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.

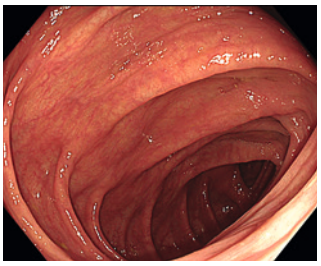
Full Focus

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.

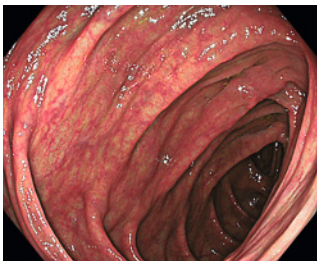
High Magnification with the Ease of Dual Focus

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.

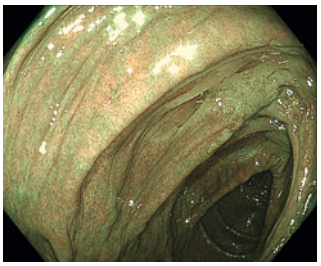
*Maximum magnification of 75x (with OEV262H) and 90x (with OEV321UH)



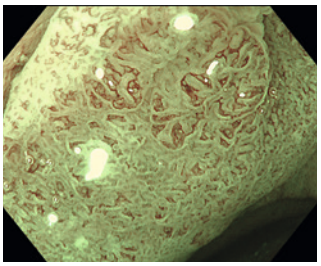
White Light Normal Focus



TXI



NBI Normal Focus

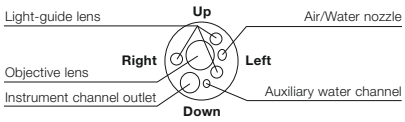


NBI Near Focus

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

OLYMPUS

OLYMPUS EUROPA SE & CO. KG
Postbox 10 49 08, 20034 Hamburg, Germany
Wendenstrasse 14–18, 20097 Hamburg, Germany
Phone: +49 40 23773-0, Fax: +49 40 233765
www.olympus-europa.com

OLYMPUS

EVIS X1

EVIS X1 Video System Center

CV-1500

A Unified Platform with 5 LED Spectrum Technology

CV-1500

A Unified Platform with 5 LED Spectrum Technology

By integrating the LED light source with the video processer, Olympus has developed a powerful system that is much more compact and lightweight than the predecessors*1.

Broad Compatibility

The CV-1500 can be connected to many different types of endoscopes, providing access to a wide variety of endoscopy-supporting functions.

Enhanced Observations

In addition to conventional white light and NBI (Narrow Band Imaging) and AFI (Auto Fluorescence Imaging) observation, the CV-1500 offers three other powerful enhanced observations to improve diagnostic and therapeutic capability:

· TXI (Texture & Color Enhancement Imaging) optimizes the structure, color tone and brightness of the mucosal surface.
· RDI (Red Dichromatic Imaging) improves visibility of deep blood vessels and bleeding points.
· BAI-MAC (Brightness Adjustment Imaging with MAintenance of Contrast) improves brightness in darker portions.

Intuitive, User-friendly Functions

With One-Touch Connector for quick, easy connection and no need for white balance adjustment*2, setup is simplified, with the aim of streamlining workflow and accelerating procedure time. Touch-sensitive panel facilitates intuitive operation, while convenient functions like Pre-freeze and MyCV mode ensure user-friendly working environment. Downtime is reduced thanks to the use of LED bulbs that last years without needing replacement.

