# "ASPEED 2" SUCTION ASPIRATOR - 230V double pump

| | |
|---|---|
| **Code:** | **28281** |
| **Category:** | **Surgical aspirators and breast pump** |
| **Unit of sale:** | **1 pc.** |
| **Minimum order:** | **1** |
| **Type:** | **Medical device** |
| **Class:** | **II A** |

**EAN13:** **8023279282818**

**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.**

**Technical Specifications:**

- **Operating voltage: 230 V-50/60 Hz**
- **Bottle capacity: 1 L**
- **High vacuum: highflow**
- **Air flow: 22 L/min**
- **Adjustable vacuum level: 0÷ -0.85 bar (0÷ -85 kPa)**
- **Weight: 3.2 kg**
- **Case material: plastic**
- **Noise level: 55 dB**

**Standard accessories:**

- **Autoclavable policarbonate jar 1000 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**

Digitally signed by Grabazei Alexandru
Date: 2019.04.26 16:38:35 EEST
Reason: MoldSign Signature
Location: Moldova

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



# Certificate

## 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**
Via Tommaso Grossi, 2
Milano - 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:*

Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*
Bilancia ad uso medicale / *Scales for medical use*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*
Dispositivi per aerosolterapia / *Nebulizer therapy devices*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per misurazione / *Measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Elettrocardiografi / *Electrocardiographs*
Sfigmomanometri / *Sphygmomanometers*

Rif. rapporto di audit/ *Ref. audit report:* 19-20-21/09/2016

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* ==

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* ==

Chief Operating Officer
Giampiero Belcredi

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

**Kiwa Cermet Italia S.p.A.**
**Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl**
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www.kiwacermet.it

Certificate

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

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

**Tipologia /** *Medical Devices:*
Aspiratori chirurgici e accessori / *Surgical aspirators and accessories*

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

**Codice NANDO /** *NANDO codes:*
MD 1106

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Aspiratori e accessori / *aspirators and accessories*

**Tipologia /** *Medical Devices:*
Bilancia ad uso medicale / *Scales for medical use*

**Classe di rischio /** *Risk class:*
I m

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

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

ASTRA - FAMILY - PEGASO

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Classe di rischio /** *Risk class:*
I s

**Codice NANDO /** *NANDO codes:*
MD 7006

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Gimabrush

Chief Operating Officer
Giampiero Belcredi

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*Technical sheet enclosed to the Certificate*

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

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Cervical Spoon

**Modello /** *Model:*
Cervix Brush Plush

**Modello /** *Model:*
Gima Collector

**Modello /** *Model:*
Gimabrush Ball

**Modello /** *Model:*
Kit ORL sterile / *Sterile ENT kit*

**Modello /** *Model:*
Kit pap test / *Pap smear kit*

**Modello /** *Model:*
Spatula legno sterile / *Sterile wooden spatula*

**Modello /** *Model:*
Spatula plastica sterile / *Sterile plastic spatula*

**Modello /** *Model:*
Speculum perno - mix / *Vaginal Speculum central pin - mix*

**Modello /** *Model:*
Speculum perno centrale - grande / *Vaginal Speculum central pin- large*

**Modello /** *Model:*
Speculum perno centrale - medio / *Vaginal Speculum central pin - medium*

**Modello /** *Model:*
Speculum perno centrale - piccolo / *Vaginal Speculum central pin - small*

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

**Tipologia /** *Medical Devices:*
Dispositivi accessori per ginecologia e otorinolaringoiatria / *Sterile gynaecology and ENT accessories*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Speculum tache - mix / *Vaginal Speculum tache - mix*

**Modello /** *Model:*
Speculum vite centrale - mix / *Vaginal Speculum middle screw - mix*

**Modello /** *Model:*
Speculum vite laterale - grande / *Vaginal Speculum side screw - large*

**Modello /** *Model:*
Speculum vite laterale - medio / *Vaginal Speculum side screw - medium*

**Modello /** *Model:*
Speculum vite laterale - mix / *Vaginal Speculum side screw - mix*

**Modello /** *Model:*
Speculum vite laterale - piccolo / *Vaginal Speculum side screw - small*

**Modello /** *Model:*
Swab plastica sterile / *Sterile plastic swab*

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

**Codice NANDO /** *NANDO codes:*
MD 7006

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Proctoscopio adulti / *Adult proctoscope*

