

X-RAY ILLUMINATORS - LIGHT BOXES

MADE IN ITALY

X-RAY ILLUMINATORS

GIMA light boxes are designed according to clinical standards for an extra white light for an accurate and precise reading of any detail. They incorporate a 3 mm acrylic screen compliant with safety norms (fuses, Schuko plug, green light On/Off, ...). Can be used on the table placed horizontally or vertically, depending on model or wall mounted. Body made of oven-fired epoxy powder coated aluminium and injected ABS (colour RAL 7035).

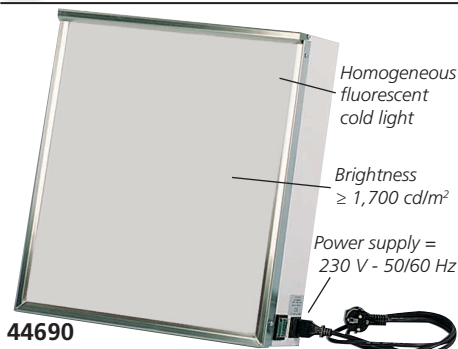
TECHNICAL SPECIFICATIONS

Colour temperature: Cool white 6,500 °K
Power supply: 230 V - 50 Hz (60 Hz available with surcharge)
Protection fuse: 2x1A
Bipolar light switch
Schuko plug with 2 m cable
All components UL, DVE, IMQ approved



GIMA code	X-RAY ILLUMINATORS - LIGHT BOXES	External dimensions (cm)				Types
		Length	Height	Depth	Weight	
27364	Light box 38x38 cm	43	43	12	6	1 panel
27365	Light box 38x62 cm	67	43	12	8	1,5 panel
27366	Light box 38x92 cm	97	43	12	11	2 panels
27367	Light box 38x122 cm	127	43	12	14	3 panels
27368	Light box 38x153 cm	158	43	12	18	4 panels
27369	Light box 76x122 cm	127	2x43	12	28	2x3 panels
27370	Light box 76x153 cm	158	2x43	12	36	2x4 panels
27372	Light box 92x38 cm	43	97	12	11	2 panels vertical
27373	Light box 122x38 cm	43	127	12	14	3 panels vertical
27378	Neon tube for 27364					
27379	Neon tube for 27366, 27372					
27388	Neon tube for 27365					

VALUE FOR MONEY LIGHT BOXES



GIMA X-ray illuminators have been designed according to clinical recommendations for an extra white light to give an accurate and precise reading of any detail. Made of enamelled sheet steel. Unbreakable white monochromatic diffuser, stainless steel gripping system. On/off switch for separate use of each panel for 44692.

MADE IN ITALY

GIMA code	X-RAY ILLUMINATORS - LIGHT BOXES	External dimensions (cm)				Types
		Length	Height	Depth	Weight	
44690	40x43 cm	43	46	14	6	1 panel
44692	80x43 cm	83	46	14	10	2 panels
44695	Round fluorescent light 32 W - spare					

ILLUMINATED AND NOT ILLUMINATED OPTOMETRIC CHARTS

MADE IN ITALY



GIMA luminous optotypes have been designed according to clinical recommendations for an extra white light to give an accurate and precise reading of any detail.

Manufactured with acrylic screen, and according to safety norms (fuses, Schuko plug, green light On/Off,...)



OPTOMETRIC CHARTS	Illuminated GIMA code	Not illuminated GIMA code
Armagnac - 5 m	27380	27390
Monoyer - 3 m	27381	27391
Mixed decimal - 3m	27382*	27392*
Children - 3 m	27383	27393
Animals - 5 m	27384	-
Spare Tube 700	27388	-

TECHNICAL SPECIFICATIONS

Viewing Area: 24 x 62 cm 24 x 61 cm
External dimensions: 29.5x67.5x12 cm 29 x 66 x 2.5 cm
Weight: 6 kg 2 kg
Power supply: 230 V - 50 Hz (60 Hz on request) only 27380-4
Other specifications like X-ray illuminators 27364-72

MONOYER
3m
• 27381

MIXED DECIMAL
3m
• 27382*

ARMAGNAC
5m
• 27380

CHILDREN
3m
• 27383

ANIMALS
5m
• 27384

*Not suitable for Portugal

See economic optometric charts at page 273

MD SCOPE VIDEO OTOSCOPE

MD SCOPE VIDEO OTOSCOPE

Instant View

A clear and sharp image can be acquired and displayed instantly on a built-in screen. Just press a single button and wait for 3 seconds.

Real Time Interaction

Medical image can be captured and shared simultaneously to improve interaction between health professionals and patients.

Electronic medical record

A medical image is automatically generated to support most of the stand-alone health information system. Simply plug the cable into the video-out socket to retrieve the image.