⁎1 Combination of EVIS EXERA III/EVIS LUCERA ELITE series light source and processor ⁎2 Olympus 1100/1200/1500 series endoscopes only

Specifications

Power Supply	Rated voltage	100-240 V AC; Within ±10%
	Frequency	50/60 Hz; within ±3 Hz
	Rated input	600 VA
Size	Dimensions (W x H x D)	370 x 198 x 488 mm; 398 x 218 x 580 mm (maximum)
	Weight	19.4 kg
Classification (Medical Electrical Equipment)	Type of protection against electric shock	Class I
	Degree of protection against electric shock of applied part	Depend on applied part. (The degree of protection against electric shock of this product is BF type if the mounting part to be connected to this product is BF type. However CF type is not subject to combination in this product.)
	Degree or protection against explosion	The video system center should be kept away from flammable gases.
Observation	Analog signal output	VBS composite
	Digital signal output	12G-SDI (SMPTE ST 2082), 3G-SDI (SMPTE424M), HD-SDI (SMPTE292M), SD-SDI (SMPTE259M)
	User settings	The function settings for up to 20 users can be stored.
	Color tone adjustment	Adjust the color tone of each endoscopic image for White light observation mode, NBI observation mode, and RDI observation mode. · Red adjustment : ±8 steps · Blue adjustment : ±8 steps · Chroma adjustment : ±8 steps
	Automatic gain control (AGC)	The image can be electronically amplified when the light is inadequate due to the distal end of the endoscope being too far from the object.
	Contrast	· H (High) : Darkens the dark part and brightens the bright part. · L (Low) : Brightens the dark part and darkens the bright part.
	BAI-MAC	Brightness adjustment with maintenance of contrast
	Iris	The iris modes can be switched. · Auto : The brightness is adjusted based on the brightest part of the central part and the average brightness of the periphery part. · Peak : The brightness is adjusted based on the brightest part of the endoscopic image. · Average : The brightness is adjusted based on the average brightness of the endoscopic image.
	Image enhancement settings	Fine patterns or edges in the endoscopic images can be enhanced electrically to increase the image sharpness. · Enhancement type A : Emphasizes the pattern and contour of the endoscopic image. · Enhancement type B : Emphasizes the finer parts than structure emphasis type A.
	Switching the enhancement modes	The enhancement level can be selected from 3 levels (OFF, 1, 2, and 3)
	Image size selection	The size of the endoscopic image can be selected from 2 modes. (Except SDTV)
	Electric zoom	Switch between mode 1, mode 2, and mode 3.
	PIP/POP	Switch between PIP and POP.
	Aspect ratio	Switch between 16:9 and 4:3. (Except SDTV)
	Freeze	Freeze the endoscopic image.
	Pre-freeze	The image with the least blur is selected from the images captured in the set time period before freeze operation and displayed.
	Optical-digital observation	The optical-digital observation can be performed. The endoscope compatible with the optical-digital observation is required. · NBI observation : This observation mode uses the narrow band light. · RDI observation : This observation mode uses the red dichromatic lights. · AFI observation : This observation mode uses the blue light. · TXI observation : This observation mode enhances color, texture and brightness.
	Beginning and ending examination	Beginning and ending examination timing can be set interlock with the particular operation.
	Custom switch	Assign specific functions to the following buttons. · Remote switches (Up to 5) · Foot switches (Up to 2) · Keyboard custom key (Up to 4) · Touch panel custom button of basic functions screen (Up to 3) · Touch panel custom button of custom functions screen (Up to 10)
	MyCV mode	Switch setting values of multiple functions at once.
Documentation	Remote control	The following peripheral device can be controlled (specified models only). · Portable memory · Video recorder · Color video printer · Image filing system · Server
	Patient information	The following data can be displayed on the monitor. · Patient ID · Patient name · Gender · Age · Date of birth · Comment
	Displaying the record state	The recording state of the following peripheral device can be displayed on the monitor. · Portable memory : Remaining capacity · Video recorder : Number of shots / Recording status · Color video printer : Number of shots · Image filing system : Number of shots
	Displaying the image information	The following data can be displayed on the monitor. · Image enhancement · Electric zoom ratio · Color mode · Focus · Observation mode
	Advanced registration of patient information	Up to 50 patient information can be registered. · Patient ID · Patient name · Gender · Age · Date of birth
	Recording format	Standard image quality: TIFF; Low image quality: JPEG
Memory Backup	Memorization of user settings	The settings are held in memory even after the video system center is turned OFF.
	White balance	The white balance that is once set is held in memory (only when using the compatible endoscope).

EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500

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

OLYMPUS

OLYMPUS EUROPA SE & CO. KG
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Phone: +49 40 23773-0, Fax: +49 40 233765
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OLYMPUS

EVIS X1

Gastrointestinal Videoscope

GIF-EZ1500

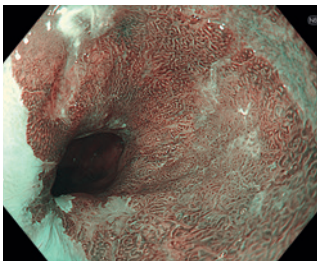
Full Focus and High Magnification for Observational Excellence

GIF-EZ1500

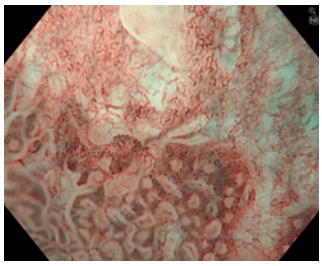
Full Focus and High Magnification for Observational Excellence

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.



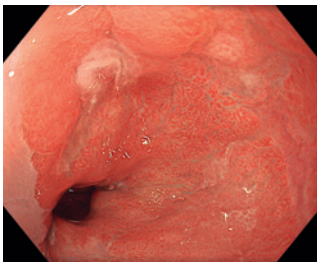
NBI Normal Focus



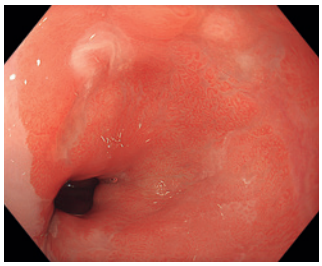
NBI Near Focus

Full Focus

Thanks to EDOF technology, the GIF-EZ1500 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.



TXI



White Light

High Magnification with the Ease of Dual Focus

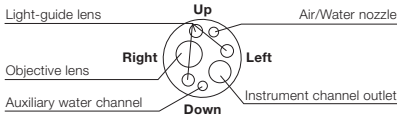
The GIF-EZ1500 offers high magnification* when the Near Focus mode is engaged via a simple scope switch, supporting better observation of details. The combination of high magnification and wide depth of field allows for clearer, more detailed imaging throughout the field of view, even from a tangential direction and regardless of whether the subject is moving or not. In combination with proven NBI technology, the GIF-EZ1500's advanced optics is designed to assist accurate, high-confidence optical diagnosis.

* Maximum magnification of 85x (with OEV262H) and 100x (with OEV321UH).

Other Features

- Compatible with TXI, RDI and NBI when connected to CV-1500
- ErgoGrip
- WaterJet
- Waterproof one-touch connector

Specifications

Optical System	Field of view	Normal focus mode: 140° Near focus mode: 140°
	Direction of view	Forward viewing
	Depth of field	Normal focus mode: 3-100mm Near focus mode: 1.5-5.5mm
Insertion Section	Distal end outer diameter	ø 9.9 mm
	Distal end enlarged	
	Insertion tube outer diameter	ø 9.6 mm
	Working length	1030 mm
Instrument Channel	Channel inner diameter	ø 2.8 mm
	Minimum visible distance*1	3 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 210° / Down 90° / Right 100° / Left 100°
Total Length	1350 mm	
Compatible System	Video system center OLYMPUS CV-1500	

*1 Distance from the distal end of the endoscope.

GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500

M00252EN · 03/20 · OEKG

OLYMPUS

OLYMPUS EUROPA SE & CO. KG
Postbox 10 49 08, 20034 Hamburg, Germany
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Phone: +49 40 23773-0, Fax: +49 40 233765
www.olympus-europa.com

OLYMPUS

4K UHD LCD Monitor

OEV321UH

32-Inch LCD Monitor Optimized for Olympus Endoscopy Systems

86260

OEV321UH

High-Performance Display

This 32-inch LCD monitor with Ultra High Definition picture quality brings out the full potential of Olympus endoscopy systems. The 4K upscaling function accommodates existing HD imaging systems.