**Modello /** *Model:*
Proctoscopio pediatrico / *Pediatric proctoscope*

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*Technical sheet enclosed to the Certificate*

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

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

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

**Codice NANDO /** *NANDO codes:*
MD 1102

**Marca /** *Brandname:*
AKOD PHARMA

**Modello /** *Model:*
AEROSOL A PISTONE

**Modello /** *Model:*
AEROSOL AD ULTRASUONI

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
AEROSOL MISTRAL

**Modello /** *Model:*
AEROSOL A PISTONE

**Modello /** *Model:*
AEROSOL A PISTONE CORSIA

**Modello /** *Model:*
AEROSOL A PISTONE EOLO

**Modello /** *Model:*
AEROSOL AD ULTRASUONI


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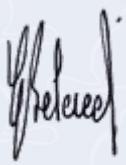
Chief Operating Officer
Giampiero Belcredi



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

**Tipologia /** *Medical Devices:*
Dispositivi per la misurazione della saturazione di O2 / *Oxygen saturation measuring devices*

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

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

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

PULSOSSIMETRO / *PULSE OXIMETER*

**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

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale classico Farmamed / *Classic digital Farmamed thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Farmamed / *Digital Farmamed thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Linea F flessibile / *Digital linea F thermometer flexible*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed / *NUB Farmamed Digital thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB Farmamed Baby / *NUB Farmamed Baby Digital thermometer*

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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*

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmamed / *Farmamed ecologic thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico linea F / *Linea F ecologic thermometer*

**Marca /** *Brandname:*
CARREFOUR GS

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Carrefour / *Digital Carrefour thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale GS / *Digital GS thermometer*

**Marca /** *Brandname:*
CRAF

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale classico Linea F / *Classic digital linea F thermometer*

**Marca /** *Brandname:*
FederFARMA.co

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Profar / *Profar ecologic thermometer*

**Marca /** *Brandname:*
GABBIANO

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale Farmasan / *Farmasan Digital thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico Farmasan / *Farmasan ecologic thermometer*

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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*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale / *Digital thermometer*

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale NUB / *NUB Digital thermometer*

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico / *Ecologic thermometer*

**Marca /** *Brandname:*
PB PHARMA

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale / *Digital GS thermometer*

**Marca /** *Brandname:*
QUIDNOVI PHARMA

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro ecologico TECNICO Eco / *TECNICO Eco ecologic thermometer*

**Marca /** *Brandname:*
SSL HEALTHCARE

**Modello /** *Model:*

Termometri ecologici senza mercurio -Termometro clinico Realcheck mercury free / *Clinical thermometer Realcheck mercury free*

**Marca /** *Brandname:*
T&B

**Modello /** *Model:*

Termometri clinici digitali -Termometro digitale 36.2 T&B / *Digital 36.2 T&B thermometer*

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

**Tipologia /** *Medical Devices:*
Dispositivi per misurazione / *Measuring devices*

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

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

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

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

**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 1102

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Cannule di Guedel sterili / *Sterile Guedel airways*

**Modello /** *Model:*

Kit pallone silicone adulti / *Silicone resuscitator kit - adult*

**Modello /** *Model:*

Maschere laringee riutilizzabili / *Reusable laryngeal mask airways*

**Modello /** *Model:*

Mascherina per rianimazione CPR / *CPR resuscitator mask*

**Modello /** *Model:*

Palloni rianimatori / *Resuscitators*

**Modello /** *Model:*

Accessori -Maschere in silicone autoclavabili / *Silicone autoclavable face masks*

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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*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Accessori -Maschere in silicone con cuscinetto e cuffia autoclavabili / *Silicone autoclavable cushion face masks*

**Modello /** *Model:*

Accessori -Maschere ossigeno / *Oxygen masks*

**Modello /** *Model:*

Accessori -Mascherine monouso PVC a cuscino d'aria iniettabile / *Disposable PVC injectable air cushion face masks*

**Modello /** *Model:*

Accessori -Occhiali ossigeno / *Nasal cannula*

**Modello /** *Model:*

Accessori -Tubo ossigeno / *Oxygen tubing*

**Modello /** *Model:*

Accessori -Valvola PEEP / *Peep valve*

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

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

**Codice NANDO /** *NANDO codes:*
MD 1403

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*

Ghiaccio istantaneo monouso Farmamed Gelo Pack / *Farmamed disposable instant ice cold pack*

