

Digitally signed by Grabazei Alexandru
Date: 2021.09.30 15:02:38 EEST
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Location: Moldova



Taking a step beyond



The new standard for routine screening

One step beyond precise imaging

One step beyond operating efficiency

One step beyond routine usability

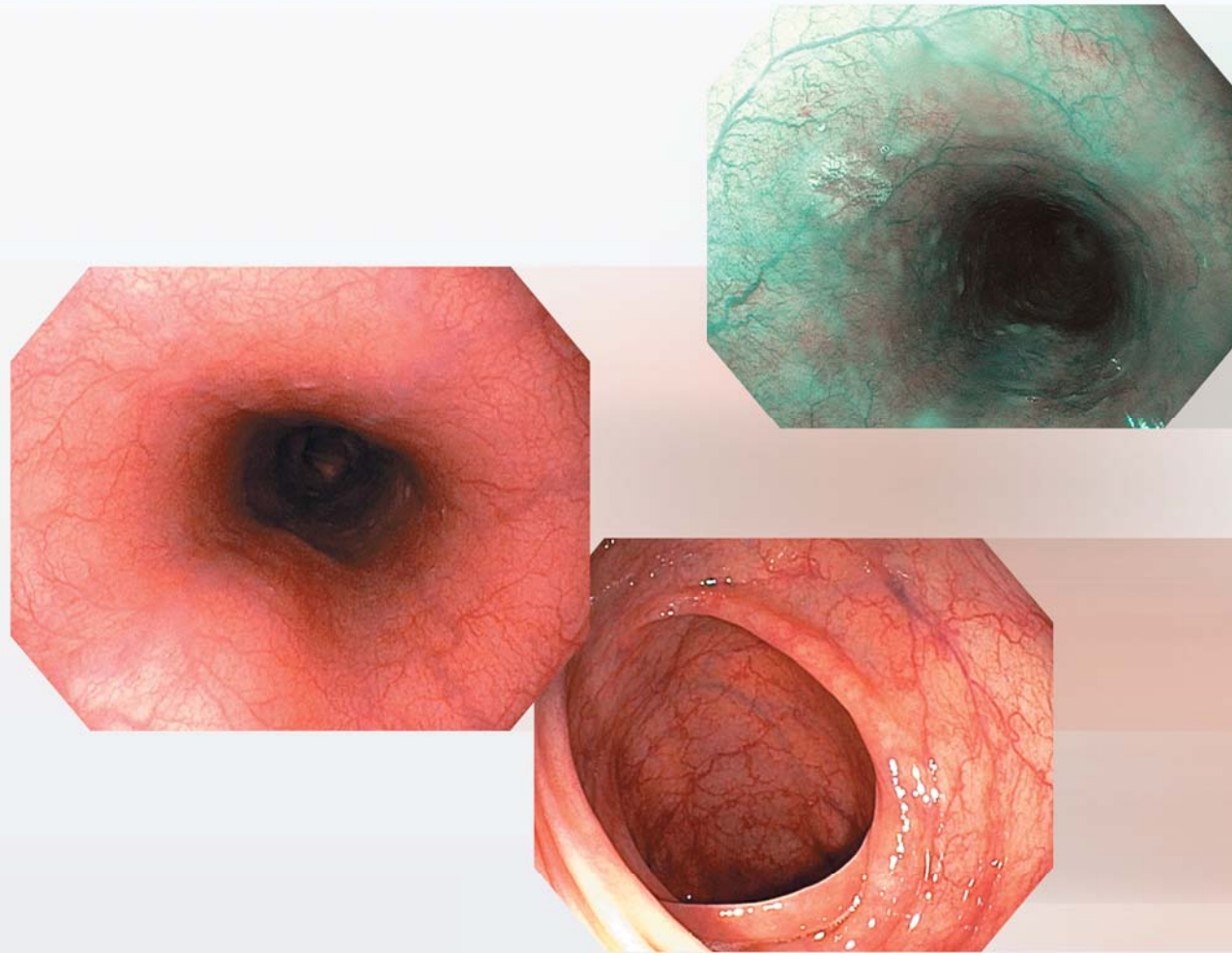
OLYMPUS endoscopic systems set the pace around the world. Consistently, we have tried to create new values for medical professionals by making the best of our technology. And we will continue to expand the possibilities of endoscopy. Now, our technology is concentrated in an even more compact package, adding tremendous value to routine screening. The previously impossible is now the new standard. OLYMPUS Optera is here.

Optera



*This trolley is not available in some areas.

HDTV image capturing and processing takes
routine screening one step further with
advanced observation capabilities



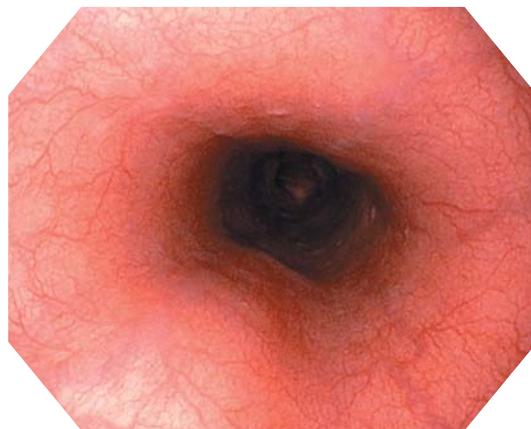
One Step Beyond
**Precise
Imaging**



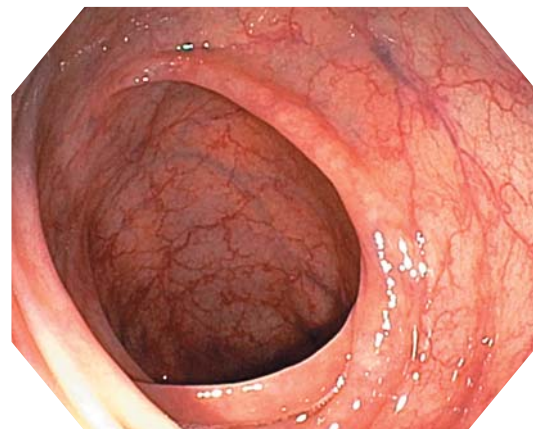
HDTV

Featuring HDTV imaging capability, Optera endoscopes* deliver an edge-to-edge high-resolution image with sharp and clear details. The result is superior imaging with minimal halation and image noise. From now on, high-definition imaging will become standard.