With video otoscope MS102



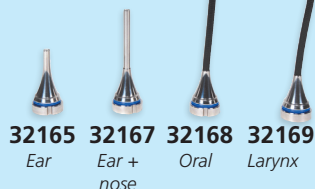
25.5x16x7 cm

32163

• 32163 ELITE PACK MS102

- MD Scope with
- 1 camera probe 47 mm Ø 4.2 mm
- mini USB cable set
- 12 disposable specula
- internal Li-ion battery and charging cradle
- carrying case

Detachable camera modules are designed for different examinations as needed



32165 32167 32168 32169

Ear Ear + nose Oral Larynx



With video otoscope MS101

32162

• 32161 DELUXE PACK MS101 - 2 cameras

• 32162 DELUXE PACK MS101 - 4 cameras

- MD Scope with
- 2 camera probes 45 (Ø 5.2 mm)/150 (32161)
- 4 camera probes 45 (Ø 5.2 mm)/75/150/300 mm (32162)
- image dongle (32162 only)
- cable set (32176): USB and RCA cable, adaptor for image dongle
- 24 disposable specula
- 2 AA alkaline batteries
- carrying case

A video port provides simultaneous image to display on TV/monitor or to download to Mac/PC system

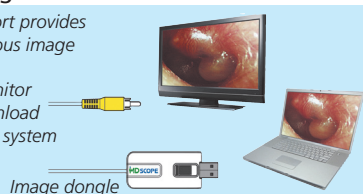


Image dongle

MS101



Size: 7.5x6.3x21.2 cm

Weight: 180 g

MS102



Size: 9.5x8.5x21 cm

Weight: 250 g

Image zoom in/out

Built-in Image storage: 1,000 photos

Brightness control

Li-ion rechargeable battery lifespan: 4 hours

32163

Colour LCD display 2.4" (32161-2) 3" (32163)

Image freeze function

Video out port

Image resolution 320x240 pixels (32161-2) 640x480 pixels (32163)

CE FDA US pat. n° 8206290

GIMA code	ACCESSORIES AND SPARE PARTS
32165	Camera probe 45 x Ø 5.2 mm - adult
32166	Camera probe 47 x Ø 4.2 mm - adult/child
32167	Long camera probe 75 x Ø 5.2 mm
32168	Flexible camera probe 150 x Ø 5.2 mm
32169	Long flexible camera probe 300 x Ø 5.2 mm
32172	Disposable rigid specula 37 x Ø 5 mm for 32165 - 32166 box of 250
32173	Reusable silicone specula 36 x Ø 4.2 mm for 32166 - box of 24
32175	Cradle for video otoscope 32160 - 32162
32176	Cable set (USB and RCA cable, adaptor)
32174	Charging cradle for video otoscope 32163

DIGITAL Wi-Fi & USB VIDEOTOSCOPE + SOFTWARE



32180

Basic software included for acquisition of photos, videos, google/apple applications

- 32180 Wi-Fi & USB VIDEOTOSCOPE with software
- Innovative, handheld colour digital Otoscope with Wi-Fi wireless transmission. Small, easy to operate, light and portable. It can be used with all the most popular smartphones, tablets and even with PC.
- Designed in Italy, made in China.

- 32188 DISPOSABLE EAR SPECULUM Ø 3.5 mm - black - box of 100

- 32189 DISPOSABLE EAR SPECULUM Ø 4.3 mm - black - box of 100

- 32192 DISPOSABLE VET SPECULUM Ø 5/6/7 mm and Ø 7/8 mm slotted for Hartmann Tweezers - kit of 5



32192

TECHNICAL SPECIFICATIONS

Operation system:	Windows (7, 10), Mac (OS X 10.7 and following), iOS, Android
Photo and video resolution:	1.3 MPixels - 1,280x1,024 (MJPG), 640x480 (MJPG), 320x240
Frame rate:	15 fps 1280x1024, 30 fps 640x480 320x240
Wi-Fi wireless transmission distance:	up to 5 m
Power consumption:	max 2.5 W
Li-ion battery:	continuous working time - approx. 2 hours, full charging time - approx. 2 hours
Power source:	DC 5.0 V / 1A
Size - weight:	Ø 36x142 mm - 88 g
Camera	
Camera sensor:	CMOS 1/4"
Optical features:	Exposure: Auto, Gamma: Auto, White balance: Auto, Black reference: Auto
Otoscope	
Magnification:	25 X - 50 X
Focus range:	8-160 mm
Object distance:	1-160 mm
Light source:	4 adjustable white LED
Lens:	high definition microscopy lens
Software interface	Mic-Fi Apps for Android and iOS system and Mic-Fi softwares for PC and MAC

STANDARD ACCESSORIES

9 disposable speculum (3x3.5, 3x4.3, 3x5.0 mm)	Plastic stand
USB AC adapter and cable	Manual (GB, FR, IT, ES, DE)
CD basic software Win (GB, FR, IT, ES, DE, UA, JP) Mac (GB)	

