OLYMPUS®

Your Vision, Our Future

# Optera


Digitally signed by Grabazei Alexandru
Date: 2021.06.25 11:11:56 EEST
Reason: MoldSign Signature
Location: Moldova

# The new standard for routine screening

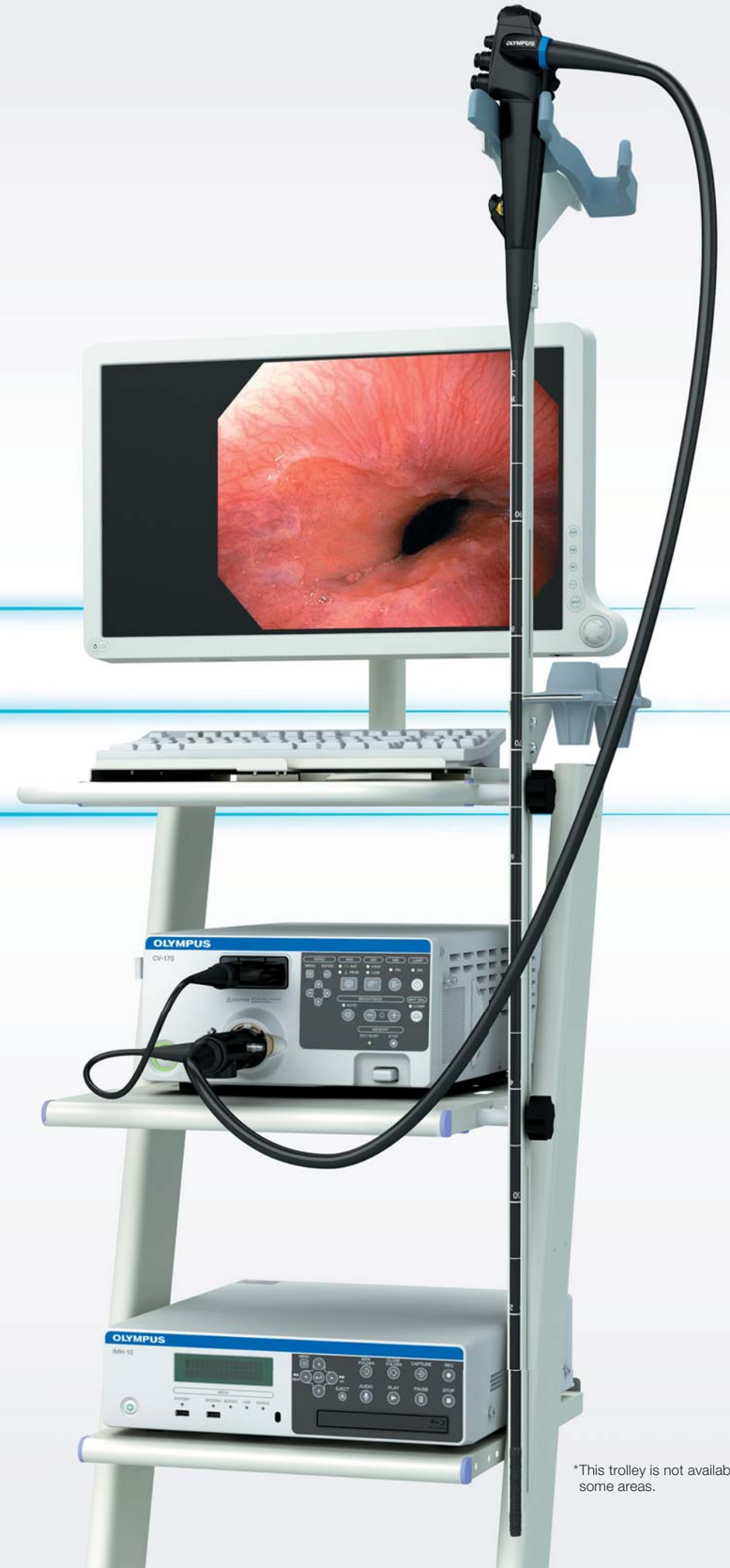
One step beyond precise imaging

One step beyond operating efficiency

One step beyond routine usability

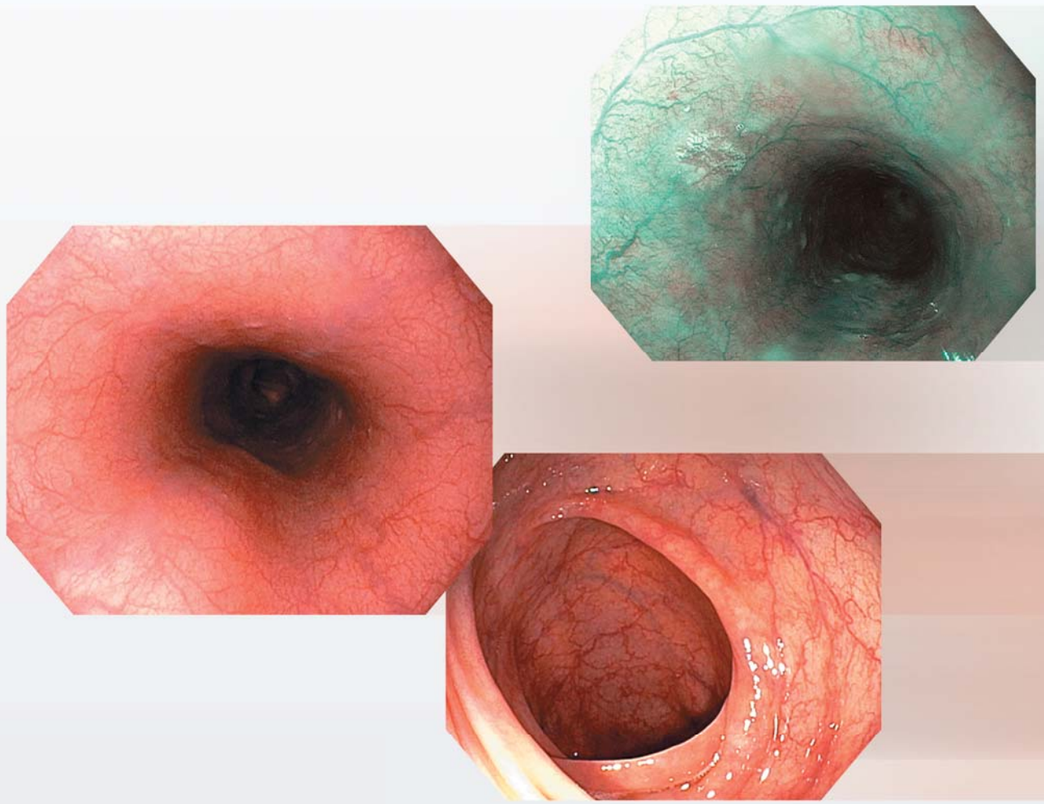
OLYMPUS endoscopic systems set the pace around the world. Consistently, we have tried to create new values for medical professionals by making the best of our technology. And we will continue to expand the possibilities of endoscopy. Now, our technology is concentrated in an even more compact package, 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