*Except the GIF-XP170N



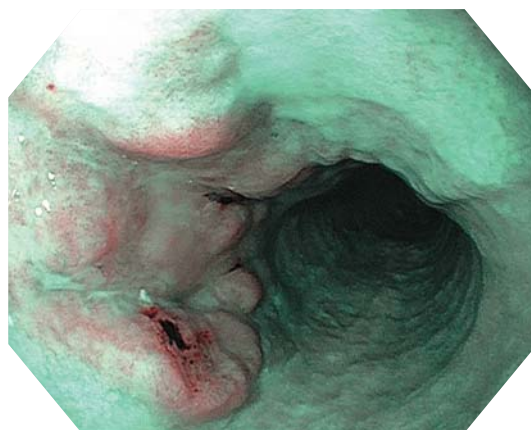
GIF-H170



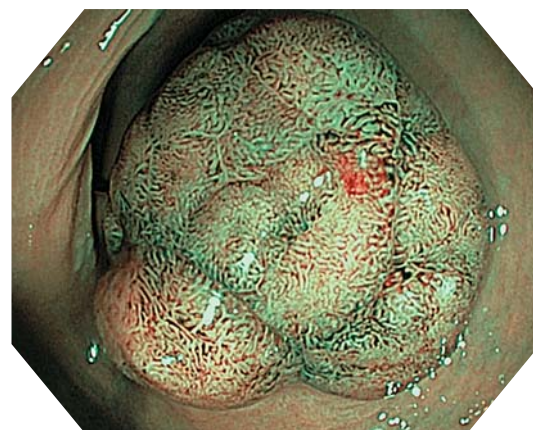
CF-H170L/I

NBI (Narrow Band Imaging)

NBI enhances the visibility of capillaries and other structures on the mucosal surface, which minimizes invasion such as unnecessary biopsies and improves examination quality. NBI is now available in the Optera system where it can be combined with HDTV for maximum effectiveness.



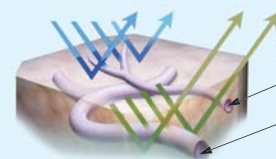
GIF-H170



CF-H170L/I

NBI Structure

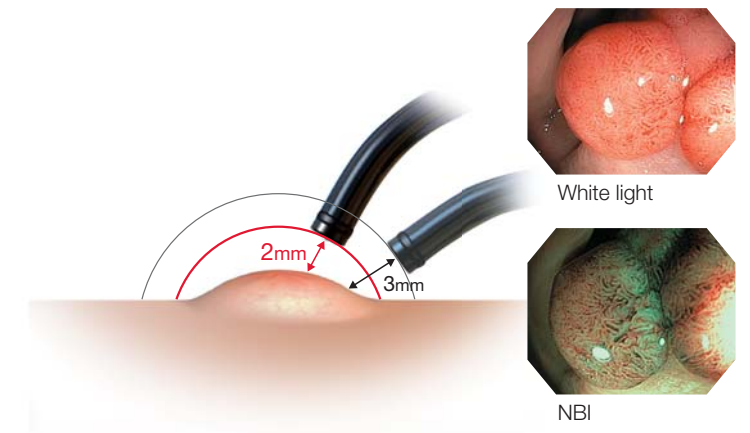
NBI is an optical image enhancement technology that improves the visibility of vessels and other structures on the mucosal surface. Because the gastrointestinal tract is mainly composed of blood vessels and mucosa, narrowband illumination, which is strongly absorbed by hemoglobin and penetrates only the surface of tissues, is ideal for emphasizing the contrast between the two.



415 nm: Capillaries on mucosal surface displayed in brown
540 nm: Veins in submucosa displayed in cyan

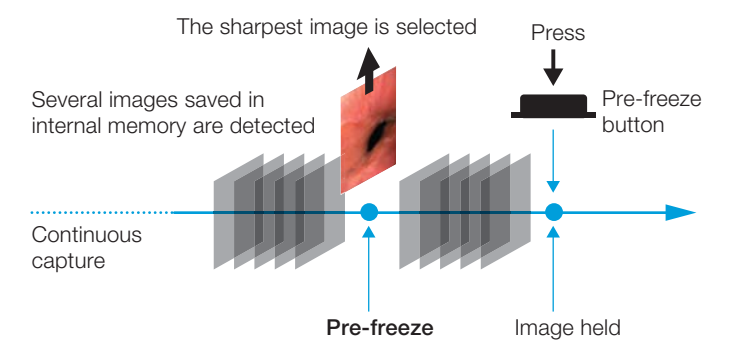
Close Focus

With the close focus function, lesions that used to be out of focus in conventional closeup observation can be observed clearly as close as 2 mm. You can observe and capture clear, large-sized images of fine mucosal tissues and vascular patterns.



Pre-freeze Function

A new pre-freeze function saves time and eliminates the physician's frustration when capturing still images. The new CV-170 automatically buffers a continuous, rapid series of procedural images. When capturing a still image, the pre-freeze function analyzes the previous images and displays and saves the sharpest image of the desired view. This function helps physicians obtain a clear visual record of the procedure in the shortest possible time.



Structure Enhancement

Structure enhancement increases the sharpness of endoscopic images by using sophisticated processing algorithms to suppress noise. It highlights subtle tissue textures and slight color variations on the mucosa. In addition to the popular Type A, Type B is also provided. Mainly, the conventional Type A is ideal for observation of larger mucosal tissues with high contrast in the lower gastrointestinal tract, while the new Type B is suitable for observation of vascular tissues in the upper gastrointestinal tract.



Structure enhancement A7



Structure enhancement B7

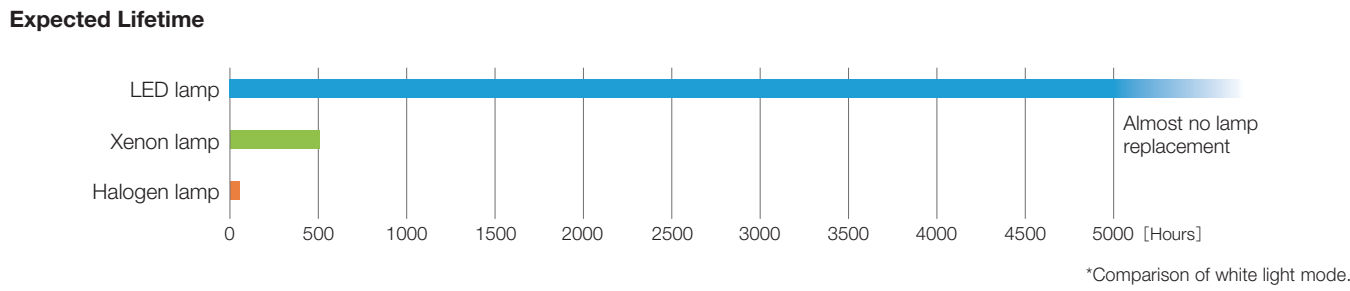
This low-maintenance system is easy to use, while running costs are drastically lower than any other conventional systems, too



