OLYMPUS

EVIS EXERA III

TJF-Q190V Duodenoscope

Supporting Your Standard of Care

42106

TJF-Q190V

Main Features

Improved Cannulation Efficiency
Square image shape and 15° backward viewing allow for expanded field of view and better view direction, improving cannulation efficiency.

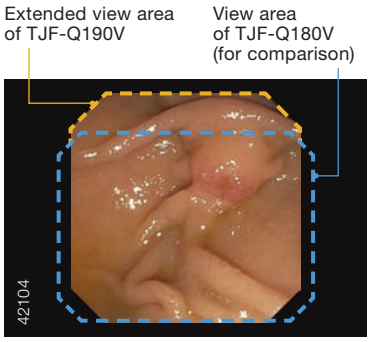


Image courtesy of Prof. Guido Costamagna

Reliable Guidewire Locking
Facilitates fast and secure short guidewire locking with dual system at the distal end.

High Force Transmission
Enables a 1:1 transfer of pushing and rotating forces to the distal end of the duodenoscope, improving ergonomics and scope responsiveness.

NBI (Narrow Band Imaging)
NBI with TJF-Q190V is significantly brighter and provides contrast, which may aid in the interpretation of mucosal and vascular patterns of the papilla.

Single-Use Distal Cover
The MAJ-2315 single-use distal cover allows better access for reprocessing accessories during manual cleaning. The cover is transparent and is destroyed during removal, preventing unintended reuse.

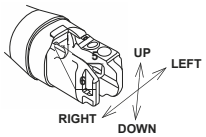
MAJ-2315 single-use distal cover for TJF-Q190V

Distal End Flushing Adapter
The new MAJ-2319 flushing adapter reduces the number of required flushing steps and ensures controlled distribution of detergent and disinfectant solution to the distal tip of the endoscope during manual reprocessing.

MAJ-2319 distal end flushing adapter for TJF-Q190V

Waterproof One-Touch Connector
A new connector design reduces the effort required for setup prior to and in between cases. In addition, it is fully submersible, eliminating the need for a water-resistant cap and the associated risk of expensive repairs due to accidental immersion.

Specifications

Optical System	Field of view	100°
	Direction of view	Backwards 15°
	Depth of field	5.0–60 mm
Insertion Section	Distal end outer diameter	13.5 mm
	Distal end enlarged	
	Insertion tube outer diameter	11.3 mm
	Working length	1,240 mm
Instrument Channel	Channel inner diameter	4.2 mm
	Minimum visible distance	10 mm from the distal end
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	

Bending Section	Angulation range	Up 120°
		Down 90°
		Right 110°
		Left 90°
Total Length	1,560 mm	
Compatible EVIS EXERA Systems	OLYMPUS CV-190 video system center	
	OLYMPUS CLV-190 xenon light source	

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OLYMPUS

Your Vision, Our Future

COMPACT TROLLEY

TC-C4

TC-C4 COMPACT TROLLEY

The TC-C4 Compact Trolley is designed as a compact trolley but which is large enough to be used in conjunction with EVIS Exera III imaging system.

Compact

The compact design means the TC-C4 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 due to its light weight and integrated handles at the front and rear of the top tray.

Monitor Support

The TC-C4 is offered with a choice of monitor arm or monitor mount allowing optimised procedure image viewing position.

Large Top Tray

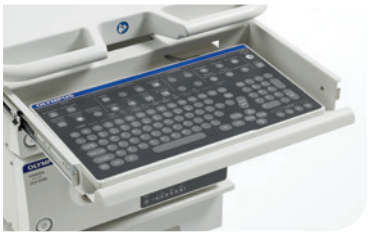
The top tray provides a large space for working or can be used to place equipment to increase storage capacity.

Cable management

Optimised cable management is achieved through channels in the columns and cable ties on rear of shelf.

Integrated Separation Transformer

Optional transformer placed under the base meaning increased shelf space for equipment loading.



Keyboard tray

A sliding keyboard tray is located under the top shelf.