Multiple Display Modes

Picture-in-Picture (PIP) and Picture-out-Picture (POP) display modes offer optimal support during procedures.

A.I.M.E.™ Technology

The Advanced Image Multiple Enhancer (A.I.M.E.™) produces sharp, vivid images by enhancing both structure and color to support a more detailed observation.

Convenient CLONE OUT Functionality

Users are able to duplicate the 4K/HD video signals as displayed on the screen, including PIP/POP to a second monitor or recording device.

Versatile Signal Routing

The OEV321UH allows 4K/HD video signals to be routed via a single 12G-SDI output. Various input and output terminals offer impressive connectivity suited to user requirements.

User-Friendly Design

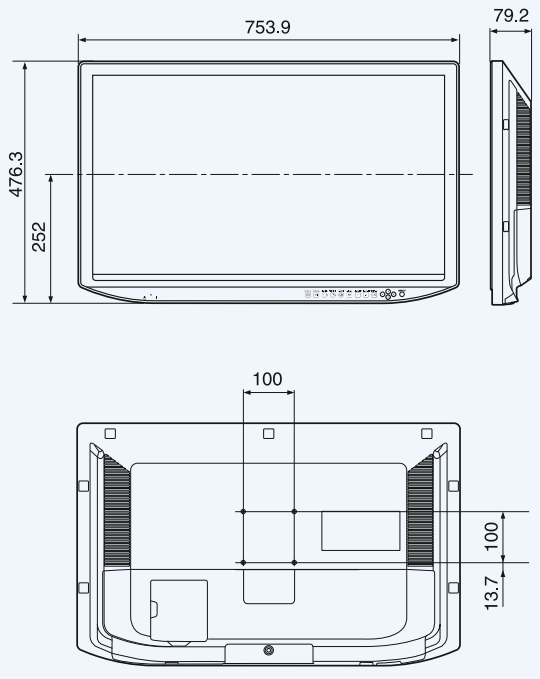
The front panel is easy to clean thanks to its flat surface including the control buttons. Due to downward-facing connectors, a detachable cable cover and a quick access window, cabling of this monitor is simplified.

Input/Output Port

OEV321UH Specifications			
Display	Display Size		31.5 in (800.8 mm)
	Panel Technology		TFT Active Matrix LCD
	Resolution / Aspect Ratio		3840 × 2160 / 16:9
	Luminance		450 cd/m²
	Contrast		1000:1
	Color Space		BT.2020 / BT.709
	Viewing Angle		178°/178°
	Colors		1.07 billion
	Backlight		LED
Functions	Image Enhancement		A.I.M.E.™
	Multiple Image Display		PIP/POP
	Flip Pattern		Rotation
Input Output	4K	in	12G-SDI ×2*, Display Port ×1, HDMI ×1
		out	12G-SDI ×2*
	2K	in	3G-SDI ×1, DVI-D x 1
		out	3G-SDI ×1
	CLONE OUT / AUX IN		12G-SDI ×1* / Any port
General	Power Supply		AC 100V-240V, 50/60Hz, 1.7A-0.8A DC supplied by the optional AC adaptor AC-300MD
	Size		753.9 × 476.3 × 79.2 mm
	Weight		11.8 kg
	Remote		RS-232C connector D-sub 9 pin

* When a 12G-SDI cable longer than MAJ-2429 (8.5 m) is used, please contact Olympus.

Size [mm]



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OLYMPUS EUROPA SE & CO. KG
Postbox 10 49 08, 20034 Hamburg, Germany
Wendenstrasse 14-18, 20097 Hamburg, Germany
Phone: +49 40 23773-0, Fax: +49 40 233765
www.olympus-europa.com

OLYMPUS

WM-NP3

Mobile Workstation

86370

WM-NP3 Workstation

Features

The WM-NP3 has been designed and manufactured to enhance the user experience and add value to the Olympus Imaging Platform systems. Using a slim line profile and offering increased loading capacity while taking up less floor space and lowering running costs, the WM-NP3 will support Olympus systems without dominating the clinical environment, making it a valuable successor to WM-NP2.