One Step Beyond
Operating
Efficiency

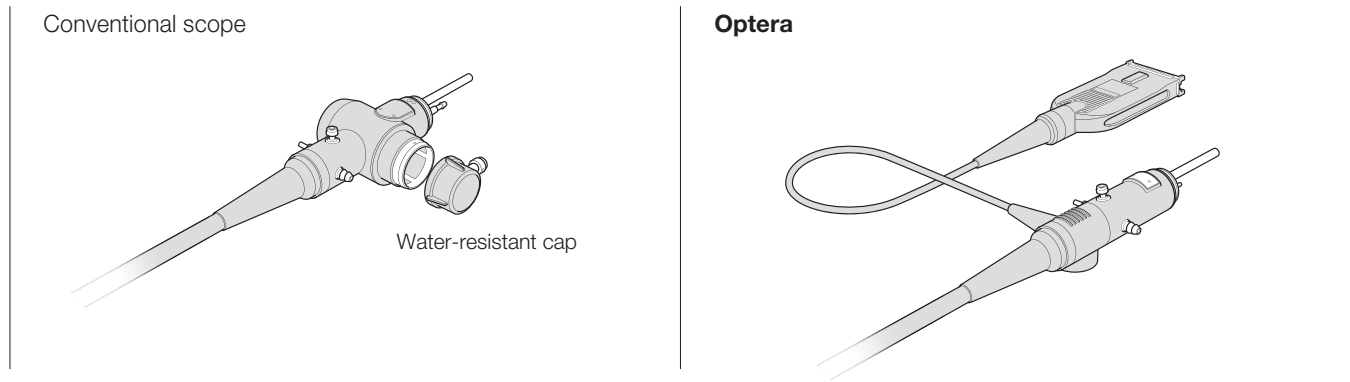
LED Light Source

The Optera processor (CV-170) is equipped with a built-in light source that uses LED lamps. LED light source offers 50% higher brightness than a 150 W halogen lamp. It achieves the sufficient level of brightness for observation in gastrointestinal tract. In addition, since it has much longer lifetime, you rarely have to change the lamp. So both maintenance time and running costs are minimized.



Waterproof Connector

Unlike previous generations of endoscopes, Optera endoscopes do not require a water-resistant cap. This simplifies reprocessing and minimizes the risk of repair costs due to liquid ingress. The enhanced efficiency delivered by the new waterproof connector also helps expedite procedure room setup and turnover.



No one has more experience than OLYMPUS,
and that translates into greater convenience and
more user-friendly functions



One Step Beyond
Routine
Usability

Variable Stiffness

Variable stiffness allows the flexibility of OLYMPUS colonoscopes to be changed incrementally by manipulating a flexibility adjustment ring. This innovative feature allows the scope to be adjusted on a case-by-case basis, to meet the unique anatomical needs of the patient and the handling preferences of the physician. You can realize more effective and smooth colonoscopy than with conventional colonoscopes.



Portable Memory Compatibility

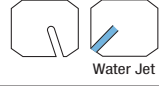
Portable memory (MAJ-1925) has become an accepted standard for data exchange. OLYMPUS now offers a memory port incorporated into the CV-170. A high-speed dedicated portable 2 GB memory is compatible with PCs. The CV-170 automatically transfers released images to the memory, allowing you to download information to a PC or recording devices. This enables you to save system settings, user preset settings and patient data. High-speed data recording using the portable memory provides you with fast and efficient data management.



OLYMPUS CV-170

Power Supply	Voltage	100-240 V AC (NTSC)/220-240 V AC (PAL): within $\pm 10\%$
	Frequency	50/60 Hz: within ± 1 Hz
	Rated input	200 VA
Size	Dimensions (W x H x D)	295 x 145 x 425 mm
	Weight	11.0 kg
Observation	Examination lamp	LED lamp
	Analog HDTV signal output	Either RGB (1080/60I: NTSC)/(1080/50I: PAL) or YPbPr (1080/60I: NTSC)/(1080/50I: PAL) output can be selected.
	Analog SDTV signal output	VBS composite (480/60I: NTSC)/(576/50I: PAL), Y/C (480/60I: NTSC)/(576/50I: PAL), and RGB (480/60I: NTSC)/(576/50I: PAL); simultaneous outputs possible.
	Digital signal output	HD-SDI (SMPTE 292M), SD-SDI (SMPTE 259M) and DVI (WUXGA, 1080p or SXGA) can be selected.
	White balance adjustment	White balance adjustment is possible using the white balance button on the front panel.
	Color tone adjustment	The following color tone adjustments are possible. • Red adjustment: ± 8 steps • Blue adjustment: ± 8 steps • Chroma adjustment: ± 8 steps
	Automatic gain control (AGC)	The image can be electronically amplified when the light is inadequate due to the distal end of the endoscope being too far from the object.
	Noise reduction	Noise is corrected by image processing.
	Iris	The auto iris modes can be selected using the "iris mode" switch on the front panel. • Peak: The brightness is adjusted based on the brightest part of the endoscopic image. • Average: The brightness is adjusted based on the average brightness of the endoscopic image.
	Image enhancement setting	Fine patterns or edges in the endoscopic images can be enhanced electrically to increase the image sharpness. Either the structural enhancement or edge enhancement can be selected according to the user setup. • Structural enhancement: Enhancement of contrast of the fine patterns in the image. • Edge enhancement: Enhancement of edges of the endoscopic image.
	Freeze	An endoscopic image is frozen using an endoscope or the "FREEZE" key on the keyboard.
	NBI observation	This is one of optical-digital observations using the narrow band observation light.
	Remote control	The following ancillary equipment can be controlled (specified models only). • DVR • Video printer • Image filing system • Flushing pump • Endoscopic CO ₂ regulation unit
Documentation	Patient data	The following data can be displayed in the endoscopic image screen. • Patient ID • Patient name • Sex • Age • Date of birth • Date of recording (time, stopwatch) • Comments
	Displaying the record state	The recording state of the following ancillary equipment can be displayed on the monitor. • Portable memory and internal buffer • DVR • Video printer • Image filing system
	Advance registration of patient data	Up to 50 patient's data can be registered. • Patient ID • Patient name • Sex and age • Date of birth
Portable Memory	Media	MAJ-1925 (OLYMPUS)
	Recording format	• TIFF: no compression • JPEG (1/5): approx. 1/5 compression • JPEG (1/10): approx. 1/10 compression
	Number of recording images	• TIFF: approx. 227 images • JPEG (1/5): approx. 1024 images • JPEG (1/10): approx. 2048 images