ACCESSORIES

MAJ-2146
Sliding Keyboard Tray

MAJ-1684
Scope Pole Kit

MAJ-2148
Rear Panel

MAJ-1686
Drawer Unit

MAJ-2147
Compact LCD Monitor Arm

MAJ-1683
LCD Monitor Mount

MAJ-1656
Footswitch Holder

MAJ-1639
CO_2 Cylinder Holder (140 mm)

MAJ-1665
Camera Head Holder

MAJ-1663
EUS Arm Mount Kit

MAJ-1658
Universal Storage Container

MAJ-110
Jar Mounting Kit TC

TC-C4 STANDARD SETS

Standard Sets include:

TC-C4 Compact Trolley plus items marked (•)

Accessories available as an optional extra (o)

MAJ Description	Part Description	Part Number	Region	Set 1	Set 2	Set 3	Set 4
			EUROPE	K10029882	K10029887	K10029892	K10029897
			JAPAN	K10029885	K10029890	K10029895	K10029900
			UK	K10029881	K10029886	K10029891	K10029896
			US	K10029884	K10029889	K10029894	K10029899
			ROW	K10029883	K10029888	K10029893	K10029898
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-2147	Compact LCD Monitor Arm	K10026879	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	K10022056	o				
MAJ-1663	EUS Arm Mount Kit	K10021797	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

TC-C4

Dimensions	1110 mm (H) x 675 mm (D) x 534 mm (W)
	Height to top tray work surface - 1100 mm
	Height with 26" LCD monitor in highest position - 1945 mm
Weight	Maximum 87 kg (unladen) including fitted transformer

Voltage

The TC-C4 can be supplied with a separating transformer based on one of the following voltage options:

MAJ-1646	WM-T2 Transformer 100V
MAJ-1647	WM-T2 Transformer 110-120V
MAJ-1648	WM-T2 Transformer 220-240V

Construction

Trolley

Columns	Extruded profiled aluminium
Shelves	Mild steel
Top Tray	Injection moulded ABS

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www.olympus.com

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OLYMPUS

Your Vision, Our Future

EVIS EXERA III

CF-H185L/I

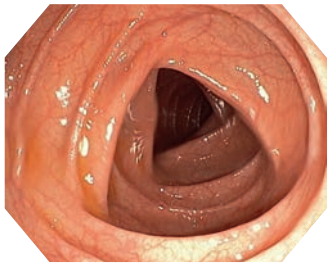
Routine colonoscopy at its best – featuring HDTV and variable stiffness.

CF-H185L/I

Main features

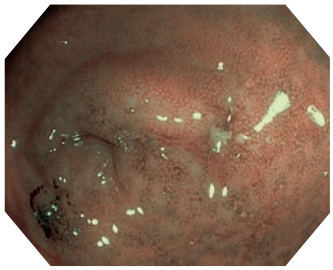
HDTV image quality

With the new EVIS EXERA III system, HDTV image quality enables observation of the mucosa and capillaries in much more detail.



NBI (Narrow Band Imaging)

NBI in EVIS EXERA III 185 series scopes provides twice the viewable distance of EVIS EXERA II 180 series scopes and offers much greater contrast between blood vessels and mucosa. The greatly improved performance of NBI opens up exciting new clinical applications and reinforces NBI's position as the standard of care for GI endoscopy.



Variable stiffness

Variable stiffness helps to prevent the endoscope from re-looping, for example at the sigmoid colon, and also allows the stiffness of the scope to be adjusted on a case-by-case basis in order to meet the unique anatomical needs of each patient or the handling preferences of the physician.

Close focus

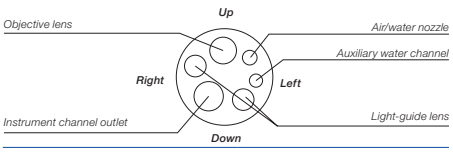
Close focus enables you to obtain an enlarged, close-up image simply by moving the scope tip as close as 2 mm from the mucosa.