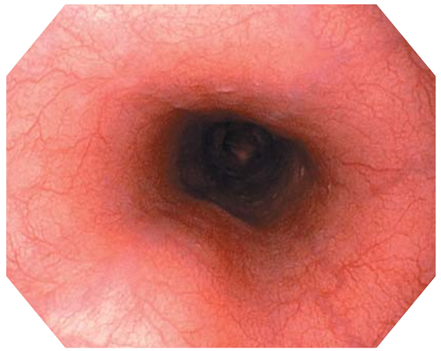
## One Step Beyond

# Precise Imaging

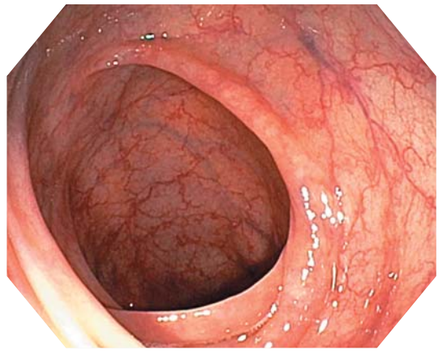
## HDTV

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



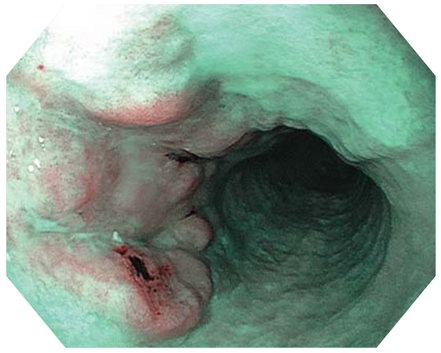
GIF-H170



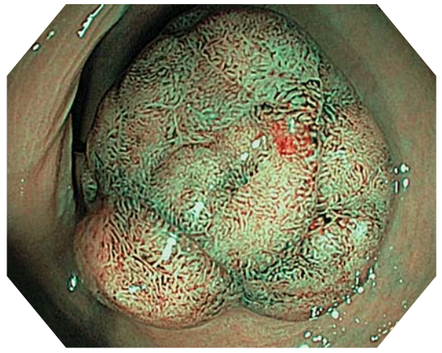
CF-H170L/I

## 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.



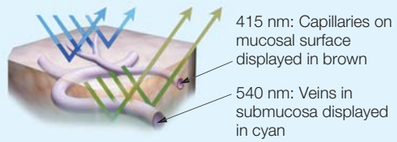
GIF-H170



CF-H170L/I

**NBI Structure**

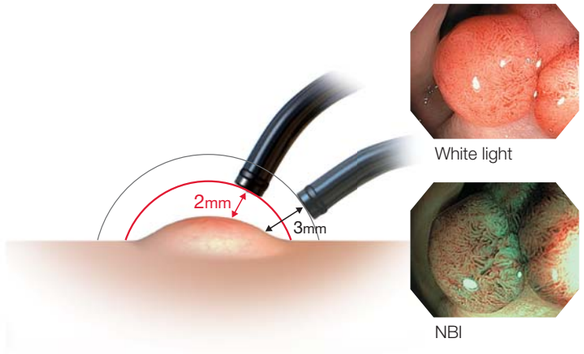
NBI is an optical image enhancement technology that improves the visibility of vessels and other structures on the mucosal surface. Because the gastrointestinal tract is mainly composed of blood vessels and mucosa, narrowband illumination, which is strongly absorbed by hemoglobin and penetrates only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





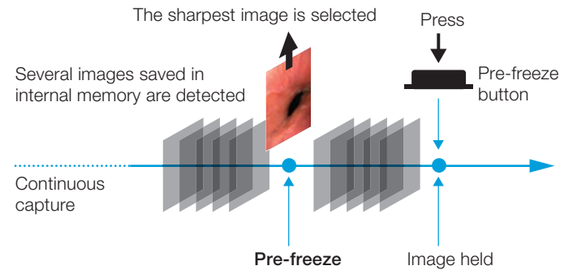

## Close Focus

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.



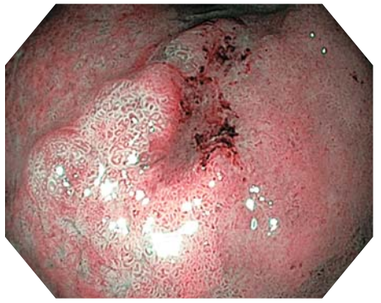

## Pre-freeze Function

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.