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Certificate

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*Technical sheet enclosed to the Certificate*

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

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

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

Ghiaccio istantaneo monouso / *disposable instant ice cold pack*

**Modello /** *Model:*

Ghiaccio istantaneo PE / *PE instant ice cold pack*

**Modello /** *Model:*

Ghiaccio istantaneo TNT / *TNT instant ice cold pack*

**Marca /** *Brandname:*
MENARINI

**Modello /** *Model:*

Ghiaccio istantaneo monouso Menarini / *Menarini disposable instant ice cold pack*

**Tipologia /** *Medical Devices:*
Elettrocardiografi / *Electrocardiographs*

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

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

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*

ECG PALMARE

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*Notified Body nr. 0476*

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

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

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

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

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

**Marca /** *Brandname:*
ACRAF

**Modello /** *Model:*
SFIGMO DIGITALE DA POLSO ROSS ANGELINI

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS ANGELINI

**Marca /** *Brandname:*
AKOD PHARMA

**Modello /** *Model:*
SFIGMO DIGITALE DA BRACCIO HL AKOD

**Modello /** *Model:*
SFIGMO DIGITALE DA POLSO HL AKOD

**Modello /** *Model:*
SFIGMO DIGITALE DA TAVOLO HL AKOD

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
a mercurio -STAR

**Modello /** *Model:*
a mercurio -YTON

**Modello /** *Model:*
a mercurio -YTON PLAUNAZIDE

**Modello /** *Model:*
Aneroidi -BOSTON

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

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
Aneroidi -BOSTON COMBISARTAN

**Modello /** *Model:*
Aneroidi -BOSTON LATEX-FREE

**Modello /** *Model:*
Aneroidi -BOSTON LOBIVON

**Modello /** *Model:*
Aneroidi -BOSTON VALPRESSION

**Modello /** *Model:*
Aneroidi -BOSTON OLPRESS

**Modello /** *Model:*
Aneroidi -DALLAS

**Modello /** *Model:*
Aneroidi -GIMATONO

**Modello /** *Model:*
Aneroidi -LONDON

**Modello /** *Model:*
Aneroidi -ROMA

**Modello /** *Model:*
Aneroidi -SIRIO

**Modello /** *Model:*
Aneroidi -TOKIO

**Modello /** *Model:*
Aneroidi -TOKIO ZANTIPRESS

**Modello /** *Model:*
Aneroidi -YTON

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*Notified Body nr. 0476*

**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.kiwacermet.it

CERMET

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



Certificate

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

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

**Tipologia /** *Medical Devices:*
Sfigmomanometri / *Sphygmomanometers*

**Marca /** *Brandname:*
GIMA

**Modello /** *Model:*
digitali -AUTOMATICO DA POLSO

**Modello /** *Model:*
digitali -24h

**Modello /** *Model:*
digitali -AMBULATORIALE

**Modello /** *Model:*
digitali -AUTOMATICO DA BRACCIO

**Modello /** *Model:*
digitali -DOMINO

**Modello /** *Model:*
digitali -SENZA MERCURIO

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO HL GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA BRACCIO ROSS GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA POLSO HL GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA POLSO ROSS GIMA

**Modello /** *Model:*
digitali -SFIGMO DIGITALE DA TAVOLO HL GIMA

**Modello /** *Model:*
digitali -YTON DIGITALE

Chief Operating Officer
Giampiero Belcredi

CE

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

**Kiwa Cermet Italia S.p.A.**
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CERMET

Certificate

| | | | |
|---|---|---|---|
| Reg. Numero / *Reg. Number* | MED 26036 | Revisione / *Revision* | 20 |
| Primo rilascio / First i*ssue date* | 2006-10-25 | Valido da / *Valid from* | 2016-10-24 |
| Scadenza / *Valid until* | 2021-10-24 | Ultima modifica / *Last change date* | 2016-11-07 |



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 Srl**
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Chief Operating Officer
Giampiero Belcredi

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

CERTIFICATE

| | | | |
|---|---|---|---|
| Reg. Number | 10164 - M | Valid From | 2018-10-01 |
| First issue date | 2012-10-15 | Last change date | 2018-10-01 |
| Valid until | 2021-10-14 | | |

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:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer
Giampiero Belcredi

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

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

This certificate is composed of 1 page.