Waterproof One-touch Connector

A new connector design minimises the effort required for set-up prior to and in between cases. In addition, it is fully submersible and eliminates the need for a water-resistant cap and the associated risk of an expensive repair 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	12.8 mm
	Distal end enlarged	
	Insertion tube outer diameter	12.8 mm
	Working length	L: 1680 mm I: 1330 mm
Instrument channel	Channel inner diameter	3.7 mm
	Minimum visible distance	3.0 mm from the distal end
	Direction from which endotherapy accessories enter and exit the endoscopic image	



Bending section	Angulation range	Up 180°
		Down 180°
		Right 160°
		Left 160°
Total length	L: 2005 mm I: 1655 mm	
Compatible EVIS EXERA system	Video system center OLYMPUS CV-190	
	Xenon light source OLYMPUS CLV-190	

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OLYMPUS

EVIS X1

Colonovideoscope

CF-EZ1500DL/I

Full Focus and High Magnification for Observational Excellence

CF-EZ1500DL/I

Full Focus and High Magnification for Observational Excellence

EDOF Technology

Our unique Extended Depth of Field (EDOF) technology combines images captured in near view with those taken in far view to generate an image with a wider depth of field that gives you greater clarity and richer detail throughout the image area, assuring superior observation with continuous wide focusing.

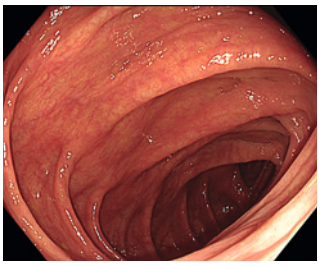
Full Focus

Thanks to EDOF technology, the CF-EZ1500DL/I can approach as close as 3 mm to the subject in normal focus mode, providing a clear, sharp view that may reduce the need to adjust the focus in routine use.

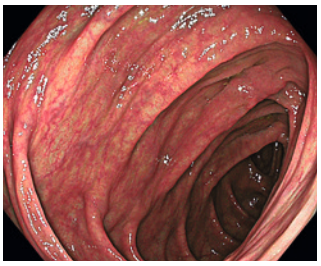
High Magnification with the Ease of Dual Focus

The CF-EZ1500DL/I offers high magnification* when the Near Focus mode is engaged via a simple scope switch, supporting better observation of details. The combination of high magnification and wide depth of field allows for clearer, more detailed imaging throughout the field of view, even from a tangential direction and regardless of whether the subject is moving or not. In combination with our proven NBI technology, the CF-EZ1500DL/I's advanced optics is designed to assist accurate, high-confidence optical diagnosis.

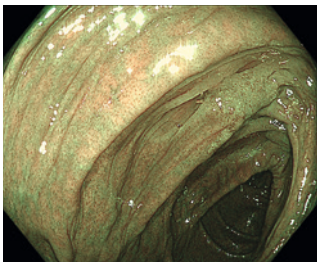
*Maximum magnification of 75x (with OEV262H) and 90x (with OEV321UH)



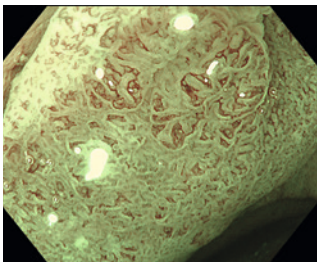
White Light Normal Focus



TXI



NBI Normal Focus

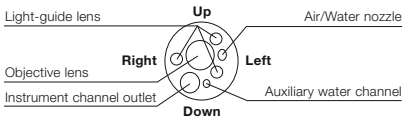


NBI Near Focus

Other Features

- Compatible with TXI, RDI and NBI when connected to CV-1500
- ErgoGrip
- RIT (Responsive Insertion Technology)
- ScopeGuide-ready
- 170° Wide viewing angle
- WaterJet
- Waterproof one-touch connector