Customization

Dedicated accessories are available to optimize system and procedural efficiency.

Electrical Safety

The WM-NP3 is supplied with a separation transformer as standard. Output from the transformer is controlled using the central on/off switch, which allows all equipment to be powered up simultaneously.

Inrush Current Control and Low-Power Standby

The WM-NP3 uses a level detector to detect mains distortion and protect the transformer from inrush current. The inrush current protection system is powered from a medically approved AC-DC power supply. To reduce the environmental impact of the WM-NP3, the low-power standby mode reduces standby power consumption giving greater efficiency and energy savings.

Easy to Move

Ergonomically designed handles and twin-wheeled castors allow the workstation to be moved into the ideal position in the clinical environment.

Cable Management

Optimized cable management has been achieved by locating the cable management modules within the workstation hoop, increasing the cable capacity and providing access to route and remove cables easily.

Imaging

The WM-NP3 workstation is offered with a choice of monitor arms that optimize the range of compatible monitors and enhance the procedural view with both swivel and tilt functionality. The MAJ-2216 has a weight range between 6.5 and 12 kg, and the MAJ-2217 has a weight range between 12 and 14 kg. Using a VESA fitting, both arms will accommodate a monitor up to 32”.

WM-NP3 Workstation

Accessories

MAJ-2154
Consumable Storage Holder

Article number – K10030423

MAJ-2158
Suction Jar Holder

Article number – K10028139

MAJ-2159
Scope Pole Kit

Article number – K10028140

MAJ-2160
Irrigation Tube Holder

Article number – K10028141

MAJ-2165
Drawer Unit

Article number – K10030178

MAJ-2166
Sterile Water Holder

Article number – K10030036

MAJ-2167
Nurses Control Arm

Article number – K10030210

MAJ-2173
Side Shelf

Article number – K10030389

MAJ-2211
Side Handles

Article number – K10035108

MAJ-2216
LCD Monitor Arm 6.5 kg - 12 kg

Article number – K10035789

MAJ-2217
LCD Monitor Arm 12 kg - 14 kg

Article number – K10035790

WM-NP3

Standard Sets include:

WM-NP3 Workstation plus items marked (•)		Region	Basic Set	GI Standard	URO Set
		EUROPE	K10035360	K10035365	K10035370
Article Number	**Part Description**	ROW	K10035363	K10035368	K10035373
	Workstation Fitting Kit		•	•	•
	Transformer (market-specific)		•	•	•
K10028141	MAJ-2160 Irrigation Tube Holder		•	•	•
K10027573	MAJ-2146 Sliding Keyboard Tray			•	•
K10028140	MAJ-2159 Scope Pole Kit			•	
K10035789	MAJ-2216 LCD Monitor Arm 6.5 - 12 kg			•	
K10035108	MAJ-2211 Side Handles			•	•
K10009210	IEC Lead Set		•	•	•

Optional Compatible Accessories

Article Number	Part Description
K10021041	MAJ-1639 CO_2 Cylinder Holder - 140
K10016952	MAJ-1642 IV Pole
K10021042	MAJ-1650 CO_2 Cylinder Holder - 205
K10021043	MAJ-1653 CO_2 Cylinder Holder - Double
K10021352	MAJ-1654 Equipotential Terminal Strip
K10021791	MAJ-1657 Keyboard Arm Side-Mounted
K10021795	MAJ-1661 Side-Mounted LCD Monitor Arm
K10021797	MAJ-1663 EUS Arm-Mount Kit
K10022056	MAJ-1665 Camera Head Holder
K10027573	MAJ-2146 Sliding Keyboard Tray
K10027575	MAJ-2149 Dual Monitor Arm
K10035790	MAJ-2217 LCD Monitor Arm 12 kg - 14 kg

