

VIDEO SYSTEM CENTER

CV-170

Combination of HDTV and NBI is now available with an LED light source in one design



Main Features

- HDTV imaging capability provides the best possible image quality for endoscopes, enabling observation of capillaries, mucosal structures, and other patterns.
- NBI (Narrow Band Imaging) enhances the visibility of capillaries and other structures on the mucosal surface.
- Newly adopted long-life LED light source minimizes lamp replacement, while reducing energy and noise.
- The pre-freeze function selects the clearest still image automatically. It may help to save time and eliminate the physician's frustration.
- Two types of structure enhancement are available – 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.
- Portable memory (MAJ-1925) is compatible, which is the standard for data management. Simply connect and upload.
- 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.
- 16:9 and 16:10 output for a HDTV monitor is available. Compatible with analog, HD-SDI, and DVI output.



Specifications

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
Classification (medical electrical equipment)	Type of protection against electric shock	Class I
	Degree of protection against electric shock of applied part	Depend on applied part. Also refer to applied part (camera head or videoscope).
	Degree of protection against explosion	The video system center should be kept away from flammable gases.
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.
	Standard color chart output	The "Color bar" or the "50% white" screen can be displayed.
	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.
	Contrast	The image contrast can be set to one of the following three modes (N, H, L). • N (Normal): Normal image • H (High): The dark areas are darker and the bright areas are brighter than in the normal image. • L (Low): The dark areas are brighter and bright areas are darker than in the normal image.
	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.
	Switching the enhancement modes	The enhancement level can be selected from 3 levels (1, 2, and 3).
	Image size selection	The size of the endoscopic image can be changed using the "IMAGE SIZE" key on the keyboard.
	Freeze	An endoscopic image is frozen using an endoscope or the "FREEZE" key on the keyboard.
	Pre-freeze	The image with the least blur is selected from the images captured in the set time period before freeze operation and displayed.
	NBI observation	This is one of optical-digital observations using the narrow band observation light.
	Reset to defaults	The following settings can be reset to their defaults. • Color tone • Iris mode • Image enhancement mode • Image size • Contrast • Freeze • Release index • Electronic zoom • Optical-digital observation • Arrow pointer • Stopwatch • Characters on screen • Brightness
	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
	Displaying the image information	The following data can be displayed on the monitor. • Structure enhancement level • Edge enhancement level • Zoom ratio • Color mode
	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
Memory Backup	User settings	Up to 20 user settings can be registered.
	Memorization of selected setting	The following settings are held in memory even after the video system center is turned OFF. • Color tone • Iris mode • Image enhancement mode • Color enhancement mode • Contrast • AGC • Color mode • White balance • Brightness adjustment method • Brightness • Air feeding
	Lithium battery	Life: 5 years

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

GASTROINTESTINAL VIDEOSCOPE

GIF-H170

Outstanding HDTV image quality while keeping a slimmer outer diameter



Main Features

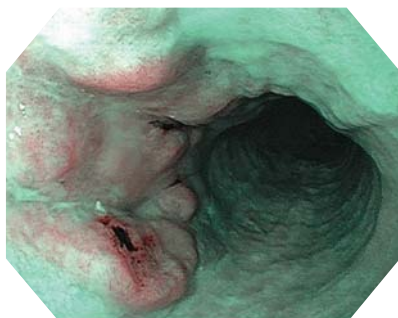
HDTV Image Quality

HDTV captures and displays clear images with precise details and accurate colors, helping you to perform more advanced procedures.



NBI (Narrow Band Imaging)

NBI facilitates observation of capillaries and other structures on the mucosal surface. It helps identify suspicious areas.



Close Focus

Close focus enables you to obtain an enlarged, close-up image by moving the scope tip as close as 2 mm from the mucosa.

Slim Design

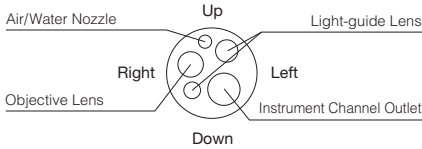
GIF-H170 offers an excellent balance of both size and performance with its 9.2 mm outer diameter.