Specifications

Optical System	Field of view	Normal focus mode: 170° Near focus mode: 160°
	Direction of view	Forward viewing
	Depth of field	Normal focus mode: 3 - 100 mm Near focus mode: 1.5 -5.5 mm
Insertion Section	Distal end outer diameter	ø 13.2 mm
	Distal end enlarged	
	Insertion tube outer diameter	ø 12.8 mm
	Working length	L: 1680 mm I: 1330 mm
Instrument Channel	Channel inner diameter	ø 3.7 mm
	Minimum visible distance*1	4 mm (Normal focus mode)
	Direction from which EndoTherapy accessories enter and exit the endoscopic image	
Auxiliary Water Channel	Direction from which water jet appears in the endoscopic image	

Bending Section	Angulation range	Up 180° / Down 180° / Right 160° / Left 160°
Total Length	L: 2005 mm I: 1655 mm	
Compatible System	Video system center OLYMPUS CV-1500	

*1 Distance from the distal end of the endoscope.
*2 Standard when CV-1500 (high air pressure) is used.

COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL/I

M00254EN · 03/20 · OEKG

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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

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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

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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 Requirements	DC 12V, 1.49A	DC 12V, 1.58A	DC 12V, 1.72A
On Mode	11W (On)	13W (On)	14W (On)
Standby Mode	< 0.5W	< 0.5W	< 0.5W
Off Mode	< 0.3W	< 0.3W	< 0.3W
Power Supply	External	External	External
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 Start Guide, Warranty Card	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	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

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Specifications	X-22E	X-24E
Panel		
Panel Type	LED-Backlit TFT LCD (TN Technology)	LED-Backlit TFT LCD (VA Technology)
Panel Size	21.5"	23.8"
Max. Resolution	FHD 1920 x 1080	FHD 1920 x 1080
Pixel Pitch	0.248 mm	0.274 mm
Brightness	250 cd/m²	250 cd/m²
Contrast Ratio	20,000,000:1 (DCR)	20,000,000:1 (DCR)
Viewing Angle (H/V)	170°/160°	178°/178°
Display Colour	16.7M	16.7M
Response Time	3 ms	5 ms
Surface Treatment	-	Seriesant1-Glare Treatment (Haze 40%), 3H Hard Coating
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 Requirements	DC 12V, 3.33A	DC 12V, 3.33A
On Mode	15W (On)	18W (On)
Standby Mode	< 0.5W	< 0.5W
Off Mode	< 0.3W	< 0.3W
Power Supply	External	External
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°	3° to 21°
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 392.8 x 196.0 mm (22.1" x 15.4" x 7.7")
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 249.0 mm (26.5" x 20.4" x 9.8")
Weight		
Product w/o Base	6.1 kg (13.4 lb)	7.0 kg (15.4 lb)
Product with Base	6.7 kg (14.7 lb)	7.8 kg (17.2 lb)
Packaging	8.7 kg (19.1 lb)	10.9 kg (24.0 lb)
Regulation Approval		
Certifications & Compliance	CB, CE, RoHS, WEEE, REACH, EAC	CE, LVD, WEEE, RoHS, 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, CD
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/X24EB0 Version 5.0, 20210531

REACH RoHS COMPLIANT WEEE

www.agneovo.com

Global Headquarters
Taipei, Taiwan

EMEA Regional Headquarters
Capelle a/d Ijssel, The Netherlands

North & South America Regional Headquarters
San Jose, CA, U.S.A.

