



# GIMA

## "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 polycarbonate 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

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## 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 O<sub>2</sub> / 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



Organismo Notificato n. 0476  
Notified Body nr. 0476

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

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

**Tipologia / Medical Devices:**

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:**

Jimabrush

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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:**

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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#### **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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**CERMET**

Chief Operating Officer  
Giampiero Belcredi

**CE**

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**Allegato tecnico al Certificato/  
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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**Certificate**

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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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#### **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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### **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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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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**CERMET**

Chief Operating Officer  
Giampiero Belcredi

**CE**

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### **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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**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

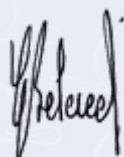
**Modello / Model:**

Aneroidi -TOKIO ZANTIPRESS

**Modello / Model:**

Aneroidi -YTON

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**CERMET**



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**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

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Scadenza / Valid until	2021-10-24	Ultima modifica / Last change date	2016-11-07

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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.*

# Certificate

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](mailto:info@kiwacermet.it)  
[www.kiwacermet.it](http://www.kiwacermet.it)

**CERMET**

Chief Operating Officer  
Giampiero Belcredi

**CE**

Organismo Notificato n. 0476

Notified Body nr. 0476



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

Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: [info@kiwacermet.it](mailto:info@kiwacermet.it)

[www.kiwacermet.it](http://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° 0041  
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.

**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



Notified Body

*M. Aihara*  
M.Sc. M. Aihara

**Date:** 2017-10-12

Traducere din limba engleza



**APROBARE**  
**Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4**  
**Sistem complet de asigurare a calității**  
**Echipeamente 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 și dezvoltare, producție de sisteme de endoscopie medicală, produse de diagnostic, operație și tratament.  
(a se vedea atasamentele pentru produse și locații suplimentare incluse)  
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirării: 02.11.2022

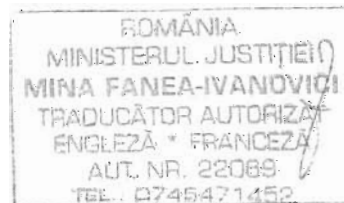
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită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

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

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

**TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva  
93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg

Atasament la  
Certificat

Nr. de înregistrare: HD 60123878 0001  
Nr. raport: 12018179 022

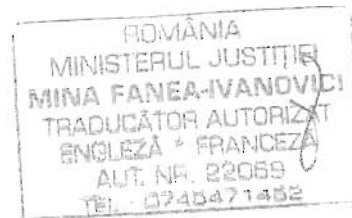
**Producător:** Olympus Medical Systems Corp.  
2951 Ishikawa-cho  
HACHIOJI-SHI, TOKIO 192-8507  
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
  - Endoscoape
  - Echipamente endoterapie
  - Procesoare de imagine
  - Pompe pentru endoscopie
  - Surse de lumină
  - Unități de detectare poziție
  - Unități de cauterizare electrotermică
  - Sisteme endochirurgicale integrate
  - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde și traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.10.2012

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







**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



**CERTIFICAT CE**  
**Directiva CE 93/42/CEE Anexa V**  
**Asigurarea calității producției**  
**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 împreună cu endoscoape, instrumente sterile non-actives utilizate împreună cu endoscoape și instrumente sterile non-actives utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.  
Înlocuiește Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirării: 02.11.2022

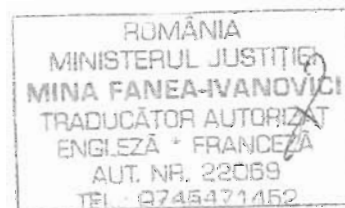
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea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

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

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

**TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



## CF-H170L/I

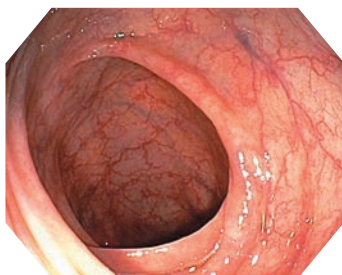
A powerful tool for routine colonoscopy – with HDTV and improved insertability



## Main features

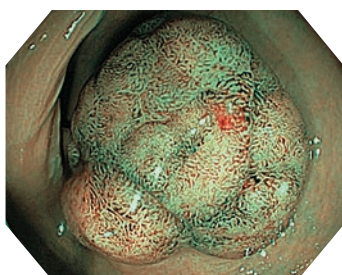
### HDTV image quality

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.

