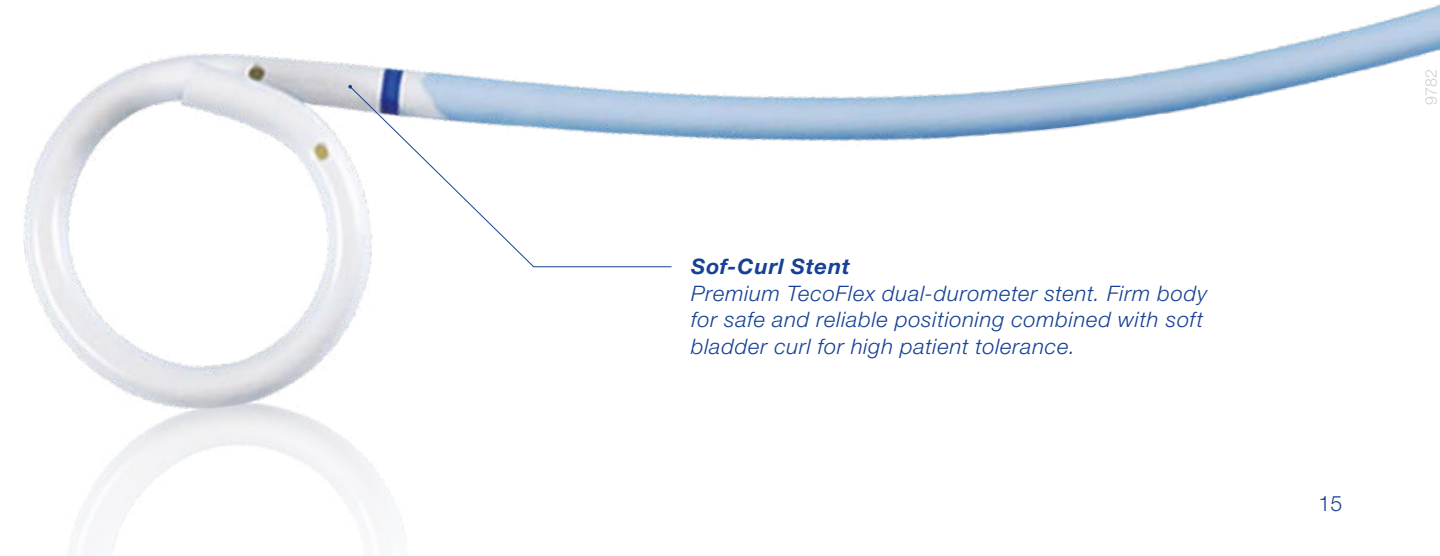
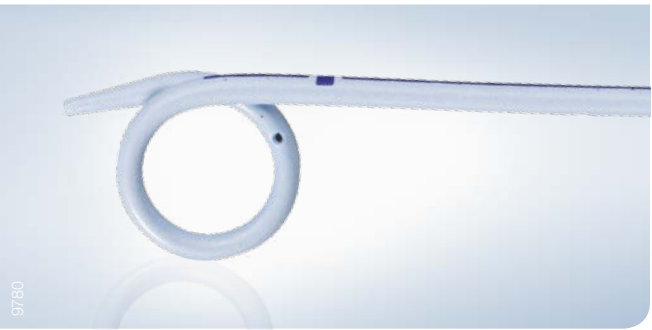
Quadra-Coil Stent
Soft TecoFlex stent with specially designed bladder curl. The multilength concept allows for patient adjusted placement from 22–28 cm.



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

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

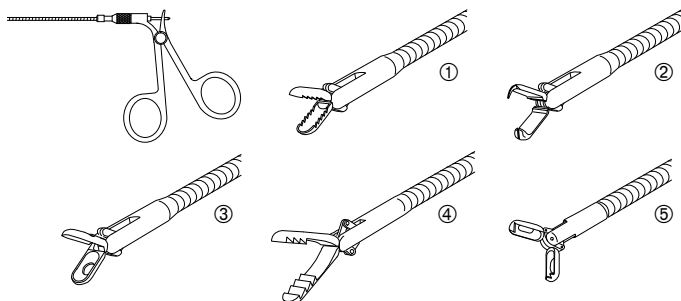
Sof-Curl Ureteral Stents (open ends)

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.