Specifications

WM-NP3

Dimensions	1400 mm (H) x 675 mm (D) x 665 mm (W)
Weight	84 kg (unladen) including fitted transformer
Maximum Load Capacity	Maximum 20 kg on top tray
	Maximum 31 kg per shelf
	Maximum 35 kg on base panel
Castors	125 mm diameter
	2x braked conductive twin-wheeled castors
	2x braked twin-wheeled castors

Voltage

The WM-NP3 is supplied with a separation transformer based on one of the following voltage options:

MAJ-2155	WM-T3 Transformer 100 V
MAJ-2156	WM-T3 Transformer 110-120 V
MAJ-2157	WM-T3 Transformer 220-240 V

Construction

Workstation

Hoop	Extruded profiled aluminum
Shelves	Mild steel
Top Tray	Injection-molded ABS

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OLYMPUS®
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Postbox 10 49 08, 20034 Hamburg, Germany
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Phone: +49 40 23773-0, Fax: +49 40 233765
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ENDO STRATUS™

Irrigation Pump and CO_2 Insufflator

Procedure

CANTEL

ADVANCED CO_2 INSUFFLATION

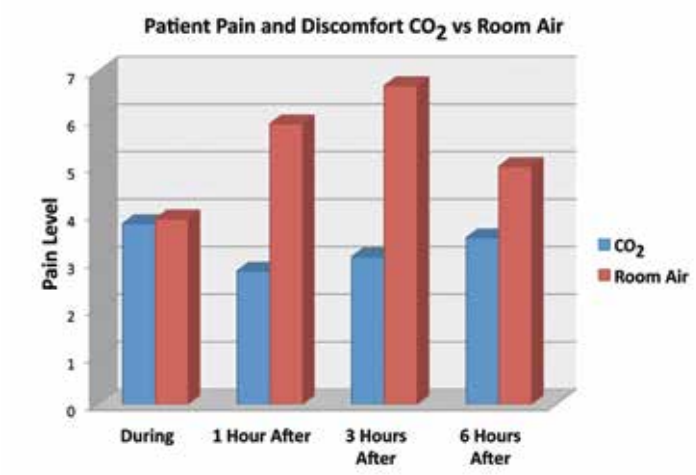
FOR FASTER PROCEDURES AND BETTER PATIENT OUTCOMES