Asia-Pacific Regional Headquarters
Taipei, Taiwan

Canada Sales Office
Vancouver, B.C., Canada

China Sales Office
Shanghai, China

Czech Republic Sales Office
Brno, Czech Republic

Denmark Sales Office
Støvring, Denmark

Germany Sales Office
Mechernich, Germany

Italy Sales Office
Livorno, Italy

Poland Sales Office
Warsaw, Poland

Spain Sales Office
Barcelona, Spain

Ukraine Sales Office
Lviv, Ukraine

www.agneovo.com

AG neovo

ENDO STRATUS™

Irrigation Pump and CO_2 Insufflator

Procedure

CANTEL

ADVANCED CO_2 INSUFFLATION

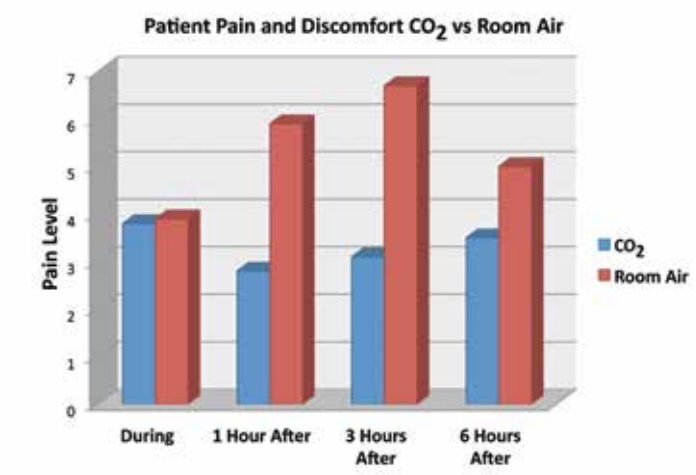
FOR FASTER PROCEDURES AND BETTER PATIENT OUTCOMES

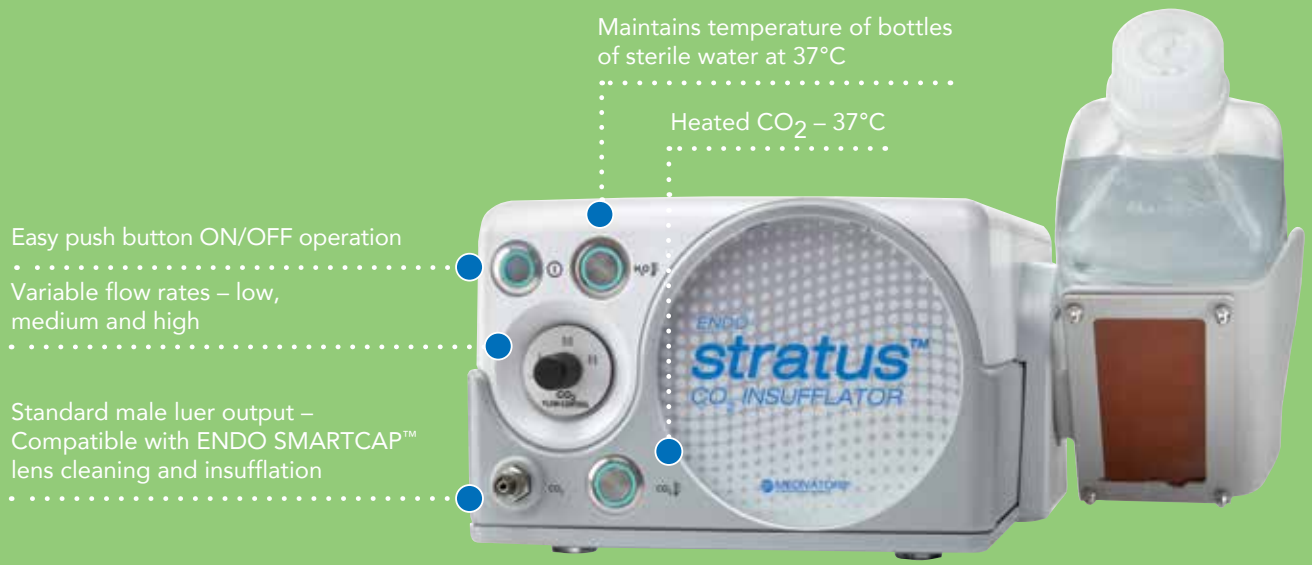
QUICKER PATIENT TURNAROUND*

- Improved cecal intubation rates[1]
- Greater small bowel intubation depths[2]
- 38% reduction in nursing attention[4]

HIGHER PATIENT SATISFACTION

- Less discomfort, pain and bloating[3,4,1]
- Warm water technology minimises chances of spastic colon
- Quicker recovery times[4]
- Decreased gas distension
- Absorbed 150 times faster than room air and is promptly eliminated via the lungs





THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, **only Cantel delivers the Complete Circle of Protection,** a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimise your success.