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	140°
	Direction of view	Forward viewing
	Depth of field	2-100 mm
Insertion Section	Distal end outer diameter	9.2 mm
	Distal end enlarged	
		
	Insertion tube outer diameter	9.2 mm
	Working length	1030 mm

Instrument Channel	Channel inner diameter	2.8 mm
	Minimum visible distance	3.0 mm from the distal end
Instrument Channel	Direction from which endotherapy accessories enter and exit the endoscopic image	
High-frequency	Cauterization treatment	Available
Bending Section	Angulation range	Up 210°
		Down 90°
		Right 100° Left 100°
Total Length	1350 mm	

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

TC-C3

Compact Trolley



Compact Trolley

TC-C3

The TC-C3 Compact Trolley is designed as a compact trolley to be used in conjunction with Optera CV-170.

Compact

The compact design means the TC-C3 is ideal for use in the outpatient or doctor's office where space is limited.

Easy to Move

The Compact Trolley is easy to move and position due to its light weight and ergonomically designed handles at the front of the top tray.

Easy to Clean

The TC-C3 is easy to clean due to limited dirt traps and no exposed fittings.

Monitor Support

The TC-C3 is offered with a monitor mount that supports monitors up to 26" with unrestricted swivel and tilt movement, allowing good viewing positions of the procedure image.

Large Top Tray

The top tray provides a clear working space at a comfortable height. The increased range of accessories enables the trolley to be utilized for a range of procedures.

Integrated Separation Transformer

The TC-C3 can be supplied with a separating transformer that is placed under the base, this means increased shelf space for equipment loading.



Accessories

TC-C3

MAJ-2146

Sliding Keyboard Tray



MAJ-1684

Scope Pole Kit



MAJ-2148

Rear Panel



MAJ-1686

Drawer Unit



MAJ-1685

IV Bag Hanger



MAJ-1683

LCD Monitor Mount



MAJ-1656

Footswitch Holder



MAJ-1639

CO₂ Cylinder Holder (140 mm)



MAJ-1665

Camera Head Holder



MAJ-2145

ENT Scope Hanger



MAJ-1658

Universal Storage Container



MAJ-110

Jar Mounting Kit TC



TC-C3

Standard sets include:

TC-C3 Compact Trolley plus items marked (•)

Accessories available as an optional extra (o)

			Region	Set 1	Set 2	Set 3	Set 4
			EUROPE	K10030123	K10034675	K10030133	K10034676
			UK	K10030124	K10034675	K10030134	K10034676
			ROW	K10030125	K10034675	K10030135	K10034676
MAJ	Part	Part					
Description	Description	Number					
MAJ-2146	Sliding Keyboard Tray	K10027573	o	•	•	•	•
MAJ-1684	Scope Pole Kit	K10027281	o	•	•		
MAJ-2148	Rear Panel	K10027574	o				
	Transformer			•		•	
MAJ-1686	Drawer Unit	K10027569	o				
MAJ-1685	IV Bag Hanger	K10027568	o				
MAJ-1683	LCD Monitor Mount	K10026888	o	•	•	•	
MAJ-1656	Footswitch Holder	K10021790	o				
MAJ-1639	CO ₂ Cylinder Holder (140 mm)	K10021041	o				
MAJ-1665	Camera Head Holder	K10028704	o				
MAJ-2145	ENT Scope Hanger	K10026497	o				
MAJ-1658	Universal Storage Container	K10021792	o				
MAJ-110	Jar Mounting Kit TC	K7503556	o				
MAJ-1654	Equipotential Terminal Strip	K10021352	o				
	Blister Pack Toolkit		o	•	•	•	•
	IEC Lead Set		o	•		•	