**Kiwa Cermet Italia S.p.A.**
**Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl**
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.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
SGA N° 010D
PRD N° 069B
FSM N° 004I
PRS N° 089C

# 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)

OLYMPUS

Your Vision, Our Future

Optera

# CF-H170L/I

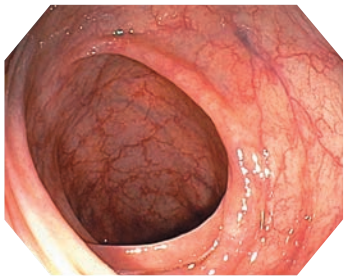
**A powerful tool for routine colonoscopy – with HDTV and improved insertability**

# CF-H170L/I

## Main features

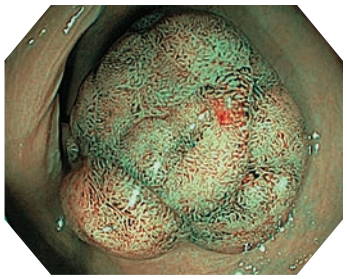
### HDTV image quality

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



### NBI (Narrow Band Imaging)

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



### Close Focus

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

### Variable Stiffness

Variable stiffness helps to avoid re-looping of the endoscope, 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.

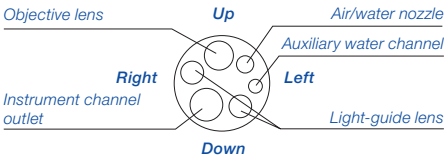
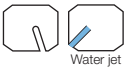
### Water Jet

This technology removes mucus and debris inside the colon at the press of a button on the scope or the foot-switch unit, providing a clear view.

### Waterproof Connector

The newly designed connector is fully submersible and therefore eliminates the need for a water-resistant cap, while minimising the risk of damage due to accidental immersion.

## Specifications

| | | |
|---|---|---|
| **Optical system** | Field of view | 140° |
| | Direction of view | Forward viewing |
| | Depth of field | 2–100 mm |
| **Insertion section** | Distal end outer diameter | 12.8 mm |
| | Distal end enlarged |  |
| | Insertion tube outer diameter | 12.8 mm |
| | Working length | L: 1,680 mm<br>I: 1,330 mm |
| **Instrument channel** | Channel inner diameter | 3.7 mm |
| | Minimum visible distance | 5.0 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: 2,005 mm I: 1,655 mm | |





E0429349 · 1.000 · 07/13 · PR



OLYMPUS

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www.olympus-europa.com

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# CV-170

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

# CV-170

## Main features

- HDTV imaging capability provides the best possible image quality for endoscopes, enabling the observation of capillaries, mucosal structures and other patterns.
- NBI (Narrow Band Imaging) enhances the visibility of capillaries and other structures on the mucosal surface.
- Newly adopted long-life LED light sources minimise lamp replacement, while reducing energy and noise.
- The pre-freeze function selects the clearest still image automatically. It may help to save time and eliminate the physician's frustration.
- Two types of structure enhancement are available – in general, the conventional Type A is ideal for observation of larger mucosal tissues with high contrast in the lower gastrointestinal tract, while the new Type B is suitable for observation of vascular tissues in the upper gastrointestinal tract.
- Compatible portable memory (MAJ-1925) is the standard for data management. Simply connect and upload.
- Compatible with EVIS 100/130/140 series, Actera 150 series, EVIS EXERA 160 series, EVIS EXERA II 180 series and GI/BF/VISERA series scopes.
  **Please note that there are some exceptions.*
- 16:9 and 16:10 output for an HDTV monitor is available. Compatible with analogue, HD-SDI and DVI output.