PROCEDURE Reducing the risk of patient cross contamination is at the forefront of infection prevention. Cantel innovates infection control products designed to improve patient outcomes, while increasing procedural efficiency.

ENDO STRATUS™ IRRIGATION PUMP AND CO_2 INSUFFLATOR

ENDO STRATUS™ CO_2 Insufflator

Compatible with

- ENDO SMARTCAP™ Irrigation tubing (works with wall source or tanks (C or E size)
- All major GI endoscopes

ENDO STRATUS™ Irrigation Pump

Compatible with

- ENDOGATOR™ tubing and connectors
- All major GI endoscopes

Pump includes comfortable, universal foot pedal

WARM WATER IRRIGATION IMPROVES YOUR VISIBILITY AND YOUR PATIENT'S COMFORT

Adjustable water bottle holder with integrated water heater

Easy and quick to adjust flow rate

Compatible with ENDOGATOR™ tubing and connectors

Automatic prime button provides instant irrigation upon foot pedal depression

ENDO STRATUS™ CO_2 Insufflator specification

MODEL	EGA-501E	
Dimensions	121 mm (H) x 197 mm (W) x 349 mm (D)	
Weight	4.8 kg	
Power	Max 82W 240V 50-60Hz	
CO_2	IN: max 1900psi, 1/4” OUT: nom 8psi (max 12psi) Luer, male	
Insufflation (CO_2)	3 fixed settings: 1.4 l/min.	
Features	Heater CO_2 37°C ±3 Heated water 37°C ±3 Overpressure: Max 12psi	Connects to high pressure CO_2 for bottle/tank Connects to low pressure CO_2 (wall outlet per EN15908, B11 CO_2)

ENDO STRATUS™ Irrigation Pump specification

MODEL	EGA-500E
Dimensions	121 mm (H) x 197 mm (W) x 349 mm (D)
Weight	4.8 kg
Power	Max 82W 240V 50-60Hz
Flow Rates	Aux Water Channel: 0-300 ml/min Biospy Channel: 0-650 ml/min
Features	Heated water 37°C ±3 20 second automatic ‘prime’

ENDO STRATUS™ Pumps ordering information

MODEL	DESCRIPTION	UNITS PER BOX
EGA-500E	ENDO STRATUS™ Irrigation Pump	1
EGA-501E	ENDO STRATUS™ Insufflator unit	1
EGA-7011	3 Foot tank hose (High pressure) unit	1
EGA-7024	9 Foot tank hose (High pressure)	1
EGA-2071	NIST Adapter	1
EGA-7026	DIN Bottle connector	1
EGA-7012	PIN Index Yoke Bottle connector	1

1. Singh, R., Neo, E., & Nordeen, N. (2012, July). Carbon dioxide insufflation during colonoscopy in deeply sedated patients. World Journal of Gastroenterology, 18(25), 3250-3253.
2. Bretthauer, MD, PhD, M. (2010). Turning science into clinical practice – the case of carbon dioxide insufflation. Endoscopy 2010, 42(), 1104-1105. doi:http://dx.doi.org/ 10.1055/s-0030-1255973
3. Bretthauer, MD, PhD, M. (2007, September). Carbon dioxide insufflation improves intubation depth in double−balloon enteroscopy: a randomized, controlled, double−blind trial. Endoscopy 2007, 39(), 1064-1067. doi:DOI 0.1055/s−2007−966990
4. Lynch, MBA, BSN, RN, Hayes BSN, RN, CGRN, Buffum DNSc, APRN, CS. (2012). Insufflation Using CO_2 vs Room Air During Colonoscopy: Comparison of Patient Comfort, Recovery Time, and Nursing Resources [PowerPoint slides]. Veterans Affairs Medical Center San Francisco.