Specifications

Dimensions	1,110 mm (H) × 563.9 mm (D) × 489.5 mm (W)
	Height to top tray work surface – 1,100 mm
	Height with 26" LCD monitor in highest position – 1,945 mm
Weight	Maximum 82 kg (unladen) including fitted transformer

Voltage

The TC-C3 can be supplied with a separating transformer based on one of the following voltage options:

MAJ-2205	Transformer 110-120 V
MAJ-2206	Transformer 220-240 V

Trolley Construction

Columns	Extruded profiled aluminum
Shelves	Mild steel
Top Tray	Injection-moulded ABS

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

OLYMPUS

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 Postbox 10 49 08, 20034 Hamburg, Germany
 Wendenstrasse 14-18, 20097 Hamburg, Germany
 Phone: +49 40 23773-0, Fax: +49 40 233765
www.olympus-europa.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

MD-2702 CLINICAL REVIEW MONITOR



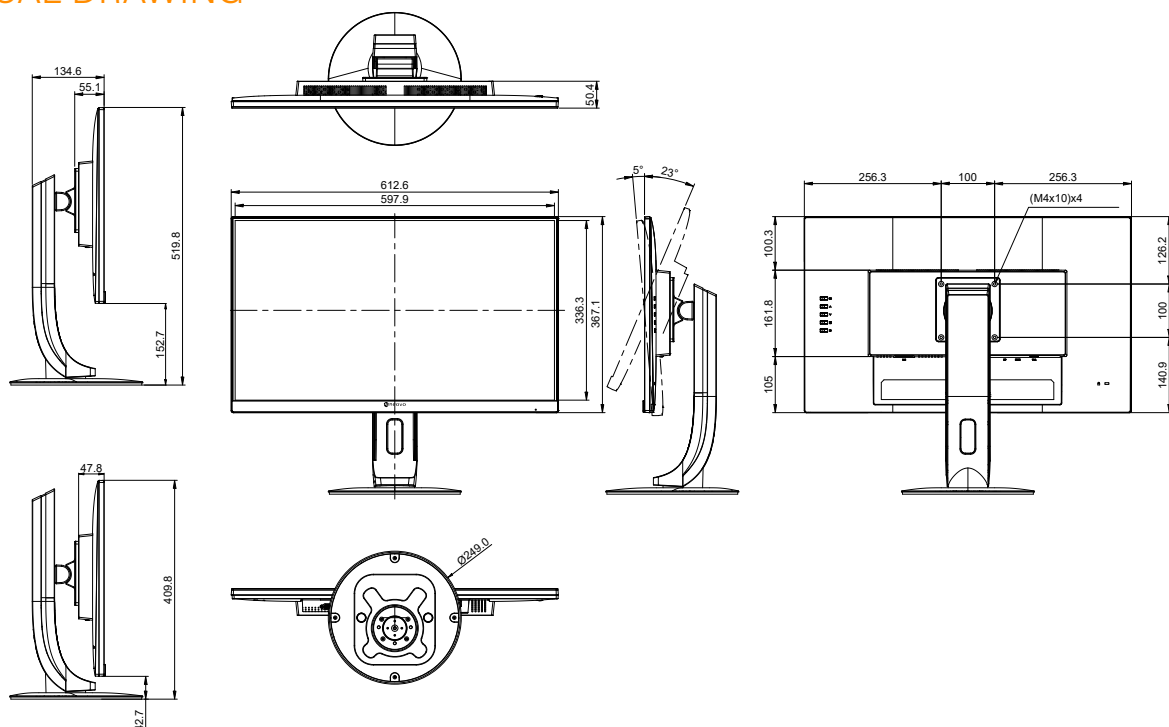
FEATURES

- Full HD 1920 x 1080 resolution
- 178° / 178° wide viewing angle
- Support DICOM Part 14 with calibrated greyscale and brightness
- Crisp 20,000,000:1 dynamic contrast ratio
- 3-sided narrow bezel design for seamless multi-display setups
- Medical adapter certified to the IEC/EN 60601-1 medical standard
- White exterior design for easy contaminant detection
- Versatile Connectivity: DisplayPort, HDMI and VGA
- HDMI inputs for Full HD connectivity with a variety of devices
- Selectable aspect ratio
- VESA mounting for flexible installation in healthcare settings
- Height adjustable stand allows users to tilt, pivot and swivel