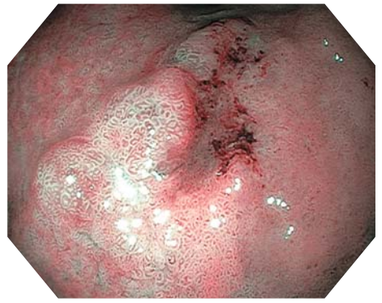



## Structure Enhancement

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

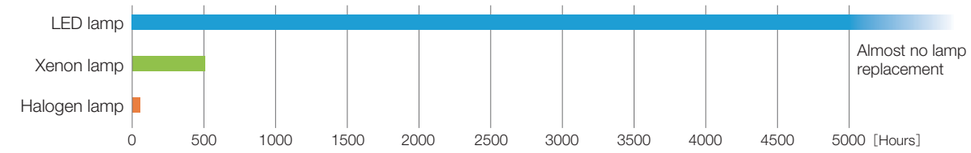
# Operating Efficiency



## 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.

**Expected Lifetime**

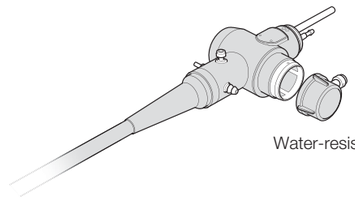



*Comparison of white light mode.

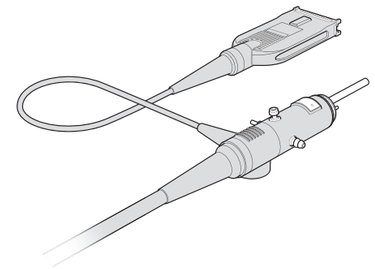
## Waterproof Connector

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.

Conventional scope




**Optera**



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

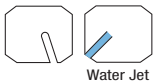
Portable memory (MAJ-1925) has become an accepted standard for data exchange. OLYMPUS now offers a memory port incorporated into the CV-170. A high-speed dedicated portable 2 GB memory is compatible with PCs. The CV-170 automatically transfers released images to the memory, allowing you to download information 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.

Video System Center

## OLYMPUS CV-170

| | | |
|---|---|---|
| Power Supply | Voltage | 100-240 V AC (NTSC)/220-240 V AC (PAL): within ±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 (SMTPE 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.<br>• 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.<br>• Peak: The brightness is adjusted based on the brightest part of the endoscopic image.<br>• 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.<br>Either the structural enhancement or edge enhancement can be selected according to the user setup.<br>• Structural enhancement: Enhancement of contrast of the fine patterns in the image.<br>• 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).<br>• 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.<br>• 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.<br>• 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.<br>• 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<br>OLYMPUS GIF-H170 | Gastrointestinal Videoscope<br>OLYMPUS GIF-XP170N | Colonovideoscope<br>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 |  |  |  <br>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 |



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For a complete listing of sales and distribution locations visit:
www.olympus.com

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# 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™


- 

134°C AUTOCLAVE 273°F

| 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 | |

# PROFESSIONAL ASPIRATORS - HIGH VACUUM


28280-1

CE 0434
EN ISO 10079-1
Class I
Type B


28244-6

**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 policarbonate 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 | | ASPEED 2 | |
|---|---|---|---|---|
| | 28244 | 28245/6* | 28280 | 28281 |
| Operating voltage: | 230 V-50 Hz | | | 230 V - 50/60 Hz |
| | | *110-60 Hz | other voltage on request | |
| Bottle capacity: | 1 l | 1 l | 1 l | 1 l |
| High vacuum: | low flow | low flow | low flow | high flow |
| Air flow: | 15 l/min | 22 l/min | 15 l/min | 22 l/min |
| Adjustable vacuum level: | 0÷ -0.85 bar (0÷ -85 kPa) | | | |
| Weight: | 3.5 kg | 4.5 kg | 2.5 kg | 3.2 kg |
| Case material: | metal | | plastic | |
| Noise level: | 55 dBA | 65 dBA | 55 dBA | 55 dBA |


28258 *Autoclavable Jar, h 19.2 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

28224

CE 0476

*Silicone tube 6x10 mm (see page 159)*

*Adaptor for catheter (code 28252)*

**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 | 28224Super 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 |

THE DISPLAY CHOICE
OF PROFESSIONALS™

# X-Series LED-backlit Display 15” | 17” | 19” | 22” | 24”


The X-Series durable displays are designed for reliable 24/7 operation in the demanding environments. With the selectable gamma curves and versatile connectivity, the enhanced X-Series provides an optimal visual experience with excellent colour, brightness, and contrast ratio. NeoV™ Optical Glass and metal casing shield it from scratches and other damages which make it ideal for public, retail, laboratory, and industrial applications.

X-22E / X-24E

X-15E / X-17E / X-19E

displays.agneovo.com

THE DISPLAY CHOICE
OF PROFESSIONALS™

Others

AG Neovo X-Series

## Enhanced Gamma Selection

Selectable gamma curves visually optimise different kinds of images. The AG Neovo specialised image settings enhance colour, brightness, sharpness and contrast ratio, allowing the X-Series to improve the light, shadows and colour balance of videos.

## Versatility, Productivity and Compatibility

Visualize critical data and engage with multiple video sources and PC applications with versatile connectivity options, including DisplayPort and HDMI, and PiP/PbP to increase productivity and efficiency. Selectable aspect ratio and zoom functions provide compatibility with different video sources.


## High Reliability

Designed for 24/7 operation, these durable metal-housed displays protected with NeoV™ Optical Glass take advantage of superior components to ensure a long product lifetime.