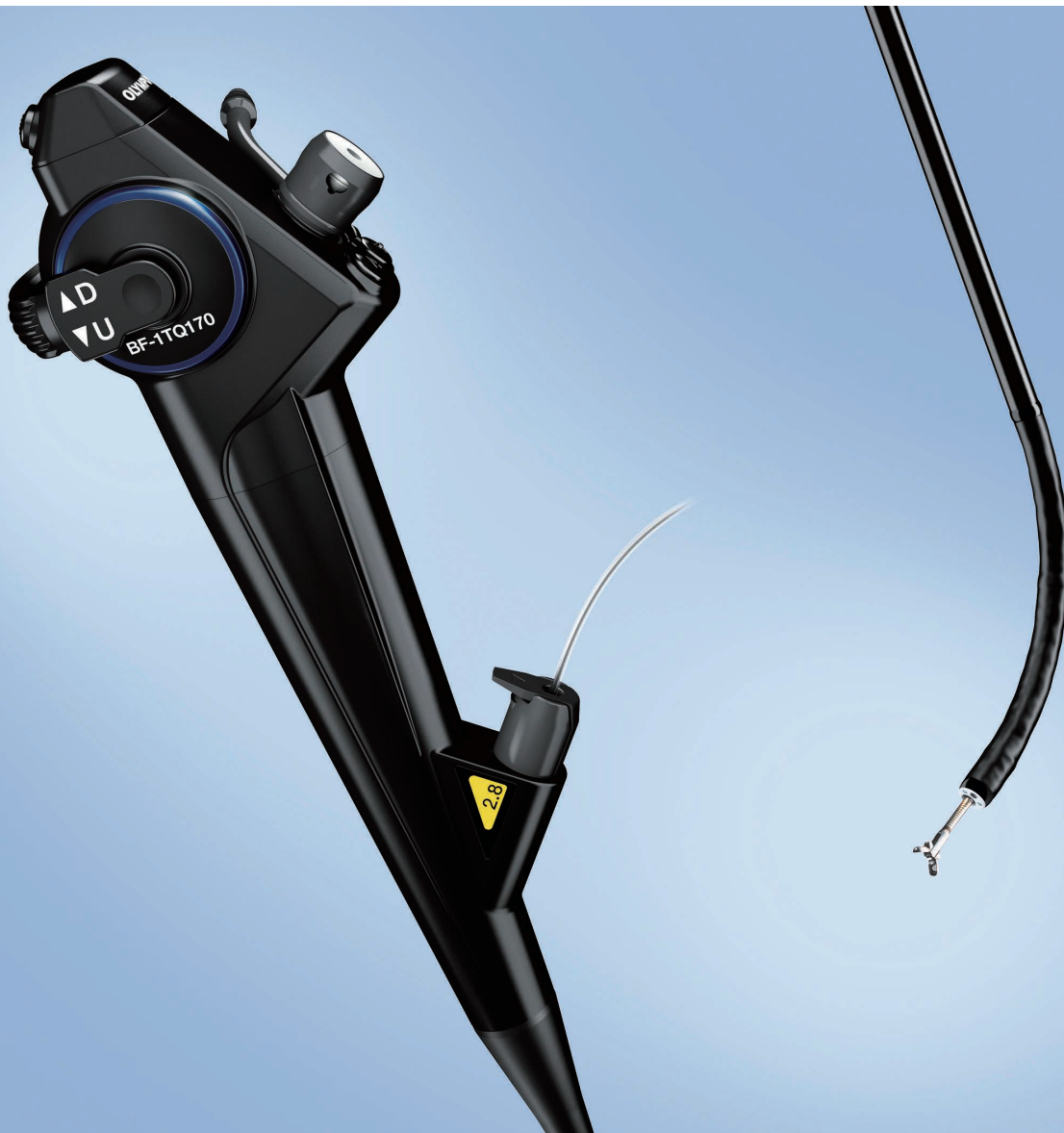
Compatible with EVIS 100/130/140 Series, Actera 150 Series, EVIS EXERA 160 Series, EVIS EXERA II 180 Series and GI/BF/VISERA Series scopes.
Please note that there are some exceptions.

		Gastrointestinal Videoscope OLYMPUS GIF-H170	Gastrointestinal Videoscope OLYMPUS GIF-XP170N	Colonovideoscope OLYMPUS CF-H170L/I
Optical System	Field of view	140°	140°	140°
	Direction of view	Forward viewing	Forward viewing	Forward viewing
	Depth of field	2-100 mm	3-100 mm	2-100 mm
Insertion Section	Distal end outer diameter	9.2 mm	5.4 mm	12.8 mm
	Insertion tube outer diameter	9.2 mm	5.8 mm	12.8 mm
	Working length	1030 mm	1100 mm	L: 1680 mm I: 1330 mm
Instrument Channel	Channel inner diameter	2.8 mm	2.2 mm	3.7 mm
	Minimum visible distance	3.0 mm from the distal end	2.0 mm from the distal end	5.0 mm from the distal end
	Direction from which endotherapy accessories enter and exit the endoscopic image			 Water Jet
High-frequency	Cauterization treatment	Available	Available	Available
Bending Section	Angulation range	Up 210° Down 90°	Up 210° Down 90°	Up 180° Down 180°
		Right 100° Left 100°	Right 100° Left 100°	Right 160° Left 160°
Total Length		1350 mm	1420 mm	L: 2005 mm I: 1655 mm

Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

BRONCHOVIDEOSCOPE
BF-1TQ170

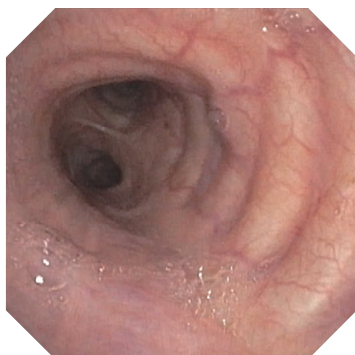
Therapeutic bronchoscope with high image quality and a 2.8 mm instrument channel



Main Features

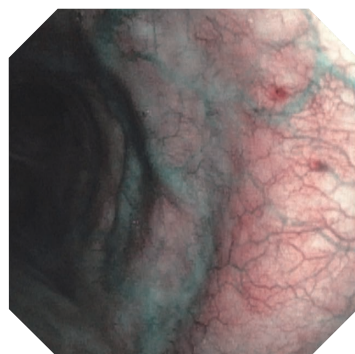
Excellent image quality

High-resolution image quality.