www.cantelmedical.co.uk

TO PLACE AN ORDER

p: 01702 291878 | **e:** orders@cantelmedical.co.uk

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

TÜVRheinland®

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

DICHIARAZIONE DI CONFORMITA CE
EC DECLARATION OF CONFORMITY

Nome del Fabbricante Manufacturer's Name	**CANTEL MEDICAL (ITALY) S.R.L.**
Indirizzo del Fabbricante Manufacturer's address	Via Laurentina, 169 – 00071 Pomezia (Roma) - Italy
Nome del Dispositivo Medico Name of the Medical Device	**MEDIVATORS ISA**
Codice Identificativo Identification code	**ISA/CE/007**
Classe del prodotto Device Class	**IIb**
Destinazione d'uso Fields covered	Lava-Disinfettatrice chimica a freddo per endoscopi. Cold chemical Wash Disinfector for endoscopes
Sistema di Qualità Quality System	**UNI EN ISO 9001 – UNI EN ISO 13485**
Organismo Notificato Notified Body	IMQ S.P.A.– via Quintiliano,43 – 20138 Milano – Italy
Numero Certificato CE CE Certificate No.	1812/MDD

La sottoscritta CANTEL MEDICAL (ITALY) S.R.L. , dichiara che il dispositivo Medico **MEDIVATORS ISA** è conforme ai requisiti dell' Allegato II della Direttiva 93/42/CEE e s.m.i. e risponde ai requisiti essenziali della direttiva suddetta ad esso applicabili, in tutte le fasi dalla progettazione al controllo finale.
La CANTEL MEDICAL (ITALY) S.R.L. dichiara, inoltre, che il prodotto è conforme alle seguenti normative:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

The undersigned CANTEL MEDICAL (ITALY) S.R.L.. declares that the medical device **MEDIVATORS ISA** meets the requirements of Annex II of EEC Directive 93/42 and its revised version and meets the applicable provisions thereof with the relevant essential requirements of the aforementioned directive from design to final inspection and testing.
CANTEL MEDICAL (ITALY) S.R.L. also claims that the product meets the following standards:

UNI EN ISO 15883-1
UNI EN ISO 15883-4
UNI CEN ISO/TS 15883-5
IEC 61010-1
IEC 61010-2-040
EN 61326-1
CEI EN 62366

MANAGING DIRECTOR

Data/date 11/09/2017 V. M. SUPEKAR

GIORNO/DAY - MESE/MONTH - ANNO/YEAR

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.

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ *has issued an IQNet recognized certificate that the organization:*

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

UNI CEI EN ISO 13485:2016

Issued on: **2021 - 01 - 21**
Expires on: ***2024 - 07 - 05***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: IT - 126041

Alex Stoichitoiu
President of IQNET

Ing. Mario Romersi
President of CISQ

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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

www.imq.it

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www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N.
CERTIFICATE N. 1250.2019

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) SRL

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA LAURENTINA 169 - 00071 POMEZIA (RM)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, sviluppo, produzione di disinfettanti, sterilizzatrici e detergenti per dispositivi medici. Progettazione, sviluppo, produzione, commercializzazione e assistenza tecnica di dispositivi per il lavaggio, la disinfezione e la sterilizzazione di dispositivi medici. Progettazione, sviluppo, gestione della produzione di sistemi di conservazione e trasporto di endoscopi
Design, development, manufacturing of disinfectants, sterilizers and detergents for medical devices. Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices. Design, development, production management of conservation and transport systems for endoscopes

Ulteriori informazioni riguardanti l'applicabilità dei requisiti UNI CEI EN ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of UNI CEI EN ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1997-07-25	2021-01-21	2024-07-05

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

La data di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

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Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CERTIFICATO CE

Certificato n. 1812/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:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene nello stabilimento di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi

Sterilizzanti chimici a freddo per dispositivi medici

Disinfettanti per dispositivi medici

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici

Disinfettanti, decontaminanti e detergenti per dispositivi medici

Disinfettanti e detergenti per dispositivi medici

Disinfettanti e decontaminanti per dispositivi medici

Sistemi di conservazione e trasporto di endoscopi

Lava disinfettatrice per endoscopi

serie e modelli indicati in Allegato

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:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

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:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

Sterilizzanti chimici a freddo per dispositivi medici
Modd. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Marca CANTEL