## Features

- LED-backlit technology with 1920 x 1080 / 1280 x 1024 / 1024 x 768 resolutions
- VA panel technology ensures accurate colours and offers high contrast ratios with wide viewing angles (15" only)
- Anti-Burn-in™ technology prevents image ghosting
- NeoV™ Optical Glass and metal housing for excellent cleanability and protection
- Crisp 20,000,000 dynamic contrast ratio
- PiP/PbP functions enable multi-source viewing simultaneously
- Image enhancer: Deinterlace / Noise Reduction
- Versatile connectivity: DisplayPort, HDMI, DVI, VGA
- Front-sided IP22 Compliant (IEC 60529 Standard) (17", 19", 22" and 24" only)
- EcoSmart Sensor automatically adjusts brightness level according to ambient lighting conditions
- Flicker-free display technology reduces eye discomfort
- Built-in speakers
- Selectable gamma curves optimise different kinds of images
- Lockable control keys to prevent tampering in public environments
- Designed and developed for continous 24/7 operation
- Premium-grade panel for high reliability and long product lifetime
- Available also in white

| Specifications | X-15E | X-17E | X-19E |
|---|---|---|---|
| **Panel** | | | |
| Panel Type | LED-Backlit TFT LCD (VA Technology) | LED-Backlit TFT LCD (TN Technology) | LED-Backlit TFT LCD (TN Technology) |
| Panel Size | 15.0" | 17.0" | 19.0" |
| Max. Resolution | XGA 1024 x 768 | SXGA 1280 x 1024 | SXGA 1280 x 1024 |
| Pixel Pitch | 0.297 mm | 0.264 mm | 0.294 mm |
| Brightness | 300 cd/m² | 250 cd/m² | 250 cd/m² |
| Contrast Ratio | 20,000,000:1 (DCR) | 20,000,000:1 (DCR) | 20,000,000:1 (DCR) |
| Viewing Angle (H/V) | 176°/176° | 170°/160° | 170°/160° |
| Display Colour | 16.2M | 16.7M | 16.7M |
| Response Time | 5 ms | 3 ms | 3 ms |
| **Frequency** | | | |
| Frequency (H) | 24 kHz-83 kHz | 24 kHz-83 kHz | 24 kHz-83 kHz |
| Frequency (V) | 50 Hz-75 Hz | 50 Hz-75 Hz | 50 Hz-75 Hz |
| **Signal Input** | | | |
| DisplayPort | x 1 | x 1 | x 1 |
| HDMI | 1.4 x 1 | 1.4 x 1 | 1.4 x 1 |
| DVI | 24-Pin DVI-D | 24-Pin DVI-D | 24-Pin DVI-D |
| VGA | 15-Pin D-Sub x 1 | 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) | Stereo Audio Jack (3.5 mm) |
| Internal Speakers | 2W x 2 | 2W x 2 | 2W x 2 |
| **Power** | | | |
| Power Supply | External | External | External |
| Power Requirements | DC 12V, 1.49A | DC 12V, 1.58A | DC 12V, 1.72A |
| On Mode | 12W (On) | 14W (On) | 15W (On) |
| Stand-by Mode | < 0.5W | < 0.5W | < 0.5W |
| Off Mode | < 0.5W | < 0.5W | < 0.5W |
| **Glass** | | | |
| Thickness | 3.0 mm (0.12") | 3.0 mm (0.12") | 3.0 mm (0.12") |
| Reflection Rate | < 1% | < 1% | < 1% |
| Transmission Rate | > 97% | > 97% | > 97% |
| Hardness | > 9H | > 9H | > 9H |
| **Operating Conditions** | | | |
| Temperature | 0°C-40°C (32°F-104°F) | 0°C-40°C (32°F-104°F) | 0°C-40°C (32°F-104°F) |
| Humidity | 10%-90% (non-condensing) | 10%-90% (non-condensing) | 10%-90% (non-condensing) |
| **Storage Conditions** | | | |
| Temperature | -20°C-60°C (-4°F-140°F) | -20°C-60°C (-4°F-140°F) | -20°C-60°C (-4°F-140°F) |
| Humidity | 5%-95% (non-condensing) | 5%-95% (non-condensing) | 5%-95% (non-condensing) |
| **Mounting** | | | |
| VESA FPMPMI | Yes (100 x 100 mm & 75 x 75 mm) | Yes (100 x 100 mm & 75 x 75 mm) | Yes (100 x 100 mm & 75 x 75 mm) |
| **Stand** | | | |
| Tilt | 0° to 20° | 0° to 22° | 0° to 22° |
| **Security** | | | |
| Kensington Security Slot | Yes | Yes | Yes |
| **Dimensions** | | | |
| Product with Base (W x H x D) | 380.0 x 359.0 x 155.0 mm (15.0" x 14.1" x 6.1") | 409.4 x 398.2 x 175.0 mm (16.1" x 15.7" x 6.9") | 445.4 x 420.2 x 175.0 mm (17.5" x 16.5" x 6.9") |
| Product w/o Base (W x H x D) | 380.0 x 315.0 x 53.5 mm (15.0" x 14.1" x 2.1") | 409.4 x 361.9 x 64.5 mm (16.1" x 15.7" x 2.5") | 445.4 x 383.9 x 64.5 mm (17.5" x 15.1" x 2.5") |
| Packaging (W x H x D) | 470.0 x 460.0 x 199.0 mm (18.5" x 18.1" x 7.8") | 506.0 x 506.0 x 225.0 mm (19.9" x 19.9" x 8.9") | 552.0 x 526.0 x 225.0 mm (21.7" x 20.7" x 8.9") |
| **Weight** | | | |
| Product w/o Base | 4.2 kg (9.3 lb) | 5.2 kg (11.5 lb) | 6.0 kg (13.2 lb) |
| Product with Base | 4.6 kg (10.1 lb) | 6.0 kg (13.2 lb) | 6.8 kg (15.0 lb) |
| Packaging | 5.8 kg (12.8 lb) | 7.5 kg (16.5 lb) | 8.5 kg (18.7 lb) |
| **Regulation Approval** | | | |
| Certifications & Compliance | CE, LVD, RoHS, WEEE, REACH, EAC | CE,LVD, RoHS, WEEE, REACH, EAC | LVD, CE, RoHS, WEEE, REACH, EAC, FCC |
| **Accessories** | | | |
| Supplied | Power Adaptor, Power Cord, VGA Cable, Audio Cable, Quick | Power Adaptor, Power Cord, VGA Cable, Audio Cable, Quick | Power Adaptor, Power Cord, VGA Cable, Audio Cable, Quick |
| **Optional Accessories** | | | |
| Ceiling Mount (Landscape only) | CMP-01+WMK-03 | 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 | WMA-01, WMK-01 |
| Desk Mount (Landscape only) | DMC-01, DMC-02D, DMS-01D, DMS-01Q, ES-02 | DMC-01, DMC-02D, DMS-01D, DMS-01Q, ES-02 | DMC-01, DMC-02D, DMS-01D, DMS-01Q, ES-02 |