## Specifications

| | | |
|---|---|---|
| **Power supply** | Voltage | 100–240 V AC (NTSC)/220–240 V AC (PAL); within ±10% |
| | Frequency | 50/60 Hz; within ±1 Hz |
| | Rated input | 200 VA |
| **Size** | Dimensions (W × H × D) | 295 × 145 × 425 mm |
| | Weight | 11 kg |
| **Classification (medical electrical equipment)** | Type of protection against electric shock | Class I |
| | Degree of protection against electric shock of applied part | Depends on applied part. Also refer to applied part (camera head or videoscope). |
| | Degree of protection against explosion | The video system centre should be kept away from flammable gases. |
| **Observation** | Examination lamp | LED lamp |
| | Analogue HDTV signal output | Either RGB (1080/60I: NTSC)/(1080/50I: PAL) or YPbPr (1080/60I: NTSC)/(1080/50I: PAL) output can be selected. |
| | Analogue SDTV signal output | VBS composite (480/60I: NTSC)/(576/50I: PAL), Y/C (480/60I: NTSC)/(576/50I: PAL) and RGB (480/60I: NTSC)/(576/50I: PAL); simultaneous outputs possible. |
| | Digital signal output | HD-SDI (SMTPE 292M), SD-SDI (SMPTE 259M) and DVI (WUXGA, 1080p or SXGA) can be selected. |
| | White balance adjustment | White balance adjustment is possible using the white balance button on the front panel. |
| | Standard colour chart output | The "Colour bar" or the "50% white" screen can be displayed. |
| | Colour tone adjustment | The following colour tone adjustments are possible:<br>· red adjustment: ±8 steps · blue adjustment: ±8 steps · chroma adjustment: ±8 steps |
| | Automatic gain control (AGC) | The image can be electronically amplified when the light is inadequate due to the distal end of the endoscope being too far from the object. |
| | Contrast | The image contrast can be set to one of the following three modes (N, H, L):<br>· N (Normal): normal image<br>· H (High): the dark areas are darker and the bright areas are brighter than in the normal image.<br>· L (Low): the dark areas are brighter and the bright areas are darker than in the normal image. |
| | Noise reduction | Noise is corrected by image processing. |
| | Iris | The auto iris modes can be selected using the "iris mode" switch on the front panel.<br>· peak: the brightness is adjusted based on the brightest part of the endoscopic image.<br>· average: the brightness is adjusted based on the average brightness of the endoscopic image. |
| | Image enhancement setting | Fine patterns or edges in the endoscopic images can be enhanced electrically to increase the image sharpness.<br>Either the structural enhancement or edge enhancement can be selected according to the user set-up.<br>· structural enhancement: enhancement of contrast of the fine patterns in the image.<br>· edge enhancement: enhancement of edges of the endoscopic image. |
| | Switching the enhancement modes | The enhancement level can be selected from 3 levels (1, 2 and 3). |
| | Image size selection | The size of the endoscopic image can be changed using the "IMAGE SIZE" key on the keyboard. |
| | Freeze | An endoscopic image is frozen using an endoscope or the "FREEZE" key on the keyboard. |
| | Pre-freeze | The image with the least blur is selected from the images captured in the set time period before the freeze operation and displayed. |
| | NBI observation | This is one of the optical-digital observation modes using the narrow band observation light. |
| | Reset to defaults | The following settings can be reset to their defaults:<br>· colour tone · iris mode · image enhancement mode · image size · contrast · freeze · release index · electronic zoom<br>· optical-digital observation · arrow pointer · stopwatch · characters on screen · brightness |
| | Remote control | The following ancillary equipment can be controlled (specified models only):<br>· DVR · video printer · image filing system · flushing pump · endoscopic $CO_2$ regulation unit |
| **Documentation** | Patient data | The following data can be displayed on the endoscopic image screen:<br>· patient ID · patient name · sex · age · date of birth · date of recording (time, stopwatch) · comments |
| | Displaying the recording state | The recording state of the following ancillary equipment can be displayed on the monitor:<br>· portable memory and internal buffer · DVR · video printer · Image filing system |
| | Displaying the image information | The following data can be displayed on the monitor:<br>· structure enhancement level · edge enhancement level · zoom ratio · colour mode |
| | Advanced registration of patient data | Up to 50 patients' data can be registered:<br>· patient ID · patient name · sex · age · date of birth |
| **Portable memory** | Media | MAJ-1925 (OLYMPUS) |
| | Recording format | · TIFF: no compression · JPEG (1/5): approx. 1/5 compression · JPEG (1/10): approx. 1/10 compression |
| | Number of recording images | · TIFF: approx. 227 images · JPEG (1/5): approx. 1,024 images · JPEG (1/10): approx. 2,048 images |
| **Memory backup** | User settings | Up to 20 user settings can be registered. |
| | Memorisation of selected setting | The following settings are stored in memory even after the video system centre is turned OFF.<br>· colour tone · iris mode · image enhancement mode · colour enhancement mode · contrast · AGC · colour mode · white balance<br>· brightness adjustment method · brightness · air feeding |
| | Lithium battery | Life: 5 years |