NBI (Narrow Band Imaging)

NBI is an optical image enhancement technology that improves the visualization of vessels on the mucosal surface.



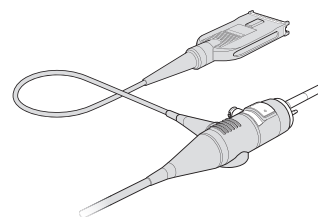
Wider EndoTherapy device capability

The large 2.8 mm instrument channel diameter enables the use of various types of EndoTherapy devices for the 2.8 mm channel outlet. This compares to previous scope BF-1T150*, which is applicable for 2.6 mm or smaller EndoTherapy devices.

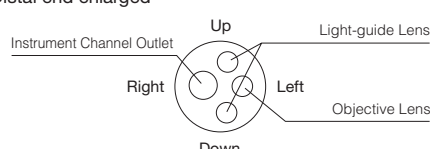
*Bronchovideoscope OLYMPUS BF TYPE 1T150

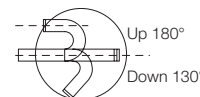
Waterproof connector

The newly designed connector is fully submersible and therefore eliminates the need for a water-resistant cap, while minimizing the risk of damage due to accidental immersion.



Specifications

Optical System	Field of view	120°
	Direction of view	Forward viewing
	Depth of field	3-100 mm
	Image quality	Q-image
Insertion Tube	Distal end outer diameter	5.9 mm
	Distal end enlarged	
		
	Insertion tube outer diameter	6.0 mm
	Working length	600 mm

Instrument Channel	Channel inner diameter	2.8 mm
	Minimum visible length	3.0 mm from the distal end
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Bending Section	Angulation range	

Endoscopic images were taken by an equivalent image quality model (EVIS EXERA III Bronchovideoscope OLYMPUS BF-Q190). Specifications, design and accessories are subject to change without any notice or obligation on the part of the manufacturer.

Product-Information-Sheet

Cleaning, Disinfection, and Sterilization

Cleaning
Brushes



Article number	Article Name	Quantity value	Description	Endoscope Compatibility	Area Compatibility
027700	MB-155	1	Water-leakage tester	All OES and EVIS endoscopes and mobile airwayscopes	

Endoscopic Ancillaries

ENDOCUFF
VISION™



Article number	Article Name	Quantity value	Description	Endoscope Compatibility	Area Compatibility
028725	MB-142	1	Adult reusable bite block	For all GI endoscopes with a maximum insertion tube outer diameter of 15 mm or less	

MD-Series LCD Monitor 24" | 27"



Clinical Review Displays Geared Toward Safety, Comfort



The MD-Series displays, with a wide viewing angle, are designed to accommodate sharing by multiple users and bring comfort to healthcare professionals at work. Their installation flexibility even in compact, hectic surroundings makes it a core component of shared workspaces in medical environments such as receptions, nurses' carts, charting stations and pharmacies.



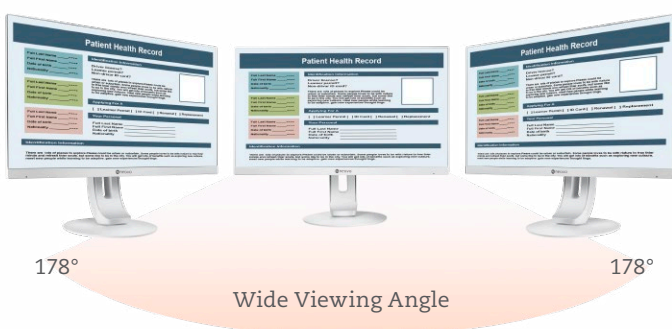


Ergonomic Design

A versatile stand also marks the MD-Series. Healthcare professionals can enjoy both comfort and convenience while making use of one of these displays: tilting, pivoting, or swivelling it, adjusting its height, or shifting to either portrait or landscape mode as warranted.

Medical-Grade Safety Certification

The MD-Series adopts a specially designed low-voltage medical-grade power supply to ensure safety, performance, and reliability—three key requirements for any professional medical environment. Compliance with the IEC/EN60601-1 standard ensures their safe and reliable performance in any medical setting.



Wide Viewing Angle and Image Clarity

The MD-Series offers a wide (178°) viewing angle and adjustable aspect ratios for different images, and deliver remarkably crisp images of precise colours and consistent brightness regardless of viewing angles. All this contributes to the benefit that doctors and patients can share information and conduct a discussion while viewing a display together.

Features

- Full HD 1920 x 1080 resolution
- IPS & VA Panel technologies offer high colour accuracy and wide viewing angles
- Crisp 20,000,000:1 dynamic contrast ratio
- 3-sided narrow bezel design for seamless multi-display setups
- EN60601-1 and IEC60601-1 medical certification
- White exterior design for easy contaminant detection
- Image Enhancer: 3D Deinterlace / Noise Reduction
- Dual inputs: HDMI and VGA
- HDMI inputs for Full HD connectivity with a variety of devices
- Flicker-free display technology reduces eye discomfort
- Selectable aspect ratio
- Built-in speakers
- VESA mounting for flexible installation in healthcare settings
- Height adjustable stand allows users to tilt, pivot and swivel

Specifications

MD-24

MD-27

Panel

Panel Type	LED-Backlit TFT LCD (IPS Technology)	LED-Backlit TFT LCD (VA Technology)
Panel Size	23.8"	27.0"
Max. Resolution	FHD 1920 x 1080	FHD 1920 x 1080
Pixel Pitch	0.275 mm	0.311 mm
Brightness	250 cd/m²	300 cd/m²
Contrast Ratio	20,000,000:1 (DCR)	20,000,000:1 (DCR)
Viewing Angle (H/V)	178°/178°	178°/178°
Display Colour	16.7M	16.7M
Response Time	5 ms	5 ms

Frequency

Frequency (H)	30 kHz-85 kHz	30 kHz-85 kHz
Frequency (V)	45 Hz-76 Hz	45 Hz-76 Hz

Signal Input

HDMI	1.4 x 1	1.4 x 1
VGA	15-Pin D-Sub x 1	15-Pin D-Sub x 1

Audio

Audio In	Stereo Audio Jack (3.5 mm)	Stereo Audio Jack (3.5 mm)
Internal Speakers	2W x 2	2W x 2