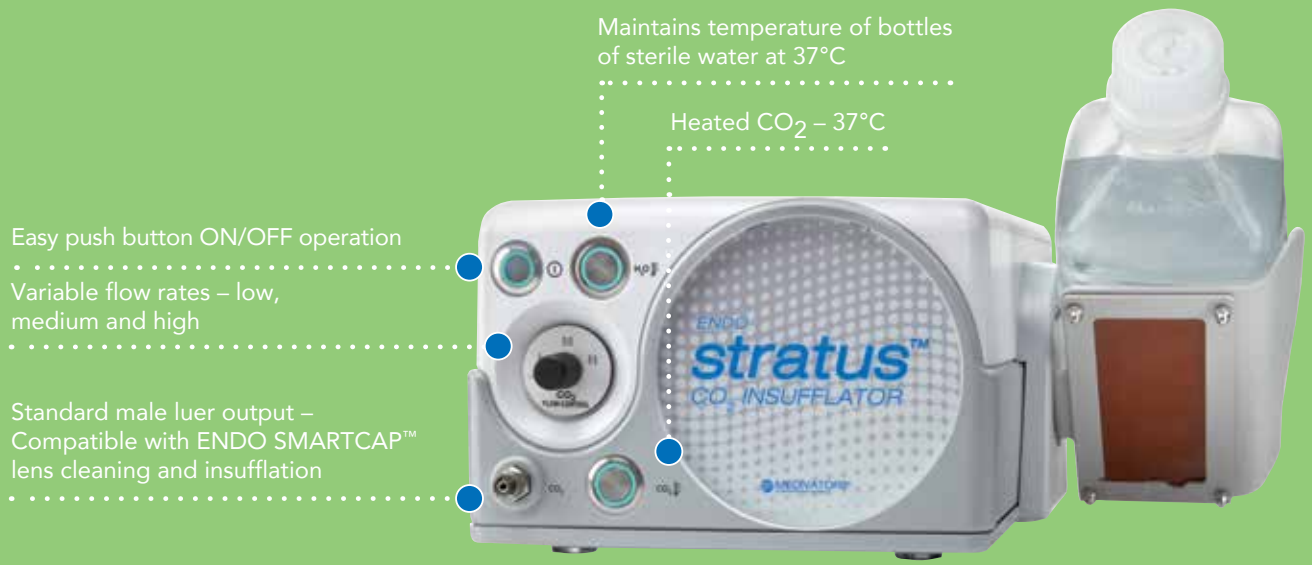
QUICKER PATIENT TURNAROUND*

- 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

"ASPEED 2" SUCTION ASPIRATOR - 230V single pump

Code:	**28280**
Category:	**Surgical aspirators and breast pump**
Unit of sale:	**1 pc.**
Minimum order:	**1**
Type:	**Medical device**
Class:	**II A**
NSIS:	**1758504**
CND:	**Z120105**
EAN13:	**8033717011382**

Description:

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.

- **Aspeed 2 15 l**
- **Power: 230 V**
- **Pump: single**
- **Case: plastic**

Technical Specifications:

Operating voltage: 230 V-50 Hz
Bottle capacity: 1 l
High vacuum: low flow
Air flow: 15 l/min
Adjustable vacuum level: 0÷ -0.85 bar (0÷ -85 kPa)
Weight: 2,7 kg
Case material: plastic
Noise level: 63 dBA

Standard accessories:

Autoclavable polycarbonate jar 1,000 cc with safety valve (overflow protection)
Disposable suction liner 1 l
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

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

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

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 No* **995**

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

CANTEL MEDICAL (ITALY) S.R.L.

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

NELLE SEGUENTI UNITA' OPERATIVE / *IN THE FOLLOWING OPERATIVE UNITS*

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169
IT - 47122 FORLI' (FC) - VIA CERVESE, 162/L

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI CEI EN ISO 13485:2016

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

Progettazione, sviluppo, produzione e vendita di disinfettanti, sterilizzanti chimici 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.

Design, development, manufacturing and sales of disinfectants, chemical sterilizing and detergents for medical devices.
Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices.

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 THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE / *FIRST ISSUE*	*25/07/1997*
DATA DELIBERA / *DECISION DATE*	*05/07/2018*
DATA SCADENZA / *EXPIRY DATE*	*05/07/2021*
EMISSIONE CORRENTE / ISSUE DATE	*05/07/2018*

CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ	n. 008	A	SSI	N. 007	G
SGA	n. 001	D	SGE	N. 001	M
SCR	n. 002	F	ISP	N. 006	O
FSM	n. 006	I	EMAS	N. 008	P
PRD	n. 008	B	ITX	N. 004	L
DAP	n. 003	H			
PRS	n. 100	C			

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

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.

C01 ED 03 010616

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/CERTIQUALITY S.r.l.
has issued an IQNet recognised certificate that the organization:

CANTEL MEDICAL (ITALY) S.R.L.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169
for the following scope

Design, development, manufacturing and sales of disinfectants, chemical sterilizing and detergents for medical devices.
Design, development, production, sales and technical service of device for washing, disinfection and sterilization of medical devices.

has implemented and maintains a
Quality Management System
which fulfills the requirements of the following standard
ISO 13485:2016

Issued on: **2018-07-05**
First issued on: **1997-07-25**
Expires on: **2021-07-05**

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-1681**

Alex Stoichitoiu
President of IQNET

Ing. Claudio Provetti
President of CISQ

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil*
FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE Turkey YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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

CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) S.R.L.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

SITI / SITES

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Disinfettanti per dispositivi medici

Disinfectants for medical devices

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato II ad esclusione del punto 4
is in compliance with the requirements of Directive 93/42/EEC, Annex *excluding section 4*

RAPPORTO DI AUDIT N° / *AUDIT REPORT NO.* **24884**

CERTIFICATO N. / *CERTIFICATE N.* **24884**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA

THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE

THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO

THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE / *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE / *CURRENT ISSUE* 12/07/2017

DATA DI SCADENZA / *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

Mod. 5.20 ED 06 260517

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **24884**

ANNEX TO CERTIFICATE N.

CANTEL MEDICAL (ITALY) S.R.L.

SITI / *SITES*

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

ELENCO PRODOTTI / *PRODUCT LIST*

ADASPOR, ADASPOR ERS, ADASPOR M, ADASPOR MONODIE, ADASPOR PENTADIE, ADASPOR SINGLE SHOT, PROLYSTICA AUTO PAA, BLUESTERIL ALCOLICO, BLUSTERIL FERRI CE, CLOREXAN FERRI, NEO PROTEOZIM PLUS 500, PROTEOZIM PLUS 400, PROTEOZIM PLUS 1000, PROTEAZONE,PROTEAZONE ERS, PROTEAZONE OD, SPOREX, SPOREX OPA, SPOREXIN PLUS DS, SPOREXIN PLUS OD, SPOREXIN PLUS SALVIETTE, SPOREXIN PLUS VACUUM, SPORIDOX, SPORIDOX PLUS, ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISACLEAN, BACTRYL SPRAY, BACTRYL WIPES, ADASPOR PLUS PRONTO, ADASPOR PLUS CONCENTRATO, ADASPOR PLUS MONODIE, ADASPOR PLUS SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE, ISASPOR ERS, ADASPOR PLUS M, ADASPOR PLUS PENTADIE, ADASPOR PLUS ERS, ISACLEAN SPRAY, SPOREXIN SPRAY, SPOREXIN VACUUM, SPOREXIN WIPES

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE *CURRENT ISSUE* 12/07/2017

DATA DI SCADENZA *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
Via G. Giardino, 4 - 20123 Milano - Tel. 02/8069171 Fax. 02/86465295 certiquality@certiquality.it - www.certiquality.it

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 negli stabilimenti 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
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

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.

Riferimento pratiche IMQ:
DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589.

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 di Aggiornamento:	2016-05-26
Sostituisce:	2015-12-17
Data Scadenza:	2021-05-25

cosign

IMQ

ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

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 factories 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
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

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.

Reference to IMQ files Nos:
DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589.

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:	2016-05-26
Substitution Date:	2015-12-17
Expirying Date:	2021-05-25

IMQ

IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

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

CERTIFICATE

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

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

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

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

Chief Operating Officer
Giampiero Belcredi

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

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

This certificate is composed of 1 page.

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

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*

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

Rif. rapporto di audit/ *Ref. audit report:* del/dated 08-14/11/2019

Chief Operating Officer
Giampiero Belcredi
Firmato digitalmente da:BELCREDI GIAMPIERO
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

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

Chief Operating Officer
Giampiero Belcredi
Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:19:37

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

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

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

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

Chief Operating Officer
Giampiero Belcredi
Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:19:59

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

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

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Dispositivi per aerosolterapia / *Aerosol therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

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

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

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

Chief Operating Officer
Giampiero Belcredi
Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:20:27

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

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

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

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

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

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:20:55

CERMET

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 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

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

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:21:18

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:*
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

Kiwa Cermet Italia S.p.A.
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Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:27/04/2020 08:21:48

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

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

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.
Società con socio unico, soggetta
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di Kiwa Italia Holding S.r.l.
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Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data: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.*

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

Chief Operating Officer
Giampiero Belcredi

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

CE
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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40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

CERMET

Chief Operating Officer
Giampiero Belcredi

CE
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

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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