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OLYMPUS

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www.olympus-europa.com

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# GIF-H170

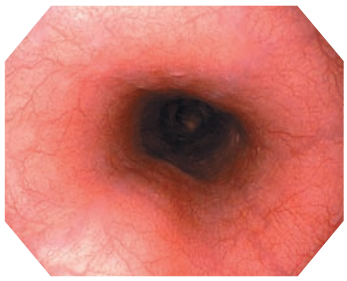
**Outstanding HDTV image quality with a slimmer outer diameter**

# GIF-H170

## Main features

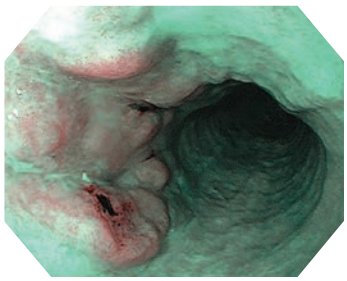
### HDTV image quality

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



### NBI (Narrow Band Imaging)

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



### Close Focus

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

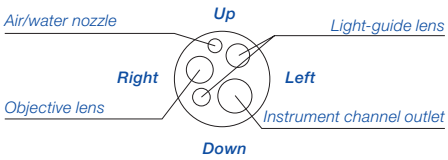
### Slim Design

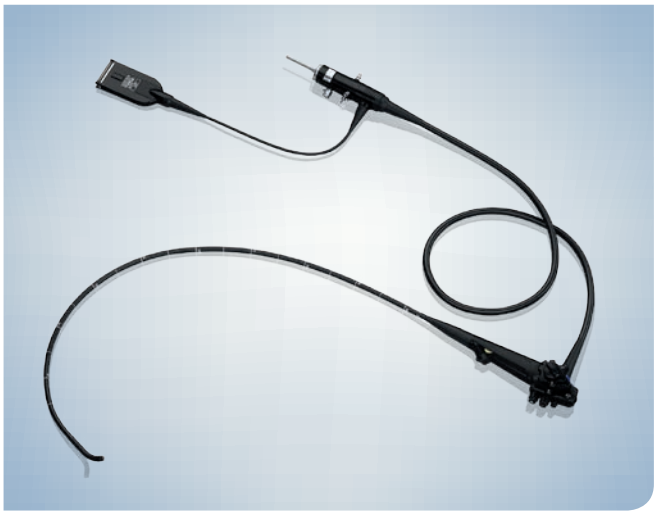
GIF-H170 offers an excellent balance of both size and performance with its 9.2 mm outer diameter.

### Waterproof Connector

The newly designed connector is fully submersible and therefore eliminates the need for a water-resistant cap, while minimising the risk of damage due to accidental immersion.

## Specifications

| | | |
|---|---|---|
| **Optical system** | Field of view | 140° |
| | Direction of view | Forward viewing |
| | Depth of field | 2–100 mm |
| **Insertion section** | Distal end outer diameter | 9.2 mm |
| | Distal end enlarged |   |
| | Insertion tube outer diameter | 9.2 mm |
| | Working length | 1,030 mm |
| **Instrument channel** | Channel inner diameter | 2.8 mm |
| | Minimum visible distance | 3 mm from the distal end |
| | Direction from which endotherapy accessories enter and exit the endoscopic image |  |
| **High-frequency** | Cauterisation treatment | Available |
| **Bending section** | Angulation range | Up 210° |
| | | Down 90° |
| | | Right 100° |
| | | Left 100° |
| **Total length** | 1,350 mm | |



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OLYMPUS

OLYMPUS EUROPA HOLDING GMBH
Postbox 10 49 08, 20034 Hamburg, Germany
Wendenstrasse 14–18, 20097 Hamburg, Germany
Phone: +49 (0)40 237 730, Fax: +49 (0)40 230 761
www.olympus-europa.com

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

THE DISPLAY CHOICE
OF PROFESSIONALS™

LED

# X-24

## With NeoV™ Optical Glass immaculately welded onto metal casing, the X-24 features seamless integration of multiple strengths that ensures its reliability in all kinds of modern professional environments.