THE DISPLAY CHOICE
OF PROFESSIONALS™

| Specifications | X-22E | X-24E |
|---|---|---|
| **Panel** | | |
| Panel Type | LED-Backlit TFT LCD (TN Technology) | LED-Backlit TFT LCD (TN Technology) |
| Panel Size | 21.5" | 23.5" |
| Max. Resolution | FHD 1920 x 1080 | FHD 1920 x 1080 |
| Pixel Pitch | 0.248 mm | 0.272 mm |
| Brightness | 250 cd/m² | 300 cd/m² |
| Contrast Ratio | 20,000,000:1 (DCR) | 20,000,000:1 (DCR) |
| Viewing Angle (H/V) | 170°/160° | 170°/160° |
| Display Colour | 16.7M | 16.7M |
| Response Time | 3 ms | 3 ms |
| **Frequency** | | |
| Frequency (H) | 24 kHz-83 kHz | 24 kHz-83 kHz |
| Frequency (V) | 50 Hz-75 Hz | 50 Hz-75 Hz |
| **Signal Input** | | |
| DisplayPort | x 1 | x 1 |
| HDMI | 1.4 x 1 | 1.4 x 1 |
| DVI | 24-Pin DVI-D | 24-Pin DVI-D |
| 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, 3.33A | DC 12V, 3.33A |
| On Mode | 20W (On) | 19W (On) |
| Stand-by Mode | < 0.5W | < 0.5W |
| Off Mode | < 0.5W | < 0.5W |
| **Glass** | | |
| Thickness | 3.0 mm (0.12") | 3.0 mm (0.12") |
| Reflection Rate | < 1% | < 1% |
| Transmission Rate | > 97% | > 97% |
| Hardness | > 9H | > 9H |
| **Operating Conditions** | | |
| Temperature | 0°C-40°C (32°F-104°F) | 0°C-40°C (32°F-104°F) |
| Humidity | 10%-90% (non-condensing) | 10%-90% (non-condensing) |
| **Storage Conditions** | | |
| Temperature | -20°C-60°C (-4°F-140°F) | -20°C-60°C (-4°F-140°F) |
| Humidity | 5%-95% (non-condensing) | 5%-95% (non-condensing) |
| **Mounting** | | |
| VESA FPMPMI | Yes (100 x 100 mm & 75 x 75 mm) | Yes (100 x 100 mm & 75 x 75 mm) |
| **Stand** | | |
| Tilt | 0° to 15° | 0° to 15° |
| **Security** | | |
| Kensington Security Slot | Yes | Yes |
| **Dimensions** | | |
| Product with Base (W x H x D) | 513.2 x 368.5 x 155.0 mm (20.2" x 14.5" x 6.1") | 562.4 x 396.8 x 155.0 mm (22.1" x 15.6" x 6.1") |
| Product w/o Base (W x H x D) | 513.2 x 324.3 x 56.2 mm (20.2" x 12.8" x 2.2") | 562.4 x 352.6 x 56.2 mm (22.1" x 13.9" x 2.2") |
| Packaging (W x H x D) | 614.0 x 477.0 x 204.0 mm (24.2" x 18.8" x 8.0") | 672.0 x 517.0 x 204.0 mm (26.5" x 20.4" x 8.0") |
| **Weight** | | |
| Product w/o Base | 6.1 kg (13.4 lb) | 7.2 kg (15.9 lb) |
| Product with Base | 6.7 kg (14.7 lb) | 7.8 kg (17.2 lb) |
| Packaging | 8.7 kg (19.1 lb) | 10.0 kg (22.0 lb) |
| **Regulation Approval** | | |
| Certifications & Compliance | CB, CE, RoHS, WEEE, REACH, EAC | CE, CB, RoHS, WEEE, REACH, EAC |
| **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 |
| **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, DMC-02D, DMS-01D, DMS-01Q, ES-02 |


P/C: X15E00/X17E00/X19E00/X22EB0/X24EA0 Version 4.0, 20200527

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# 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.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.

TÜVRheinland

Doc. 1/1, Rev.0

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

**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

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2017-10-12

M.Sc. M. Aihara

Traducere din limba engleza

TÜVRheinland®

# APROBARE

**Directiva CE 93/42/CEE Anexa II, excluzând Secţiunea 4**
**Sistem complet de asigurare a calităţii**
**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 şi dezvoltare, producţie de sisteme de endoscopie medicală, produse de diagnostic, operaţie şi tratament.
(a se vedea atasamentele pentru produse si locatii suplimentare incluse)
Înlocuieşte Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei II, excluzând secţiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa II, secţiunea 5 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate du Anexa II, secţiunea 4.