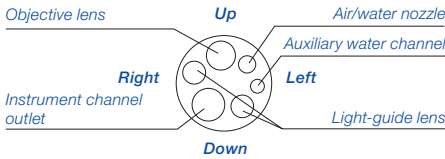
### Water Jet

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

<b>Optical system</b>	Field of view	140°
	Direction of view	Forward viewing
	Depth of field	2–100 mm
<b>Insertion section</b>	Distal end outer diameter	12.8 mm
	Distal end enlarged	
		
<b>Instrument channel</b>	Channel inner diameter	3.7 mm
	Minimum visible distance	5.0 mm from the distal end
<b>Bending section</b>	Angulation range	Up 180° Down 180° Right 160° Left 160°
	<b>Total length</b>	L: 2,005 mm I: 1,655 mm



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



## CV-170

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



## 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

<b>Power supply</b>	Voltage	100–240 V AC (NTSC)/220–240 V AC (PAL); within ±10%
	Frequency	50/60 Hz; within ±1 Hz
	Rated input	200 VA
<b>Size</b>	Dimensions (W × H × D)	295 × 145 × 425 mm
	Weight	11 kg
<b>Classification (medical electrical equipment)</b>	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.
<b>Observation</b>	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 (SMPTE 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: · 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): · N (Normal): normal image · H (High): the dark areas are darker and the bright areas are brighter than in the normal image. · 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. · 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 setting	Fine patterns or edges in the enhanced images can be enhanced electrically to increase the image sharpness. Either the structural enhancement or edge enhancement can be selected according to the user set-up. · structural enhancement: enhancement of contrast of the fine patterns in the image. · 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: · colour tone · iris mode · image enhancement mode · image size · contrast · freeze · release index · electronic zoom · optical-digital observation · arrow pointer · stopwatch · characters on screen · brightness
	Remote control	The following ancillary equipment can be controlled (specified models only): · DVR · video printer · image filing system · flushing pump · endoscopic CO <sub>2</sub> regulation unit
	<b>Documentation</b>	Patient data
Displaying the recording state		The recording state of the following ancillary equipment can be displayed on the monitor: · portable memory and internal buffer · DVR · video printer · image filing system
Displaying the image information		The following data can be displayed on the monitor: · structure enhancement level · edge enhancement level · zoom ratio · colour mode
Advanced registration of patient data		Up to 50 patients' data can be registered: · patient ID · patient name · sex · age · date of birth
<b>Portable memory</b>	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
<b>Memory backup</b>	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. · colour tone · iris mode · image enhancement mode · colour enhancement mode · contrast · AGC · colour mode · white balance · brightness adjustment method · brightness · air feeding
	Lithium battery	Life: 5 years

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

## GIF-H170

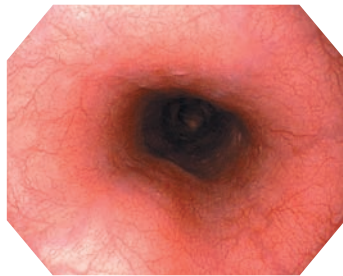
Outstanding HDTV image quality with a slimmer outer diameter