Built on an LED-backlit panel delivering 1920 x 1080 Full HD resolution, the X-24 presents life-like contrast, colours and nuances on its Advanced Image Platform™ (AIP). Its Smart Omni Viewer offers such options as Picture-in-Picture (PIP) and selectable aspect ratios. The EcoSmart Sensor detects ambient luminance and adjusts the backlight automatically.

> LED-backlit technology with high FHD 1920 x 1080 resolution
> Crisp 2,000,000 dynamic contrast ratio
> Slim 14 mm border & bezel design for a stylish look
> NeoV™ Optical Glass
> AIP technology: PIP and PBP functions; 3D Comb Filter/Deinterlace/Noise Reduction; Image rotation function
> Selectable aspect ratio for ultimate image
> EcoSmart Sensor for low watt power consumption
> Black-level alignment
> Versatile inputs: VGA, DVI, HDMI, S-Video, CVBS (RCA x 2), Audio in
> Built-in speakers
> Touch sensor control keys to prevent vandalism
> Durable metal housing
> Rigorous screening of the components for mission-critical 24/7 applications

NeoV OPTICAL GLASS

**NeoV™ Optical Glass** - The most trusted hard glass protection available. Only on AG Neovo displays

AIP ADVANCED Image Platform

# X-24

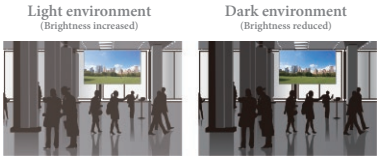
| Specifications | | X-24 |
|---|---|---|
| Panel | Panel Type | LED-backlit TFT LCD |
| | Panel Size | 23.6” |
| | Max. Resolution | FHD 1920 x 1080 |
| | Pixel Pitch | 0.2715 mm |
| | Brightness | 300 cd/m2 (Typical) |
| | Contrast Ratio | 2,000,000 : 1 (DCR) |
| | Viewing Angle (H/V) | 170°/160° (Typical) |
| | Display Colour | 16.7M |
| | Response Time | 3 ms (GTG) |
| Frequency (H/V) | | H: 24 kHz - 82 kHz<br>V: 50 Hz - 75 Hz |
| Input | VGA | 15-Pin D-Sub |
| | DVI | 24-Pin DVI-D |
| | CVBS | RCA x 2 |
| | S-Video | 4-Pin mini DIN |
| | HDMI | HDMI x 1 |
| Audio | Audio In | 1 x stereo audio in for PC (audio jack, 3.5 Ø)<br>1 x stereo audio in for CVBS (RCA) or S-Video |
| | Audio | 2W |
| Power | Power Supply | External |
| | Power Requirements | DC 12V |
| | Consumption | <29W (On)<br><0.5W (Active Off)<br><0.5W (Off) |
| NeoV™ Optical Glass | Thickness | 3.0 mm (0.12”) |
| | Reflection Rate | < 1% |
| | Transmission Rate | > 96% |
| | Coating Hardness | > 9H |
| Operating Conditions | Temperature | 0°C ~ 40°C (32°F~104°F) |
| | Humidity | 10%~90% (No condensation) |
| Storage Conditions | Temperature | -20°C ~ 60°C (-4°F~140°F) |
| | Humidity | 5%~95% (No condensation) |
| Mounting | VESA FPMPMI | Yes (100 x 100mm & 75 x 75mm) |
| Dimensions | Product (W x H x D) | 562 x 397 x 155 mm<br>(22.1” x 15.6” x 6.1”) |
| | Packaging (W x H x D) | 676 x 525 x 213 mm<br>(26.6” x 20.7” x 8.4”) |
| Weight (net) | w/o base | 7.4 kg (16.3 lbs) |
| | w base | 7.8 kg (17.2 lbs) |
| | Packaging Weight | 10.6 kg (23.4 lbs) |
| Regulation Approval | Certifications & Compliance | FCC, CB, CE, RoHS, WEEE, REACH, GOST-R |
| Accessories | Supplied | CD ROM(user manual), power cord, power adapter, 15-Pin D-Sub cable, audio cable |

Available in black or white


NeoV™ Optical Glass protects against scratches, impacts and other physical damage

On top of PIP and PBP, Smart Omni Viewer offers selectable aspect ratios and the option of 180° image rotation

Multiple video inputs (HDMI, DVI, VGA, CVBS, S-Video) make possible effortless system integration




EcoSmart Sensor and versatile capabilities ensure round-the-clock operations


P/C: X240B0, Version 3.0, 20161122