OLYMPUS

Your Vision, Our Future

EVIS EXERA III

CF-H185L/I

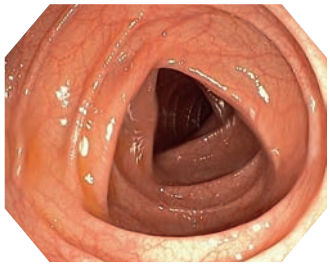
Routine colonoscopy at its best – featuring HDTV and variable stiffness.

CF-H185L/I

Main features

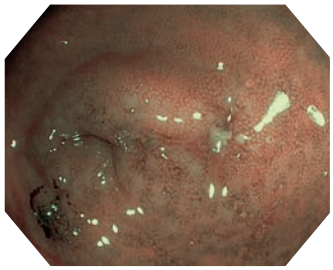
HDTV image quality

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.

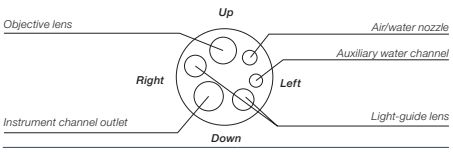
Close focus

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	

E0429292 · 5.000 · 01/13 · PR

OLYMPUS

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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.

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M00250EN · 03/20 · OEKG

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

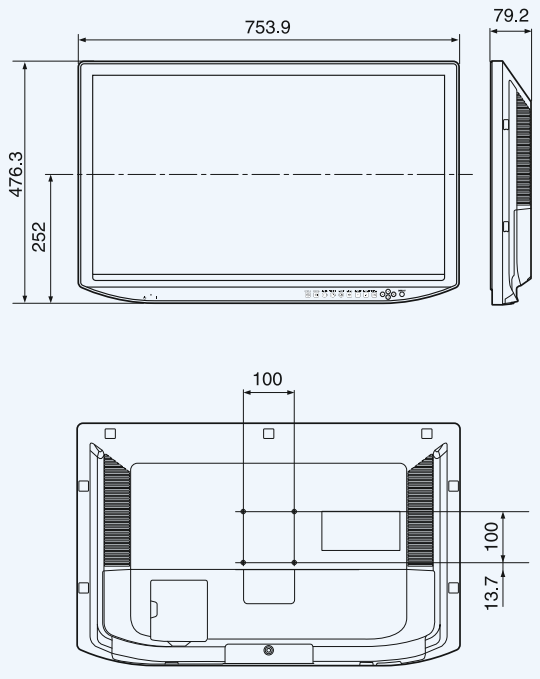
The front panel is easy to clean thanks to its flat surface including the control buttons. Due to downward-facing connectors, a detachable cable cover and a quick access window, cabling of this monitor is simplified.

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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www.olympus-europa.com

M00282EN · 04/20 · OEKG

ENDO STRATUS™

Irrigation Pump and CO_2 Insufflator

Procedure

CANTEL

ADVANCED CO_2 INSUFFLATION

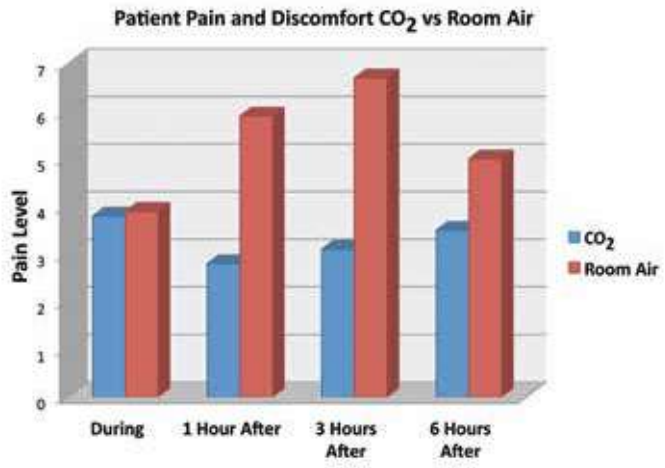
FOR FASTER PROCEDURES AND BETTER PATIENT OUTCOMES