Power

Power Supply	External	External
Power Requirements	DC 12V, 2.5A	DC 12V, 2.5A
On Mode	22W (On)	25W (On)
Stand-by Mode	< 0.5W	< 0.5W
Off Mode	< 0.5W	< 0.5W

Operating Conditions

Temperature	0°C-40°C (32°F-104°F)	0°C-40°C (32°F-104°F)
Humidity	10%-85% (non-condensing)	10%-85% (non-condensing)

Storage Conditions

Temperature	-25°C-55°C (-13°F-131°F)	-25°C-55°C (-13°F-131°F)
Humidity	5%-93% (non-condensing)	5%-93% (non-condensing)

Mounting

VESA FPMPI	Yes (100 x 100 mm)	Yes (100 x 100 mm)
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Stand

Tilt	-5° to 23°	-5° to 23°
Pivot	-2.5° to 92.5°	-2.5° to 92.5°
Swivel	± 70°	± 70°
Height Adjustment	0-110 mm	0-110 mm

Security

Kensington Security Slot	Yes	Yes
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Dimensions

Product with Base (W x H x D)	540.6 x 498.6 x 249.0 mm (21.3" x 19.6" x 9.8")	611.9 x 518.7 x 249.0 mm (24.1" x 20.4" x 9.8")
Product w/o Base (W x H x D)	540.6" x 322.6 x 49.6 mm (21.3" x 12.7" x 1.95")	611.9 x 366.6 x 49.0 mm (24.1" x 14.4" x 1.93")
Packaging (W x H x D)	632.0 x 417.0 x 282.0 mm (24.9" x 16.4" x 11.1")	715.0 x 450.0 x 305.0 mm (28.1" x 17.7" x 12.0")

Weight

Product w/o Base	3.3 kg (7.3 lb)	4.2 kg (9.3 lb)
Product with Base	5.7 kg (12.5 lb)	6.6 kg (14.5 lb)
Packaging	7.8 kg (17.1 lb)	8.9 kg (19.6 lb)

Regulation Approval

Certifications & Compliance	CE, IEC / EN 60601-1, EN 60601-1-2, MDD, WEEE, RoHS, REACH, EAC, FCC	CE, IEC / EN 60601-1, EN 60601-1-2, MDD, WEEE, RoHS, REACH, EAC, FCC
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Accessories

Supplied	Power Adaptor, Power Cord, VGA Cable, Audio Cable, Quick Start Guide, Warranty Card	Power Adaptor, Power Cord, VGA Cable, Audio Cable, Quick Start Guide, Warranty Card
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Optional Accessories

Ceiling Mount (Landscape only)	CMP-01+WMK-03	CMP-01+WMK-03
Wall Mount (Landscape only)	WMA-01, WMK-01, WMK-03, PMK-01	WMA-01, WMK-01, WMK-03, PMK-01
Desk mount (Landscape only)	DMC-01, DMC-02D, DMS-01D, DMS-01Q, ES-02	DMC-01, ES-02

Global Headquarters

Taipei, Taiwan

EMEA Regional Headquarters

Capelle a/d IJssel, The Netherlands

North & South America Regional Headquarters

San Jose, CA, U.S.A.

Asia-Pacific Regional Headquarters

Taipei, Taiwan

Canada Sales Office

Vancouver, B.C., Canada

China Sales Office

Shanghai, China

Czech Republic Sales Office

Brno, Czech Republic

Denmark Sales Office

Støvring, Denmark

Germany Sales Office

Mechernich, Germany

Italy Sales Office

Livorno, Italy

Poland Sales Office

Warsaw, Poland

Spain Sales Office

Barcelona, Spain

Ukraine Sales Office

Lviv, Ukraine

displays.agneovo.com

PROFESSIONAL ASPIRATORS - HIGH VACUUM

28280-1



CE 0434
EN ISO 10079-1
Class I
Type B

Vacuum gauge

Double pump type



Overflow regulation knob

28244-6

1 l Autoclavable Jar

ASPEED PROFESSIONAL SURGICAL ASPIRATORS

Piston-type continuous cycle electric aspirators give high performance and great durability. Equipped with a protective thermal cut-out relay. They require no maintenance or lubrication. A motor-protector cap totally prevents aspirated

liquids or secretions from reaching and damaging the vacuum pump. Ideal for clinical use. Made in Italy.

GIMA code	ASPEED ASPIRATORS	Power	Pump	Case
28244	Aspeed 15 l	230 V	single	metal
28245	Aspeed 22 l	230 V	double	metal
28246	Aspeed 22 l	110 V	double	metal
28280	Aspeed 2 15 l	230 V	single	plastic
28281	Aspeed 2 22 l	230 V	double	plastic

GIMA code	ACCESSORIES AND SPARES FOR ASPEED
28255	Hydrophobic 99% bacterial filter
28258	Autoclavable jar 1l with cover
28259	Disposable suction liner
25480	Silicone tube 6x12 mm - roll of 30 m
28254	Adaptor to connect catheter to silicone tube
28261	Adaptor kit to use jar 1l (28258) with ASPEED manufactured before 2007

STANDARD ACCESSORIES

Autoclavable polycarbonate jar 1,000 cc with safety valve (overflow protection)
Disposable suction liner 1 l
99% Antibacterial hydrophobic filter
Sterile disposable cannula
Sterile manual flow regulator
Set of atoxic sterilizable silicone tubes
Power Cable
User Manual GB, FR, IT, DE, ES

TECHNICAL SPECIFICATIONS

	ASPEED 28244	ASPEED 28245/6*	ASPEED 2 28280	ASPEED 2 28281
Operating voltage:	230 V-50 Hz	230 V-50 Hz	230 V-50/60 Hz	230 V-50/60 Hz
	110-60 Hz	110-60 Hz	other voltage on request	other voltage on request
Bottle capacity:	1 l	1 l	1 l	1 l
High vacuum:	low flow 15 l/min	low flow 22 l/min	low flow 15 l/min	high flow 22 l/min
Air flow:	15 l/min	22 l/min	15 l/min	22 l/min
Adjustable vacuum level:	0 ÷ -0.85 bar	0 ÷ -0.85 bar	0 ÷ -0.85 bar	0 ÷ -0.85 bar
Weight:	3.5 kg	4.5 kg	2.5 kg	3.2 kg
Case material:	metal	metal	plastic	plastic
Noise level:	55 dBA	65 dBA	55 dBA	55 dBA



28258 Autoclavable Jar, h 49.2 cm Ø 10 cm top, 9.7 cm base

28259 Disposable suction liner

SUCTION ASPIRATORS HIGH VACUUM, LOW AND HIGH FLOW

- 28222 TOBI - suction aspirator 220-230 V - 50/60 Hz
- 28224 SUPER TOBI - suction aspirator 220-230 V - 50/60 Hz