Featuring DICOM preset and medical-grade power supply, the MD-2702 clinical review monitor ensures correct and consistent brightness and greyscale levels of medical images in detail at any viewing angle. Its image stability, medical-grade power supply, and VESA-compatible mounts give clinical professionals confidence in clinical review and easy to set up a mobile workstation while meeting the standards of premium quality assurance and financial benefits.

TECHNICAL DRAWING



SPECIFICATIONS

Panel

Panel Type	LED-Backlit TFT LCD (VA Technology)
Panel Size	27.0"
Max. Resolution	FHD 1920 x 1080
Pixel Pitch	0.311 mm
Brightness	300 cd/m ² 180 cd/m ² (DICOM Preset)
Contrast Ratio	20,000,000:1 (DCR)
Viewing Angle (H/V)	178°/178°
Display Colour	16.7M
Response Time	5 ms

Frequency

Frequency (H)	30 kHz-83 KHz
Frequency (V)	50 Hz-76 Hz

Signal Input

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

Power

Power Supply	External
Power Requirements	DC 12V, 2.5A
On Mode	16W (On)
Stand-by Mode	< 0.3W
Off Mode	< 0.2W

Operating Conditions

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

Storage Conditions

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

Mounting

VESA FPMPI	Yes (100 x 100 mm)
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Stand

Tilt	-5° to 23°
Pivot	-2.5° to 92.5°
Swivel	± 65°
Height Adjustment	0-110 mm

Security

Kensington Security Slot	Yes
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Dimensions

Product with Base (W x H x D)	612.6 x 519.8 x 249.0 mm (24.1" x 20.5" x 9.8")
Product w/o Base (W x H x D)	612.6 x 367.1 x 50.4 mm (24.1" x 14.6" x 2.0")
Packaging (W x H x D)	700.0 x 456.0 x 282.0 mm (27.6" x 18.0" x 11.1")

Weight

Product w/o Base	3.7 kg (8.2 lb)
Product with Base	6.1 kg (14.5 lb)
Packaging	8.8 kg (19.4 lb)

Regulation Approval

Certifications & Compliance	CE, LVD, WEEE, RoHS, REACH, EAC, UKCA, BSMI
Power Adaptor Certifications	ADAPTER/ATM065T-P120: CE, FCC, PSE, WEEE, BSMI, Medical Grade

Accessories

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

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



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

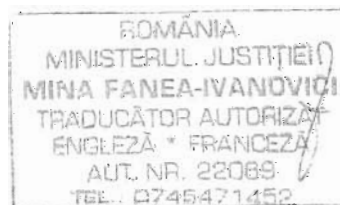
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită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



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

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

Certification Body



Date 2020-04-29



Dipl.-Ing. I. Munkler

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope: Subsidiary:

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

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope: Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope: Subsidiary:

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

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

Certification Body



Date: 2020-04-29



TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope: Subsidiary:

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

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/13, Rev.0

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Vienna
Austria

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

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

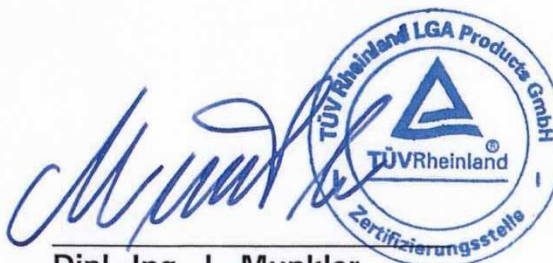
Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope: Subsidiary:

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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

Scope:

Subsidiary:

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland

Scope:

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

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler



Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

OLYMPUS EUROPA SE & Co. KG

**Amsinckstr. 63
20097 Hamburg
Germania**

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

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

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

EN ISO 13485:2016

Sistemul de management al calității este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020

Nr. înregistrare certificat: SX 60148788 0001

A fost efectuat auditul, raport nr. 60319405 001

Acest certificat este valabil până la 20.06.2023.