## Main features

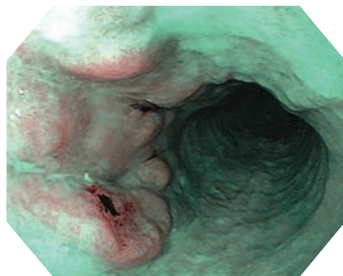
### HDTV image quality

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

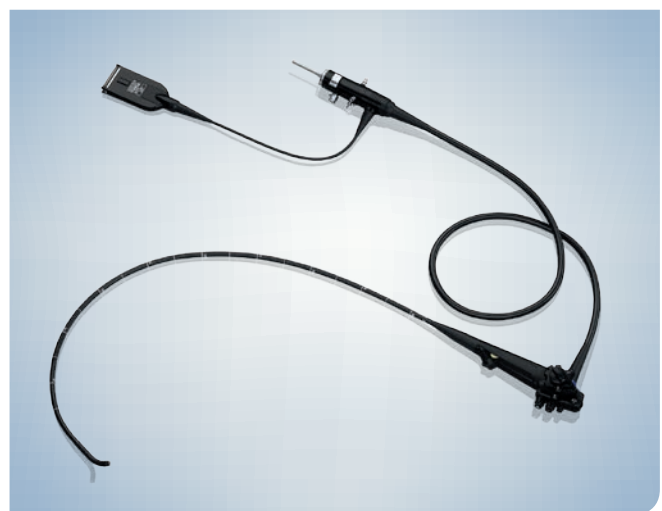
GIF-H170 offers an excellent balance of both size and performance with its 9.2 mm outer diameter.

### 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

<b>Optical system</b>	Field of view	140°
	Direction of view	Forward viewing
	Depth of field	2–100 mm
<b>Insertion section</b>	Distal end outer diameter	9.2 mm
	Distal end enlarged	
<b>Instrument channel</b>	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	
<b>High-frequency</b>	Cauterisation treatment	Available
<b>Bending section</b>	Angulation range	Up 210° Down 90° Right 100° Left 100°
	<b>Total length</b>	1,350 mm



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



# 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



Date 2018-10-30



*M. Aihara*  
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>

**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, Distribution, 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**



**Date:** 2018-10-30

  
**M.Sc. M. Aihara**



# Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

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

a implementat și aplică un sistem de management al calității pentru dispozitive medicale pentru următoarele domenii:

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

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

**EN ISO 13485:2016**

Sistemul de management al calității este supus unei supravegheri anuale.

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



Data, 30.10.2018

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

**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>

**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 și dezvoltare, producție, distribuție, service, asigurarea calității, planificare și furnizare asistență pentru endoscoape, echipamente endoterapie, surse de lumină, procesoare de imagine, unități de detectare a poziției endoscopului, unități de cauterizare electrotermică, sisteme endochirurgicale integrate, unitati de control/reglare endoscopice, capete cameră/pompe/sisteme monitorizare/sisteme înregistrare pentru endoscopie, echipamente electrochirurgicale, endoscoape capsulă și sisteme, insuflatoare laparoscopice, sisteme de imagistica pentru diagnostic ecografic, unități dezinfectare și echipamente chirurgicale cu ultrasunete, sonde și 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 și recipiente apă, tuburi alimentare apă, supape apă și întrerupătoare de picior pentru pompe.**



Data, 30.10.2018

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





## 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 - The most trusted hard glass protection available. Only on AG Neovo displays



# 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 Response Time	16.7M 3 ms (GTG)
Frequency (H/V)		H: 24 kHz - 82 kHz 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) 1 x stereo audio in for CVBS (RCA) or S-Video
	Audio	2W
Power	Power Supply	External
	Power Requirements	DC 12V
	Consumption	<29W (On) <0.5W (Active Off) <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 FPM PMI	Yes (100 x 100mm & 75 x 75mm)
Dimensions	Product (W x H x D)	562 x 397 x 155 mm (22.1" x 15.6" x 6.1")
	Packaging (W x H x D)	676 x 525 x 213 mm (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



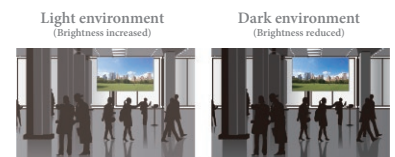
NeoV™ Optical Glass protects against scratches, impacts and other physical damage



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