Disinfettanti per dispositivi medici
Modd. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Marca CANTEL

Detergente plurienzimatico decontaminante disinfettante per dispositivi medici
Modd. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Marca CANTEL

Disinfettanti, decontaminanti e detergenti per dispositivi medici
Mod. ISACLEAN, PROTEODONT.
Marca CANTEL

Disinfettanti e detergenti per dispositivi medici
Modd. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Marca CANTEL

Disinfettanti e decontaminanti per dispositivi medici
Modd. PROTEAZONE; PROTEAZONE OD.
Marca CANTEL

Sistemi di conservazione e trasporto di endoscopi
Modd. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Marca CANTEL

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Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

DocuSign

IMQ

CERTIFICATO CE

Certificato n. 1812/MDD

Allegato

Lava disinfettatrice per endoscopi
Modd. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Marca CANTEL

Emesso il:	2015-07-20
Data aggiornamento:	2020-05-08
Sostituisce:	2020-04-07
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1812/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:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factory of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

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

Cold chemical washer disinfector and sterilizer for endoscopes

Cold chemical sterilant for medical devices

Disinfectants for medical devices

Multi-enzyme detergent, decontaminant disinfectant for medical devices

Disinfectants, decontaminants and detergents for medical devices

Disinfectants and detergents for medical devices

Decontaminants and disinfectants for medical devices

Storage and transport systems for endoscopes

Washer disinfector for endoscopes

series and type refs in the Annex

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:

DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589; DM16-0002190-01; DM19-0043082-01; DM19-0043104-01; DM20-0050214-01; DM20-0048482-01; DM20-0051086-01; DM20-0047938-01.

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:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

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EC CERTIFICATE

Certificate No 1812/MDD

Annex

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

Cold chemical sterilant for medical devices
Type ref. ADASPOR PRONTO; ADASPOR CONCENTRATO, ADASPOR M CONCENTRATO; ADASPOR MONODIE; ADASPOR PENTADIE; ADASPOR SINGLE SHOT; PROLYSTICA AUTO PAA; ISASPOR SINGLE SHOT; ADASPOR PLUS SINGLE SHOT, ADASPOR PLUS PRONTO (READY TO USE); ADASPOR PLUS CONCENTRATO; ADASPOR PLUS MONODIE; ADASPOR PLUS PENTADIE, ADASPOR PLUS M CONCENTRATO.
Trade mark CANTEL

Disinfectants for medical devices
Type ref. BLUESTERIL ALCOLICO; BLUESTERIL FERRI; BLUESTERIL SPRAY.
Trade mark CANTEL

Multi-enzyme detergent, decontaminant disinfectant for medical devices
Type ref. NEO PROTEOZIM PLUS 500; PROTEOZIM PLUS 400.
Trade mark CANTEL

Disinfectants, decontaminants and detergents for medical devices
Type ref. ISACLEAN, PROTEODONT.
Trade mark CANTEL

Disinfectants and detergents for medical devices
Type ref. BACTRYL SPRAY; BACTRYL WIPES; ISACLEAN SPRAY; SPOREXIN SPRAY; SPOREXIN WIPES; SPOREXIN VACUUM.
Trade mark CANTEL

Decontaminants and disinfectants for medical devices
Type ref. PROTEAZONE; PROTEAZONE OD.
Trade mark CANTEL

Storage and transport systems for endoscopes
Type ref. CLEANASCOPE; CLEANASCOPE ADVANTAGE.
Trade mark CANTEL

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Date: 2015-07-20
Updated: 2020-05-08
Substitution Date: 2020-04-07
Expiry Date: 2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts

EC CERTIFICATE

Certificate No 1812/MDD

Annex

Washer disinfector for endoscopes

Type ref. INNOVA E3s; INNOVA E3s CMS; INNOVA E4s CMS.
Trade mark CANTEL

Date:	2015-07-20
Updated:	2020-05-08
Substitution Date:	2020-04-07
Expiry Date:	2024-05-26

IMQ

This is a translation of the Italian text, which prevails in case of doubts