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data intrării în vigoare: 03-11-2017

Data. 12.10.2017

TÜVRheinland

Doc. 1/1 Rev. 0

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

Atasament la
Certificat
Nr. de inregistrare: 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
  - -Unităţi de detectare poziţie
  - -Unităţi de cauterizare electrotermică
  - -Sisteme endochirurgicale integrate
  - - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde şi traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme şi endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Organism notificat
Ştampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

Data: 12.10.2012

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ - FRANCEZĂ
AUT. NR. 22059
TEL.: 0745471452

# 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.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

TÜVRheinland

# CERTIFICAT CE
## Directiva CE 93/42/CEE Anexa V
## Asigurarea calităţii producţiei
## 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 împreuna cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape şi instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuieşte Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirarii: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerinţele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menţionat a stabilit şi aplică un sistem de asigurare a calităţii, care este supus unei supravegheri periodice, definită în Anexa V, secţiunea 4 a directivei menţionate anterior. Pentru comercializarea echipamentelor din clasa IIb şi clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate du Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Ştampilă:
TÜV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

TÜVRheinland®

# Certificate

**The Certification Body of**
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

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

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

**See attachments for scope**

Proof has been furnished that the requirements specified in

## EN ISO 13485:2016

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

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

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date 2018-10-30

M.Sc. M. Aihara

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

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

**Attachment to Certificate**
**Registration No.:** SX 60133824 0001
**Report No.:** 12018179 027

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

**Scope:**

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

**Certification Body**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

**Date:** 2018-10-30

M.Sc. M. Aihara

Traducere din limba engleză

# Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizaţia

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

a implementat şi aplică un sistem de management al calităţii pentru dispozitive medicale pentru urmatoarele domenii:

**A se vedea ataşamentul pentru domeniul de aplicabilitate**

S-a furnizat dovada faptului ca au fost indeplinte cerintele specificate in

## EN ISO 13485:2016

Sistemul de management al calităţii este supus unei supravegheri anuale.

ROMÂNIA
MINISTERUL JUSTIȚIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471452

Data intrării în vigoare: 04.11.2018
Nr. înregistrare certificat: SX 60133824 0001
A fost efectuat auditul, raport nr. 12018179 027
Acest certificat este valabil până la 26.07.2021

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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

Data, 30.10.2018

**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

TÜVRheinland®

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

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

Organizatie:

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Data, 30.10.2018

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

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL. 0745471452

# CERTIFICATO CE

Certificato n. 1951/MDD

## Dichiarazione di approvazione del sistema qualità

*(Sistema completo di garanzia qualità)*

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

**3A HEALTH CARE S.r.l.**

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

mantiene nello stabilimento di:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

**Apparecchi per aerosolterapia**

**Accessori per apparecchi per aerosolterapia**

**Aspiratori**

**Aspiratori per ambulanza**

Modd. come da documento "Elenco prodotti 3A HEALTH CARE S.r.l." Rev. 06 del 07/04/2020; valido solo se provvisto del timbro IMQ.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01; DM20-0048704-01; DM20-0051712-01.

**Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.**

| | |
|---|---|
| *Emesso il:* | 2017-11-18 |
| *Data aggiornamento:* | 2020-05-22 |
| *Sostituisce:* | 2020-02-25 |
| *Data scadenza:* | 2024-05-26 |

**IMQ**

# EC CERTIFICATE

Certificate No 1951/MDD

## Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

**3A HEALTH CARE S.r.l.**

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

manages in the factory of:

25017 LONATO DEL GARDA (BS) - VIA MARZIALE CERUTTI 90F/G (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

**Aerosoltherapy equipment**

**Accessories for aerosoltherapy equipment**

**Suction equipments**

**Suction equipments for ambulance**

Type ref. as to document "List of devices 3A HEALTH CARE S.r.l." Rev. 06 dated 2020/04/07; valid only if provided with IMQ stamp.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM17-0016835-01; DM18-0024812-01; DM18-0029038; DM18-0034026-01; DM19-0036397-01; DM19-0038533-01; DM20-0048704-01; DM20-0051712-01.

**This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.**

| | |
|---|---|
| *Date:* | 2017-11-18 |
| *Updated:* | 2020-05-22 |
| *Substitution Date:* | 2020-02-25 |
| *Expiry Date:* | 2024-05-26 |

DocuSign

**IMQ**

| | | | |
|---|---|---|---|
| 3A HEALTH CARE | **Elenco prodotti**<br>***List of devices***<br>**3A *HEALTH CARE S.r.l.*** | Date: **07/04/2020** | Rev. **06** |

## Apparecchi per aerosolterapia
## *Aerosoltherapy equipment*

| | |
|---|---|
| Modello<br>*Model* : | **HAPPYNEB II ; HAPPYNEB III ; AIRJOLIE 2 DELUXE ; HOSPYNEB professional ; COMP-A NEB ; ATOMIZER ; RESPIRO ; ISINEB ; NEBBY ; NEBBY PLUS ; SPEEDY ; PICONEB ;**<br>**FUN-NEB ; MIDINEB ; MIKRONEB ; MYNEB ; TURBONEB ;** |
| *Trade mark:* | 3A HEALTH CARE S.r.l. |

| | |
|---|---|
| Modello<br>*Model* : | **AEROSAN +** *Trade mark:* Messer Medical ;<br>**JC-117 ; JC-118 ; JC-118G ; JC-1301; JC-117P** *Trade mark:* Joycare;<br>**m213A** *Trade mark:* Medicura ;<br>**Salus 54901** *Trade mark:* Olimpic ;<br>**DOCTORNEB** *Trade mark:* Imetec ;<br>**AIROFAMILY MAX** *Trade mark:* Airssential Home ;<br>**Beper 40.110** *Trade mark:* Beper ;<br>**SANITY Inhalator PRO** *Trade mark:* Sanity ;<br>**TARTU' ; Arya ; Kosmo** *Trade mark:* Prontex ;<br>**LTK150 - NYXY ; LTK160 - NYXY FAMILY ; LTK170 - NYXY PRO ;**<br>**LT139- Hospyneb professional** *Trade mark:* Moretti ;<br>**Inhalator Amineb 2** *Trade mark:* PMT ;<br>**NIVEC III** *Trade mark:* MGE ;<br>**ECONEB** *Trade mark:* Trister ;<br>**Air 100** *Trade mark:* Colpharma ; |