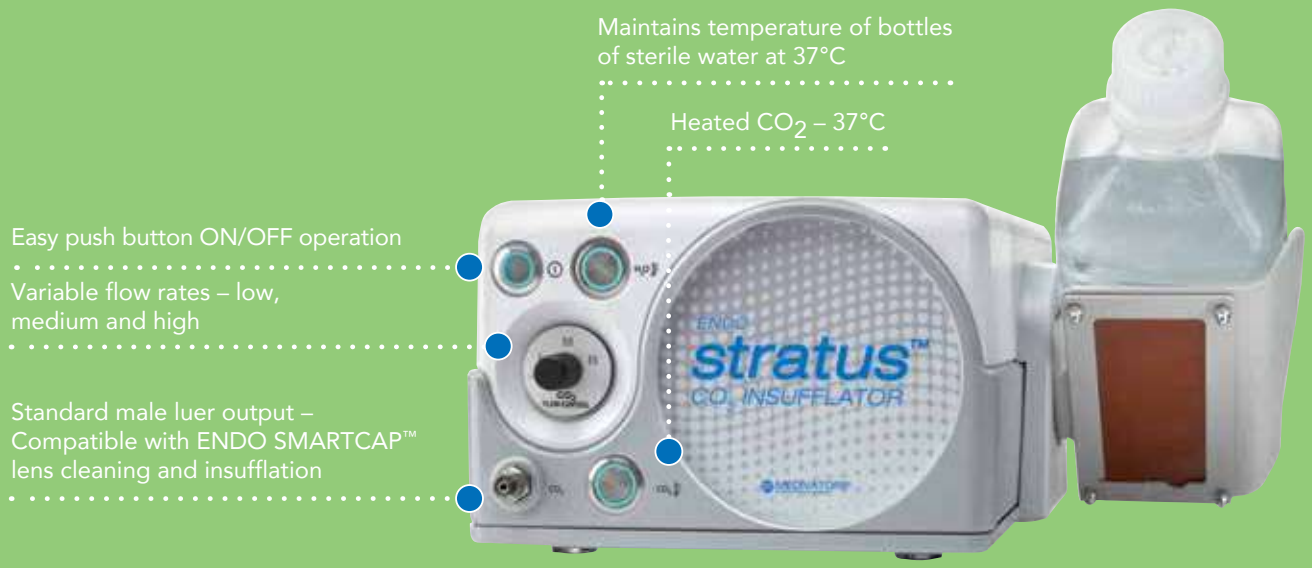
QUICKER PATIENT TURNAROUND*

- 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



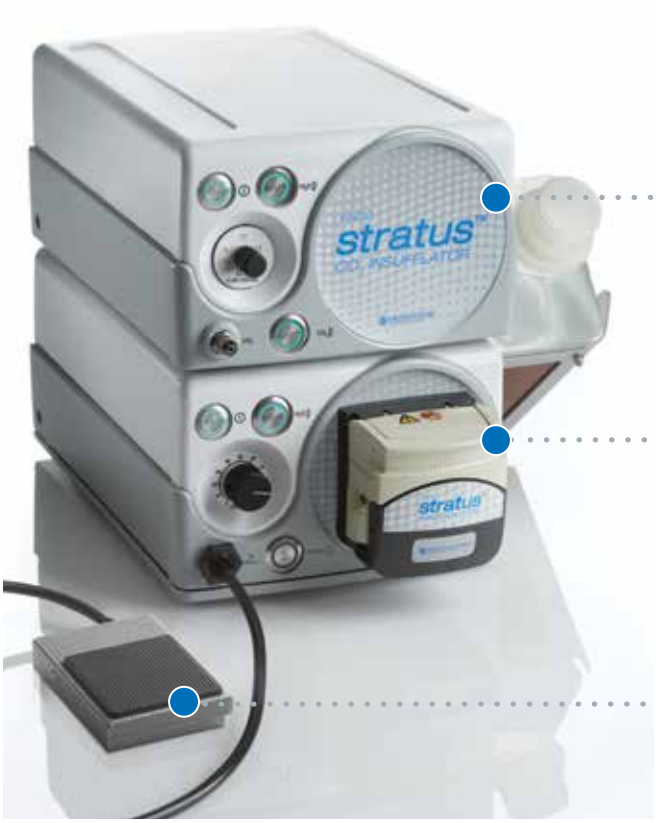


THE COMPLETE CIRCLE OF PROTECTION

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

PROFESSIONAL ASPIRATORS - HIGH VACUUM

28280-1

CE 0434
EN ISO 10079-1
Class I
Type B

28244-6

ASPEED PROFESSIONAL SURGICAL ASPIRATORS
Piston-type continuous cycle electric aspirators give high performance and great durability. Equipped with a protective thermal cut-out relay. They require no maintenance or lubrication. A motor-protector cap totally prevents aspirated liquids or secretions from reaching and damaging the vacuum pump. Ideal for clinical use.
Made in Italy.

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

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

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

TECHNICAL SPECIFICATIONS

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

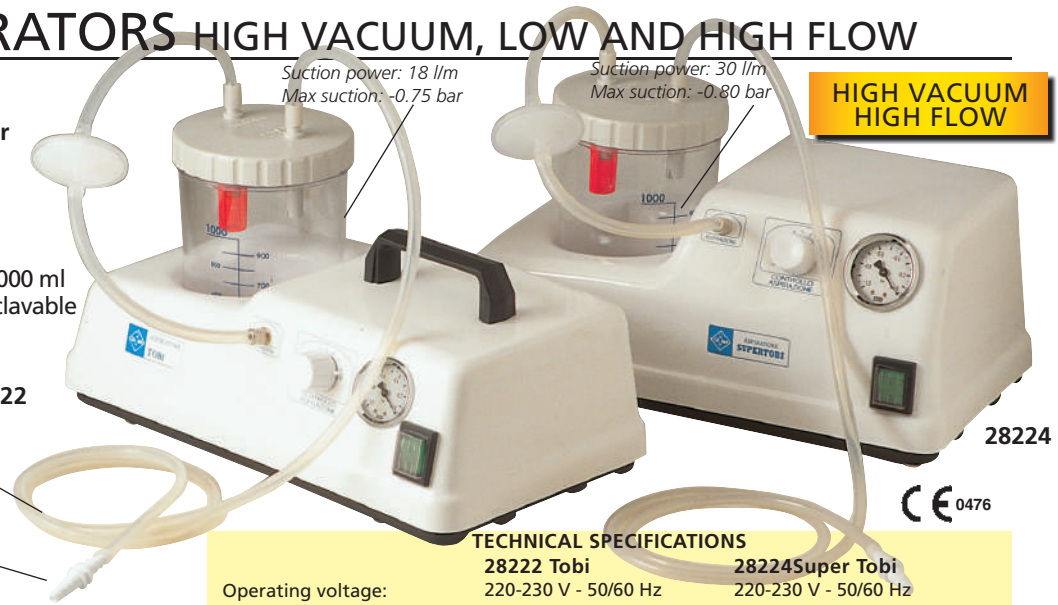
28258 *Autoclavable Jar, h 19.2 cm Ø 10 cm top, 9.7 cm base*

28259 *Disposable suction liner*

SUCTION ASPIRATORS HIGH VACUUM, LOW AND HIGH FLOW

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

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



28222

28224

CE 0476

Silicone tube 6x10 mm (see page 159)

Adaptor for catheter (code 28252)

STANDARD ACCESSORIES

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

TECHNICAL SPECIFICATIONS

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

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

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

Certification Body

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date 2020-04-29

Dipl.-Ing. I. Munkler

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TÜVRheinland®

Doc. 1/13, Rev.0

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH
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Zertifizierungsstelle

Date: 2020-04-29

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TÜV Rheinland
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Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope: Subsidiary:

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

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

Certification Body

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 6/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 7/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 8/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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

TÜVRheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 9/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 10/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Vienna
Austria

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

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 11/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