Portable suction aspirators, ideal for tracheotomy and small surgery. Vacuum continuously adjustable with vacuum indicator. Have unbreakable 1,000 ml standard bottle (2,000 ml optional) autoclavable at 120°C with safety float control valve to prevent overflow. Silicone connection tube. ABS plastic case. Made in Italy

28222

Silicone tube 6x10 mm (see page 159)

Adaptor for catheter (code 28252)



Suction power: 18 l/min
Max suction: -0.75 bar

Suction power: 30 l/min
Max suction: -0.80 bar

HIGH VACUUM
HIGH FLOW

28224

CE 0476

STANDARD ACCESSORIES

	Tobi	Super Tobi
Bottle 1,000 ml with cover	1	1
Antibacterial Filter	1	1
Suction catheter	1	1
Silicon Tube set	1	1
User manual GB, FR, IT, DE, ES	1	1

TECHNICAL SPECIFICATIONS

	28222 Tobi	28224 Super Tobi
Operating voltage:	220-230 V - 50/60 Hz	220-230 V - 50/60 Hz
Power consumption:	184 W	106 W
Bottle capacity:	1,000 ml	1,000 ml
Flow (air litres/min):	18 l/min	40 l/min
Max suction:	-0.75 bar (563mm/Hg)	-0.80 bar (600mm/Hg)
Working time: minutes	20 ON / 40 OFF	120 ON / 60 OFF
Size (cm):	37x22xh 21 cm	37x22xh 21 cm
Weight:	3.5 kg	5.25 kg
Norms:	IEC 601-1	IEC 601-1



CE – Declaration of Conformity

We hereby certify that AG Neovo complies - with the following specific products – with the requirements of the guideline in the Council Directive on the Approximation of the Laws of the Member States relating to Electromagnetic Compatibility (2014/30/EU) , ErP Directive (2009/125/EC) and the RoHS Directive (2011/65/EU ; 2015/863/EU).

Brand Name : AG Neovo
Product : MD-27
Type of Equipment : LCD Monitor

Name of the Manufacturer: ASSOCIATED INDUSTRIES CHINA, INC.

Address of the Manufacturer: 5F-1, NO. 3-1, PARK STREET, NANGANG DISTRICT TAIPEI,
11503, TAIWAN

Tel: +886-2-2655-8080 Fax: +886-2-2655-7878

In accordance with the following standards:

- ◆ EN 60601-1-2:2015
- ◆ CISPR 32:2012+Cor 2, Class B
- ◆ IEC 61000-3-2:2014, IEC 61000-3-3:2013
- ◆ IEC 61000-4-2:2008, IEC 61000-4-3:2006+A1:2007+A2:2010
- ◆ IEC 61000-4-4:2012
- ◆ IEC 61000-4-5:2014
- ◆ IEC 61000-4-6:2013
- ◆ IEC 61000-4-8:2009
- ◆ IEC 61000-4-11:2004
- ◆ EN 60601-1:2006 + A11: 2011 + A1: 2013 + A12: 2014

In case of product changes that are not previously agreed by AG Neovo, this declaration of Conformity will lose its validity.

Date of CE Mark: July 28, 2017

Date of Issue: August 28, 2017

Place of the signature: Taiwan

A handwritten signature in cursive script that reads 'Tony Chu'.

Tony Chu (Senior Manager)

This declaration of conformity is issued under the sole responsibility of the manufacturer.



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MED 26036

Revisione /
Revision

23

Primo rilascio /
First issue date

2006-10-25

Valido da /
Valid from

2021-05-24

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 1 di / of 12

Certificato CE del Sistema di Garanzia della Qualità EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

GIMA S.p.A.

Sede Operativa / Operational Headquarter:

Via Marconi, 1
20060 Gessate, MI - Italia

Sede Legale / Registered Headquarter

Via Tommaso Grossi, 2
20121 Milano, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

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Rif. rapporto di audit/ *Ref. audit report:* del/dated 1-2/3/2021

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:11:29



Organismo Notificato n. 0476
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Reg. Numero /
Reg. Number

MED 26036

Revisione /
Revision

23

Primo rilascio /
First issue date

2006-10-25

Valido da /
Valid from

2021-05-24

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 2 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi attivi per l'aspirazione di sostanze e liquidi / Active substances and liquids suctioning devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1104

Marca / Brandname:

VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

28220 ; 28216 ; 28209 ; 28214 ; 28210 ; 28232 ; 28211 ; 28202 ; 28212 ; 28233 ; 28243 ; 28234 ; 28222 ; 28194 ; 28224 ; 28196 ; 28208 ; 28198 ; 28190 ; 28200 ; 28191 ; 28192 ; 28201 ; 28231 28203 ; 28215 ; 28204 ; 28193 ; 28183 ; 28182

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
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Data: 25/05/2021 10:11:56



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MED 26036

Revisione /
Revision

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Valid from

2021-05-24

Scadenza /
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2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 3 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

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Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

Spatula cervicale monouso sterile in plastica o legno / Disposable sterile plastic or wooden cervical spatula

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

Speculum vaginale monouso sterile perno centrale - mix / Disposable sterile vaginal speculum central pin - mix

Codici / Codes:

29991

Modello / Model:

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / Disposable sterile vaginal speculum central pin - small, medium, large

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix

Codici / Codes:

29987

Modello / Model:

Speculum vaginale monouso sterile vite centrale - mix / Disposable sterile vaginal speculum middle screw - mix

Codici / Codes:

29995

Modello / Model:

Speculum vaginale monouso sterile vite laterale - mix / Disposable sterile vaginal speculum side screw - mix

Codici / Codes:

29986

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Primo rilascio /
First issue date

2006-10-25

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2021-05-24

Scadenza /
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2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 4 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

Speculum vaginale monouso sterile vite laterale (piccolo, medio, grande) / Disposable sterile vaginal speculum side screw - small, medium, large

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasporto in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

Marca / Brandname:

Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

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Data:25/05/2021 10:12:32



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Notified Body nr. 0476



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MED 26036

Revisione /
Revision

23

Primo rilascio /
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2006-10-25

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2021-05-24

Scadenza /
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Ultima modifica /
Last change date

2021-05-24

Pagina / Page 5 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

Aerosol a pistone adulti e bambini / Adult and Kids compressor nebulizers

Codici / Codes:

28091 ; 28092

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / Brandname:

MISTRAL

Modello / Model:

Aerosol professionale a pistone per uso domiciliare / Professional compressor nebulizers for home healthcare environment

Codici / Codes:

28102

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Chief Operating Officer
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Data:25/05/2021 10:12:51



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MED 26036

Revisione /
Revision

23

Primo rilascio /
First issue date

2006-10-25

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Valid from

2021-05-24

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 6 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 0104

Marca / Brandname:

BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

32731 ; 32747; 32749 ; 32719 ; 32725; 32726 ; 32709; 32727; 32728; 32738; 32734 ; 32693/10965 ; 32735 ; 32745

Marca / Brandname:

SIRIO

Modello / Model:

Manometro Aneroid / Aneroid manometer

Codici / Codes:

32904

Marca / Brandname:

YTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

32720; 32703; 32693; 32701

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MDS 7010

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Data:25/05/2021 10:13:13



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Reg. Number

MED 26036

Revisione /
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Primo rilascio /
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2006-10-25

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2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 7 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital Sphygmomanometers WRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / Brandname:

DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / Medical Devices:

Dispositivi per la misurazione della saturazione di ossigeno / Oxygen saturation measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

34266; 34282; 34285, 34285-10997, 34340; 34342; 34265; 35091; 35092; 35093; 35095; 35090 ; 35100

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Data: 25/05/2021 10:13:36



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Reg. Number

MED 26036

Revisione /
Revision

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Primo rilascio /
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2006-10-25

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Valid from

2021-05-24

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Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 8 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / Body temperature measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Marca / Brandname:

DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / Brandname:

FARMAMED / LINEA F / CARREFOUR / GS /PBpharma / 36.2 T&B / SUCCHIOTTO °C / BASALE / GIMA

Modello / Model:

Termometri clinici digitali classici e flessibili / Digital clinical thermometers classic and flexible

Codici / Codes:

25560; 305026-10945; 25561; 25560-10907; 305027-10946 ; 25608

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

Termometri clinici digitali auricolari e frontali multifunzione / Digital clinical ear and forehead multifunction thermometers

Codici / Codes:

25580 ; 25585

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Giampiero Belcredi

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Data:25/05/2021 10:13:57



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CERTIFICATE

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MED 26036

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23

Primo rilascio /
First issue date

2006-10-25

Valido da /
Valid from

2021-05-24

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 9 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione di parametri fisiologici / Physiological parameters measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1301, MD 0104

Modello / Model:

Altimetro - Plicometro - Metro per neonati / Height meter - Skinfold caliper - Baby measuring meter

Codici / Codes:

27335 ; 27344; 27331

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

34431, 34432, 34433, 34434, 34435, 34436, 34437, 34438; 34383; 34439

Modello / Model:

Maschere in silicone autoclavabili / Maschere autoclavabili in silicone GIMA PLUS / Silicone autoclavable face masks / Silicone autoclavable face masks GIMA PLUS

Codici / Codes:

34220, 34221, 34222, 34223, 34224, 34225 ; 34252, 34253, 34254, 34255; 34250

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

Chief Operating Officer
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Data:25/05/2021 10:14:45



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2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 10 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit

Codici / Codes:

34245, 34246, 34247; 34248, 34277, 34249 ; 34244

Modello / Model:

Reservoir monouso (sacche ossigeno) e valvola / Oxygen reservoir and valve

Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

Valvola PEEP e adattatore / Valvola antireflusso e posteriore / Peep valve and adapter / Non-rebreathing valve and intake valve

Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / Medical Devices:

Dispositivi per terapia termica / Thermic therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack

Codici / Codes:

34110 ; 34111

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Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:15:10



Organismo Notificato n. 0476
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Ultima modifica /
Last change date

2021-05-24

Pagina / Page 11 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Kit di strumentario chirurgico monouso sterile / Sterile single use surgical instrument kit

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

Kit per rimozione sutura / kit procedurale sutura / Suture removal pack / Suture procedure pack

Codici / Codes:

38950 ; 38951

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

Forbici per bende di Lister / Forbici chirurgiche standard / Lister bandage scissors / Standard surgical scissors

Codici / Codes:

388xx

Modello / Model:

Pinza di Magill / Pinza di Hartmann per orecchio / Magill forceps / Hartmann ear forceps

Codici / Codes:

388xx

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

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Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:15:40



Organismo Notificato n. 0476
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Last change date

2021-05-24

Pagina / Page 12 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

Codici / Codes:

388xx ; 389xx

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

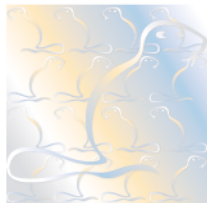
Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:16:08



Organismo Notificato n. 0476
Notified Body nr. 0476



CERTIFICATE



Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		

Previous expiry date

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico,
soggetta all'attività di
direzione e coordinamento di
Kiwa Italia Holding Srl

Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it

CERMET

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



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

Date: 2017-10-12

M. Aihara
M.Sc. M. Aihara

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

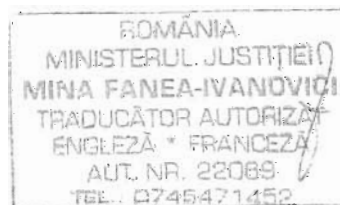
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită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

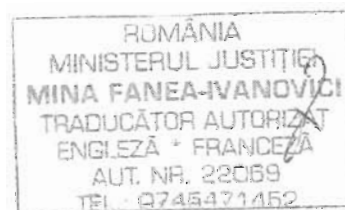
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea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



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



TÜV Rheinland LGA Products GmbH
TÜVRheinland[®]
Zertifizierungsstelle

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

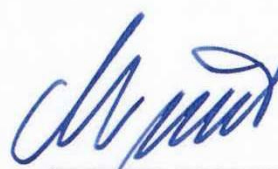
Scope:

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

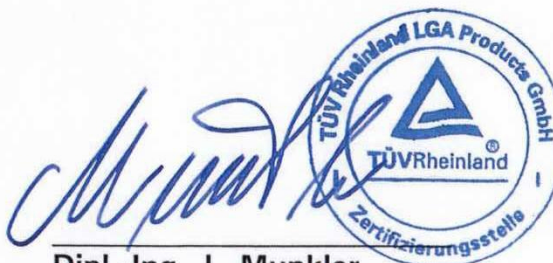
Scope:

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

**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



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Nr. raport:

60319405 001

Organizație:

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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**



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D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
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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 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
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Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

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Organizație:

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

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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 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**



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Data, 29.04.2020

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Organizație:

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

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

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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 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
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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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Organizație:

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



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