2020-05-22

| | Elenco prodotti<br>*List of devices*<br>3A *HEALTH CARE S.r.l.* | Date: **07/04/2020** | Rev. **06** |
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## Accessori per apparecchi per Aerosolterapia
## *Accessories for aerosoltherapy equipment*

| | |
|---|---|
| Modello (codice)<br>*Model*<br>*(code):* | **Forcella nasale (NEB103); Tubo di collegamento (NEB104); Mascherina adulto (NEB105); Mascherina pediatrica (NEB106); Boccaglio (NEB202);**<br>**Ampolla FASTERJET (NEB101) ; Kit accessori FASTERJET (NEB100) ; Boccaglio con valvola (NEB102); Kit accessori FASTERJET (NEB120) ; Kit accessori FASTERJET (NEB130); Kit accessori FASTERJET (NEB140); Kit accessori FASTERJET per TURBONEB (NEB141) ; Kit accessori FASTERJET (NEB150); Kit accessori FASTERJET (NEB160); Ampolla NEBJET con connettore (NEB201); Kit accessori NEBJET (NEB200); Kit accessori NEBJET (NEB220) ; Kit accessori NEBJET (NEB230); Kit accessori NEBJET (NEB240); Kit accessori NEBJET (NEB250) ; Kit accessori NEBJET (NEB260); Ampolla TECHNOJET (NEB1000); Kit accessori TECHNOJET (NEB1002); Ampolla QUICKJET con connettore (NEB3001); Kit accessori QUICKJET (NEB3000); NASALJET (NEB5000); NASALJET basic ;** |
| *Trade mark:* | 3A HEALTH CARE S.r.l. |

| | |
|---|---|
| Modello (codice)<br>*Model*<br>*(code):* | **Kit accessori ADAPTAIR N300K2 (NEB1001); Kit accessori NEBJET (NEB270); Doccia micronizzata Corman N100D (NEB5001)**<br>*Trade mark:* Corman ;<br><br>**kit accessori NEBJET c/mascherina pediatrica (NEB214); kit accessori NEBJET c/mascherina adulto (NEB215); Ampolla NEBJET (NEB217);**<br>*Trade mark:* PMT ;<br><br>**NASALJET - LTK185 (NEB5009); Ampolla FASTERJET - LTR140 (NEB129); Ampolla NEBJET - LTR141 (NEB225)** *Trade mark:* Moretti ;<br><br>**Rapid Mask - kit completo per aerosolterapia (NEB248); Rapid Ampolla nebulizzatrice con raccordo e curva (NEB249); RHINO CARE** *Trade mark:* Prontex ;<br><br>**Kit accessori NEBJET (NEB226)** *Trade mark:* Messer Medical ;<br><br>**Kit ampolla NEBJET +nasale+boccaglio+filtri (NEB219); Kit accessori NEBJET+filtri (NEB241)**<br>*Trade mark:* Rosner ;<br><br>**SANITY Nosalek JET (NEB5007); Kit accessori Sanity Inhalator Pro (NEB1028); Ampolla Sanity Inhalator Pro (NEB1029)**<br>*Trade mark:* Sanity<br><br>**Ampolla NEBJET 5317 - BN3050 (NEB239); Raccordo snodabile 5317 - BN3070 (NEB242); Kit nasale/boccaglio 5317 - BN3040 (NEB243); Maschera adulto 5317-BN3030 (NEB244); Tubo aria 1 mt 5317-BN3020 (NEB245); Mascherina regol. GWM 5317-BN3010 (NEB246)**<br>*Trade mark:* Imetec ;<br><br>**Doccia nasale LAICA ANE052 (NEB5010)**<br>*Trade mark:* Laica ; |

2020-05-22

| | Elenco prodotti<br>*List of devices*<br>3A *HEALTH CARE S.r.l.* | Date: **07/04/2020** | Rev. **06** |
|---|---|---|---|

## Aspiratori
## *Suction Equipments*

| | |
|---|---|
| Modello<br>*Model* : | **ASPEED PROFESSIONAL - 1 POMPA; ASPEED PROFESSIONAL - 2 POMPE; ASPEED 3.0; ASPEED 2 - 1 POMPA; ASPEED 2 - 2 POMPE; MINIASPEED BATTERY PLUS; MINIASPEED BATTERY PRO; MINIASPEED BATTERY EVO; MAXIASPEED 6.2; MAXIASPEED 6.2P; MAXIASPEED 6.4; MAXIASPEED 6.4P; MAXIASPEED 9.2; MAXIASPEED 9.2P; MAXIASPEED 9.4; MAXIASPEED 9.4P** |
| *Trade mark:* | 3A HEALTH CARE S.r.l. |

| | |
|---|---|
| Modello<br>*Model* : | **SAM HOSPY 2 POMPE; SAM 420 LX** *Trade mark:* MGE ;<br>**Promedic SP-00 ; Promedic SP-01** *Trade mark:* Trimpeks;<br>**VORTECO AS-100 EMERGENCY** *Trade mark:* Alsa ;<br>**IREDEEM MINIASPEED BATTERY EVO** *Trade mark:* Iredeem ;<br>**ASPIMED 1.8 - LTA410; ASPIMED 1.8 - LTA415; ASPIMED 1.9 - LTA420; ASPIMED 4.1; ASPIMED 4.2** *Trade mark:* Moretti ; |

## Aspiratori per ambulanza
## *Suction equipments for ambulance*

| | |
|---|---|
| Modello<br>*Model* : | **MINIASPEED BATTERY EVO PLUS** *Trade mark:* 3A HEALTH CARE S.r.l.<br>**IREDEEM MINIASPEED BATTERY EVO PLUS** *Trade mark:* Iredeem ; |

2020-05-22

CERTIFICATE

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|---|---|---|---|
| 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**
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www.kiwa.it

**GIMA S.p.A.**
**Registered Headquarters**
- Via Grossi, 2 20121 Milano Italia

**Certified Sites**
- Via Marconi, 1 20060 Gessate ( MI ) Italia

SGQ N° 007A

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 22 |
| Primo rilascio / *First issue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2020-04-24 |