Flexible Forceps



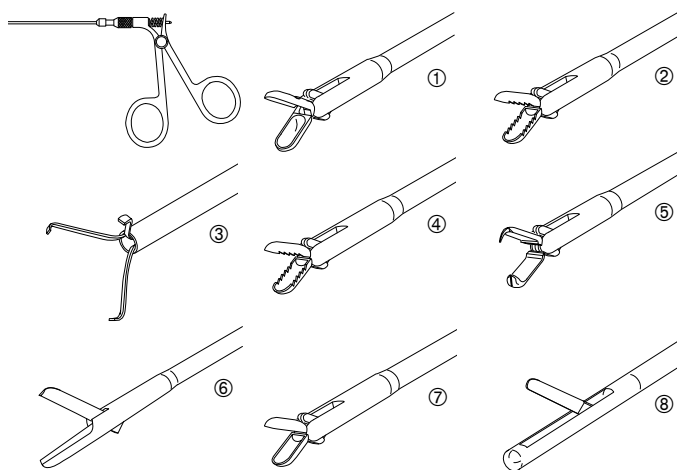
- | | |
|-----------------|--|
| ① A2421 | Grasping forceps, 5 Fr. x 640 mm, toothed, for removal of stones, restoring spring |
| ② A2422 | Grasping forceps, 5 Fr. x 640 mm, rat tooth, for removal of stones, restoring spring |
| ③ A2423 | Biopsy forceps, 5 Fr. x 640 mm, for biopsy, restoring spring |
| ④ A2580 | Grasping forceps, 3 Fr. x 600 mm, for grasping of stone fragments, double action jaws, restoring spring |
| ⑤ 025852 | Biopsy forceps "FB-56D-1", 3.5 Fr. x 1150 mm, oval cups <ul style="list-style-type: none"> ▪ For routine biopsies ▪ Rat tooth to aid anchorage ▪ Ellipsoid cups for deeper biopsies |

Accessories



- | | |
|--------------|--|
| A0400 | Sealing cap, blue, for Luer-lock, 6 pcs. |
|--------------|--|

Semi-Flexible Forceps



- | | |
|----------------|---|
| ① A2499 | Biopsy forceps, 5 Fr. x 570 mm, double action, restoring spring |
| ② A2500 | Grasping forceps, 5 Fr. x 570 mm, stone grasper, double action, restoring spring |
| ③ A2592 | Grasping forceps, 5 Fr. x 570 mm, three-nail, double action, restoring spring |
| ④ A2574 | Grasping forceps, 5 Fr. x 600 mm, double action, restoring spring |
| ⑤ A2575 | Grasping forceps, 5 Fr. x 600 mm, mice teeth, double action, restoring spring |
| ⑥ A2576 | Scissors, 5 Fr. x 600 mm single action, for cutting of strictures, restoring spring |
| ⑦ A2577 | Biopsy forceps, 5 Fr. x 600 mm double action, restoring spring |
| ⑧ A2578 | Scissors, 5 Fr. x 600 mm, retrograde cutting, for cutting of strictures, restoring spring |

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

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

See attachments for scope

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: 2018-11-04
Certificate Registration No.: SX 60133824 0001
An audit was performed. Report No.: 12018179 027
This Certificate is valid until: 2021-07-26

Certification Body



Date 2018-10-30



M. Aihara
M.Sc. M. Aihara

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 60133824 0001
Report No.: 12018179 027

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

Scope:

Design and Development, Manufacture, Distribution, Service, Quality Assurance, Planning and Delivery support of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/ Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units and Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump

Certification Body



Date: 2018-10-30


M.Sc. M. Aihara



Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japonia

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

A se vedea atașamentul pentru domeniul de aplicabilitate

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: 04.11.2018

Nr. înregistrare certificat: SX 60133824 0001

A fost efectuat auditul, raport nr. 12018179 027

Acest certificat este valabil până la 26.07.2021



Data, 30.10.2018

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
M.Sc.M. Aihara

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**

Atasament la
Nr. înregistrare certificat SX 60133824 0001
Nr. raport: 12018179 027

Organizație:
**Olympus Medical Systems Corp.
2951 Ishikawa-cho
Hachioji-shi, Tokyo 192-8507
Japonia**

Domeniul de aplicabilitate: **Proiectare și dezvoltare, producție, distribuție, service, asigurarea calității, planificare și furnizare asistență pentru endoscoape, echipamente endoterapie, surse de lumină, procesoare de imagine, unități de detectare a poziției endoscopului, unități de cauterizare electrotermică, sisteme endochirurgicale integrate, unitati de control/reglare endoscopice, capete cameră/pompe/sisteme monitorizare/sisteme înregistrare pentru endoscopie, echipamente electrochirurgicale, endoscoape capsulă și sisteme, insuflatoare laparoscopice, sisteme de imagistica pentru diagnostic ecografic, unități dezinfectare și echipamente chirurgicale cu ultrasunete, sonde și traductoare pentru litotriptoare cu ultrasunete, instrumente sterile inactive utilizate împreună cu endoscoape, echipamente sterile pentru endoterapie utilizate împreună cu endoscoape, echipamente sterile inactive utilizate împreună cu sisteme medicale de imagistica pentru diagnostic ecografic și recipiente apă, tuburi alimentare apă, supape apă și întrerupătoare de picior pentru pompe.**



Data, 30.10.2018

Organism de certificare
(Semnătură indescifrabilă și șampilă TÜV
Rheinland LGA Products GmbH)
M.Sc.M. Aihara



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. 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 D197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**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
Echipamente 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

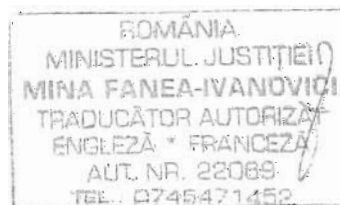
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită 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
Șampilă:
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. 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.

Traducere din limba engleza



CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calității producției
Echipamente 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