Data, 29.04.2020

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

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg

Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com <http://www.tuv.com/safety>



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

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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





TÜVRheinland®

Doc. 4/13 Rev. 0

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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate:

Filială

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

Domeniul de aplicabilitate:

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



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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





TÜVRheinland®

Doc. 7/13 Rev. 0

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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate:

Filială

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

Domeniul de aplicabilitate:

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



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

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





TÜVRheinland[®]

Doc. 8/13 Rev. 0

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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate:

Filială

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

Domeniul de aplicabilitate:

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



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

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





TÜVRheinland®

Doc. 9/13 Rev. 0

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

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Viena
Austria

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate:

Filială

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Elveția

Domeniul de aplicabilitate:

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



Data, 29.04.2020

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



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

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

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

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Elveția

Domeniul de aplicabilitate:

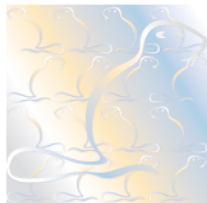
Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

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





Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

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 production, packaging and service of:

General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).

Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

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.

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

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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





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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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Last change date

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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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Pagina / Page 3 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:

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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Giampiero Belcredi

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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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Chief Operating Officer
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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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Valid from

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Valid until

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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 Aneroido / 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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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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Giampiero Belcredi

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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

Chief Operating Officer

Giampiero Belcredi

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CERTIFICATE

Kiwa Cermet Italia S.p.A.
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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
Giampiero Belcredi

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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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Chief Operating Officer
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Revision

23

Primo rilascio /
First issue date

2006-10-25

Valido da /
Valid from

2021-05-24

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Valid until

2024-05-26

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 26036

Revisione /
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23

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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.

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Chief Operating Officer
Giampiero Belcredi

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Data: 25/05/2021 10:16:08



Organismo Notificato n. 0476
Notified Body nr. 0476



CERTIFICATE



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), Low-voltage Directive (2014/35/EU), and the ErP Directive (2009/125/EC).

Brand Name : AG Neovo
Product : MD-2702
Type of Equipment : LCD Monitor

Name of the Manufacturer: ASSOCIATED INDUSTRIES CHINA, INC.
Address of the Manufacturer: 5F-1, NO.3-1, PARK ST., NANGANG DISTRICT, TAIPEI,
11503, TAIWAN
TEL: +886-2-2655-8080 FAX: +886-2-2655-7878

In accordance with the following standards:

- ◆ EN 55032:2015 / AS/NZS CISPR 32:2015 / CISPR 32:2015, Class B
- ◆ EN 55032:2015+AC:2016 / EN 55032:2015+A11:2020 / CISPR 32:2015+COR1:2016, Class B
- ◆ EN 55032:2015+A1:2020 / AS/NZS CISPR 32:2015+AMD1:2020, Class B
- ◆ EN 55035:2017 / CISPR 35:2016
- ◆ EN 55035:2017+A11:2020
- ◆ IEC 61000-3-2:2014 / EN 61000-3-2:2014, Class D
- ◆ IEC 61000-3-2:2018 / EN IEC 61000-3-2:2019, Class D
- ◆ EN IEC 61000-3-2:2019+A1:2021, Class D
- ◆ IEC 61000-3-3:2013 / EN 61000-3-3:2013
- ◆ IEC 61000-3-3:2013+A1:2017 / EN 61000-3-3:2013+A1:2019
- ◆ EN IEC 62368-1:2020+A11:2020
- ◆ IEC 62368-1:2018
- ◆ IEC 62368-1:2014 / EN 62368-1:2014; A11:2017

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: September 23, 2021
Date of Issue: September 24, 2021
Place of the signature: Taiwan



Tony Chu (Senior Manager)

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