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 / *Oxigen 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 08-14/11/2019

Chief Operating Officer
*Giampiero Belcredi*
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Data:27/04/2020 08:18:48

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

## 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 e vasi di ricambio / Surgical aspirators and jars

**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

**Modello** / Model:

Kit pap test / Pap smear kit

**Modello** / Model:

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

**Modello** / Model:

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

**Modello** / Model:

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


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Chief Operating Officer
*Giampiero Belcredi*
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*Notified Body nr. 0476*

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|---|---|---|---|
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| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2020-04-24 |



## 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 tache - mix / Disposable sterile vaginal speculum tache - mix

**Modello** / Model:

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

**Modello** / Model:

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

**Modello** / Model:

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

**Modello** / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab

**Marca** / *Brandname:*
Gimabrush Ball / Gimabrush / Gima Collector

**Modello** / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

**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

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Chief Operating Officer
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## Allegato tecnico al Certificato/
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**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

**Marca** / *Brandname:*
EOLO / CORSIA

**Modello** / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

**Marca** / *Brandname:*
MISTRAL

**Modello** / Model:

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

**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 1302, MD 0104

**Marca** / *Brandname:*
BOSTON / BOSTON OLPRESS / BOSTON LOBIVON / BOSTON COMBISARTAN / BOSTON VALPRESSION / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TOKIO ZANTIPRESS / DAYTON

**Modello** / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

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## Allegato tecnico al Certificato/
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**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia** / *Medical Devices:*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*

**Marca** / *Brandname:*
SIRIO

**Modello** / Model:
Manometro Aneroide / Aneroid manometer

**Marca** / *Brandname:*
YTON

**Modello** / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302, MD 0104, MDS 7010

**Modello** / Model:
Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

**Modello** / Model:
Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

**Marca** / *Brandname:*
DA POLSO/WRIST - DA BRACCIO/ARM / 24 H ABPM

**Modello** / Model:
Sfigmomanometri Digitali Automatici / Digital Automatic Sphygmomanometers

**Marca** / *Brandname:*
YTON / DOMINO

**Modello** / Model:
Sfigmomanometri Digitali / Digital Sphygmomanometers

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Chief Operating Officer
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Data:27/04/2020 08:20:55

CERMET

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*Notified Body nr. 0476*

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## 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 saturazione di ossigeno / *Oxigen 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

**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

**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

**Marca** / *Brandname:*
FARMAMED / LINEA F / GIMA

**Modello** / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

**Marca** / *Brandname:*
PBpharma /GIMA

**Modello** / Model:

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


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Chief Operating Officer
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Data:27/04/2020 08:21:18

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| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 22 |
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CERTIFICATE

## Allegato tecnico al Certificato/
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**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

**Codice NANDO** / *NANDO codes:*
MD 1301, MD 0104, MDS 7010

**Modello** / Model:

Bilancia pesapersona / Scales - ASTRA - FAMILY - PEGASO

**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

**Modello** / Model:

Cannule di Guedel sterili / Sterile Guedel airways

**Modello** / Model:

Maschera per rianimazione CPR / CPR resuscitator mask

**Modello** / Model:

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

**Modello** / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

**Modello** / Model:

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

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**Chief Operating Officer**
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Data:27/04/2020 08:21:48

CERMET

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**Organismo Notificato n. 0476**
*Notified Body nr. 0476*

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|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 22 |
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| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2020-04-24 |



## 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:

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

**Modello** / Model:

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

**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

**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 Ethylene oxide gas sterilization (EOG)

**Modello** / Model:

Kit per sutura standard / Kit per rimozione sutura / kit procedurale sutura / kit standard per parto / Standard suture pack / Suture removal pack / Suture procedure pack / Standard delivery pack

Kiwa Cermet Italia S.p.A.
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di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
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E-mail: info@kiwacermet.it
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Chief Operating Officer
*Giampiero Belcredi*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:22:12

CERMET

CE
Organismo Notificato n. 0476
*Notified Body nr. 0476*

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 22 |
| Primo rilascio / *First issue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2020-04-24 |



CERTIFICATE

## 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*

**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:

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

**Modello** / Model:

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

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

**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

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*

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:22:36

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Organismo Notificato n. 0476
*Notified Body nr. 0476*

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036B | Revisione / *Revision* | 2 |
| Primo rilascio / *First issue date* | 2015-07-06 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2019-03-11 |



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 completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full 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 II escluso il pto 4, 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 II without point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Monitor e doppler fetali / *Monitor and Fetal Doppler*

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CERMET

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CERTIFICATE

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|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036B | Revisione / *Revision* | 2 |
| Primo rilascio / *First issue date* | 2015-07-06 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2019-03-11 |



## Allegato tecnico al Certificato/
*Technical sheet enclosed to the Certificate*

**Identificazione dei Dispositivi Medici/** *Identification of Medical Devices:*

**Tipologia** / *Medical Devices:*
Monitor e doppler fetali / *Monitor and Fetal Doppler*

**Classe di rischio** / *Risk class:*
II a

**Codice NANDO** / *NANDO codes:*
MD 1302

**Marca** / *Brandname:*
GIMA

**Modello** / Model:

Spot check PC-300 - Doppler fetale

**Classe di rischio** / *Risk class:*
II b

**Codice NANDO** / *NANDO codes:*
MD 1302

**Marca** / *Brandname:*
GIMA

**Modello** / Model:

VITAL multiparametrico - UP7000 - Multiparametrico PC 3000 - Fetale singolo - Fetale gemellare

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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CERMET

Chief Operating Officer
*Giampiero Belcredi*

CE

Organismo Notificato n. 0476
*Notified Body nr. 0476*

## 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 : | X-24E |
| 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 55032:2012+AC:2013
- EN 55024:2010
- EN 61000-3-2:2014, EN 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 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013

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: December 29, 2016
Date of Issue: January 29, 2017
Place of the signature: Taiwan

Tony Chu (Senior Manager)

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