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

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

Certification Body

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

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 12/13, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148788 0001
Report No.: 60319405 001

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

Scope:

Subsidiary:

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland

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

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Date: 2020-04-29

Dipl.-Ing. I. Munkler

TÜVRheinland®

Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizaţia

OLYMPUS EUROPA SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania

a implementat şi aplică un sistem de management al calităţii pentru dispozivite medicale pentru următoarele domenii:

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

S-a furnizat dovada faptului că au fost îndeplinte cerinţele specificate în

EN ISO 13485:2016

Sistemul de management al calităţii este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020
Nr. înregistrare certificat: SX 60148788 0001
A fost efectuat auditul, raport nr. 60319405 001
Acest certificat este valabil până la 20.06.2023.

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

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

Data, 29.04.2020

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

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

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

ROMÂNIA
MINISTERUL JUSTIŢIEI
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AUT. NR. 22069
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
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ROMÂNIA
MINISTERUL JUSTIŢIEI
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AUT. NR. 22069
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germania

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

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

ROMÂNIA
MINISTERUL JUSTIŢIEI
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ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
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TÜV Rheinland
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Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

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

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MINISTERUL JUSTIŢIEI
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TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

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Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Organism de certificare
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Data, 29.04.2020

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
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ROMÂNIA
MINISTERUL JUSTIŢIEI
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TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

Data, 29.04.2020

Organism de certificare
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Dipl.-Ing. I. Munkler

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Service intern pentru sisteme optice, opto-digitale, electronice şi mecanice precum şi accesorii corespunzătoare din domeniul endoscopiei.

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

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă şi ştampilă TÜV Rheinland LGA Products GmbH)
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TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Viena
Austria

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

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Nr. de înregistrare: SX 60148788 0001
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Organizaţie:

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

Domeniu de aplicabilitate: Filială

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

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

Data, 29.04.2020

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

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Elveţia

Domeniul de aplicabilitate:
Service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei

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

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

Data, 29.04.2020

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Ataşament la Certificat
Nr. de înregistrare: SX 60148788 0001
Nr. raport: 60319405 001

Organizaţie:

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

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Elveţia

Domeniul de aplicabilitate:
Marketing, distribuţie şi service pentru sisteme optice, opto-digitale, electronice şi mecanice, precum şi pentru accesoriile corespunzătoare şi consumabilele din domeniul endoscopiei şi microscopiei

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

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

Data, 29.04.2020

ROMÂNIA
MINISTERUL JUSTIŢIEI
MINA FANEA-IVANOVICI
TRADUCĂTOR AUTORIZAT
ENGLEZĂ * FRANCEZĂ
AUT. NR. 22069
TEL.: 0745471459

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.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Traducere din limba engleza

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.

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

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

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

DocuSign

IMQ

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

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

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* EAGLE Certification Group *USA*
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*

* 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

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 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

IMQ

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.

CERTIFICATE

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

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

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

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

Chief Operating Officer
Giampiero Belcredi

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

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
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*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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.
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Tel +39.051.459.3.111
Fax +39.051.763.382
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www.kiwacermet.it

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

Chief Operating Officer
Giampiero Belcredi

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

Organismo Notificato n. 0476
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 / Surgical aspirators

Codici / Codes:

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

Tipologia / *Medical Devices:*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

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

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
Giampiero Belcredi

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Data:25/05/2021 10:11:56

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

Modello / Model:

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

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

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

Codici / Codes:

29991

Modello / Model:

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

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

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

Codici / Codes:

29987

Modello / Model:

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

Codici / Codes:

29995

Modello / Model:

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

Codici / Codes:

29986

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Chief Operating Officer
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Data:25/05/2021 10:12:15

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasport in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

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

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / *Risk class:*
II a

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

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

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Chief Operating Officer
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Data:25/05/2021 10:12:32

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

CERTIFICATE

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

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

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1102

Modello / Model:

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

Codici / Codes:

28091 ; 28092

Marca / *Brandname:*
EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / *Brandname:*
MISTRAL

Modello / Model:

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

Codici / Codes:

28102

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CERMET

Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:12:51

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 pressione sanguigna / *Blood pressure measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / *NANDO codes:*
MD 0104

Marca / *Brandname:*
BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

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

Marca / *Brandname:*
SIRIO

Modello / Model:
Manometro Aneroide / Aneroid manometer

Codici / Codes:
32904

Marca / *Brandname:*
YTON

Modello / Model:
Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:
32720; 32703; 32693; 32701

Classe di rischio / *Risk class:*
II a

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

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Chief Operating Officer
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Firmato digitalmente da:BELCREDI GIAMPIERO
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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

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

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

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital SphygmomanometersWRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / *Brandname:*
DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della saturazione di ossigeno / *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

Codici / Codes:

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

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Chief Operating Officer
Giampiero Belcredi

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

CERMET

CE
Organismo Notificato n. 0476
Notified Body nr. 0476

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

CERTIFICATE

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

Tipologia / *Medical Devices:*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*

Classe di rischio / *Risk class:*
II a

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

Marca / *Brandname:*
DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

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

Modello / Model:

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

Codici / Codes:

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

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

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / *Brandname:*
PBpharma /GIMA

Modello / Model:

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

Codici / Codes:

25580 ; 25585

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Chief Operating Officer
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Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:13:57

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 di parametri fisiologici / *Physiological parameters measuring devices*

Classe di rischio / *Risk class:*
I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

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

Modello / Model:

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

Codici / Codes:

27335 ; 27344; 27331

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

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

Modello / Model:

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

Codici / Codes:

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

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da:BELCREDI GIAMPIERO
Data:25/05/2021 10:14:45

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
Primo rilascio / *First issue date*	2006-10-25	Valido da / *Valid from*	2021-05-24
Scadenza / *Valid until*	2024-05-26	Ultima modifica / *Last change date*	2021-05-24

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

Tipologia / *Medical Devices:*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit
Codici / Codes:

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

Modello / Model:

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

34257; 34258; 34275; 34279

Modello / Model:

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

34227 ; 34228 ; 34259 ; 34256

Tipologia / *Medical Devices:*
Dispositivi per terapia termica / *Thermic therapy devices*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack
Codici / Codes:

34110 ; 34111

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Chief Operating Officer
Giampiero Belcredi

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

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 26036	Revisione / *Revision*	23
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

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

Tipologia / *Medical Devices:*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

38950 ; 38951

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Classe di rischio / *Risk class:*
I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

388xx

Modello / Model:

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

Codici / Codes:

388xx

Classe di rischio / *Risk class:*
II a

Codice NANDO / *NANDO codes:*
MD 0106, MDS 7006 Radiation

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
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Allegato tecnico al Certificato/
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Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

Modello / Model:

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

Codici / Codes:

388xx ; 389xx

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

Kiwa Cermet Italia S.p.A.
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Chief Operating Officer
Giampiero Belcredi

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

Organismo Notificato n. 0476
Notified Body nr. 0476

AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod va
		ENDO stratus								
DM000316356	INSUFLATOR ENDOSCOPIC GASTRO-INTESTINAL CU CO2	ENDO STRATUS™	EGA-501E		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	
DM000316355	INSUFLATOR ENDOSCOPIC GASTRO-INTESTINAL CU CO2	ENDO STRATUS™	EGA-501		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	
DM000316353	POMPĂ DE IRIGARE / ASPIRAȚIE ENDOSCOPICĂ	ENDO STRATUS™	EGA-500E		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	
DM000316352	POMPĂ DE IRIGARE / ASPIRAȚIE ENDOSCOPICĂ	ENDO STRATUS™	EGA-500		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	
DM000316354	POMPĂ DE IRIGARE / ASPIRAȚIE ENDOSCOPICĂ	ENDO STRATUS™	EGA-500T		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	
DM000316357	INSUFLATOR ENDOSCOPIC GASTRO-INTESTINAL CU CO2	ENDO STRATUS™	EGA-501T		SUA	MEDIVATORS INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000185	10-08-2021	

Содержит([NameMake], 'ENDO stratus')