DIGITAL SEALING MACHINES WITH/WITHOUT DOT MATRIX PRINTER



35909, 35910

MADE IN ITALY

- **35909 D-400 SEALING MACHINE** without printer
 - **35910 D-500 SEALING MACHINE** with dot matrix printer
- Continuous sealing machines for medical pouches according to DIN rules 58953-7:2010 with or without dot matrix printer. They allow a 12 mm multi-line seal and features stand-by function and automatic infeed through photocell. D-500 is equipped with **built-in printer** to print different data on the bag (sterilization/expiry dates) during the sealing process in order to provide constant control on the sterility of your instruments, especially when the paper layer of the

sterilization bag is less tight, after 30 days, and consequently losing instruments sterility. Built in epoxy coated stainless steel. D-400 and D-500 are sophisticated units controlled by a microprocessor and equipped with a device to adjust temperature (displayed by LCD) and printing parameters. **The sealing pressure is automatically adjusted according to the material thickness.** It also guarantees 30 mm safety distance between seal and product, according to DIN rules. Easy to use and maintenance-free, they are the ideal solution for clinics and hospitals. Compatible for sealing with Tyvek rolls and envelopes. Manual in GB, IT.

- **35912 INK-CARTRIDGE D-500/700 - spare part**



TECHNICAL SPECIFICATIONS

	35909	35910
Infeed speed	6 m/min	
Temperature control	by digital thermoregulator	
Sealing temperature	40°÷200° C	40°÷180° C
Temperature tolerance	±5°C	
Seal	Multiline	
Seal width	12 mm	
Adjustable free edge	0 ÷ 30	
Power supply	230 V-50 Hz-single phase	
Absorption	500 W	600 W
Dimensions	473x235x181 mm	
Net weight	11.5 kg	12 kg

SEALING MACHINES WITH VALIDATION SYSTEM



35915, 35916

ISO 11607 P.2,
ISO/TS 16775

MADE IN ITALY

- **35915 D-600 ROTARY HEAT SEALER** - without printer
 - **35916 D-700 ROTARY HEAT SEALER** - with printer
- GIMA 600 and GIMA 700 have been designed to continuously monitor, during the whole sealing phase, all critical process parameters: Temperature, Speed, Pressure. They guarantee sealing in full respect of EN 868-5 / ISO 11607 P.2 rules, provide real-time monitoring of working temperature, applied force and running speed, time used during the sealing process.

All sealing data can be recorded on an external carrier which can be linked to the sealer through a USB port placed on the unit. They are controlled by a microprocessor.

Operator's interface is a clear 2 line display, integrated in an ergonomic keyboard placed at the upper side of the sealer in an user friendly position.

Simple use, high reliability, they are the ideal solution for hospitals and clinics.

Compatible for use with Tyvek rolls and envelopes.

Manual in GB, IT.

- **35912 INK-CARTRIDGE D-500/700 - spare**

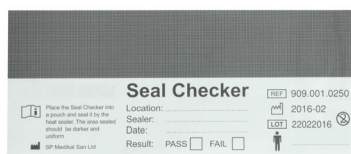
TECHNICAL SPECIFICATIONS

	35915	35916
Sealing width	12 mm	12.5 mm
Seal	multiline	
Sealing speed	6 m/min	8.5 m/min
Temperature adjustment/ tolerance	10-200°C ± 5 °C	
Alarms functioning out of tolerance	yes	yes
Automatic stand-by	yes	yes
4 key membrane keyboards	yes	yes
LCD display 2 lines	6 characters	8 characters
Multilingual menu	yes	yes
USB port	yes	yes
Data storage on pendrive	yes	yes
Power	230 V / 50 Hz - single-phase (on request 110 V, 60 Hz)	
Max electrical input:	500 W	500 W
Dimensions - Weight:	473x235x181 mm - 12.5 kg	

SEAL CHECKER

Dimension:
175x75 mm

Suitable for
all rotary heat
sealers



It can display heat sealer problems:
- too low sealing temperature
- too low sealing pressure
- seal interruptions

- **35957 SEAL CHECKER** - box of 250 pcs

The ISO-11607 standard is specifying a routine, daily check of your heat sealers.

The seal checker is a way to perform the test required and to document which sealer, which day, which person did perform the test and to easily show results of your heat sealer capacity of properly heat seal your pouch.

When place inside a pouch and seal, the sealed area will be darker and can be easily read whether the seal is consistent, regular and completely without any gaps.

3M™ ATTEST™ INSTRUMENT PROTECTOR

- **35964 3M™ ATTEST™ INSTRUMENT PROTECTOR 5x12.5 cm 13911** - box of 1000

- **35965 3M™ ATTEST™ INSTRUMENT PROTECTOR 8.9x16.5 cm 13913** - box of 1000

Designed to cover the pointed and cutting edges of surgical instruments in steam or ethylene sterilization.

Reduces the possibility of pouch puncture during sterilization.

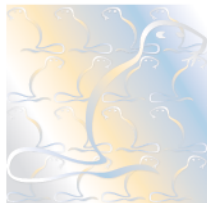
Indicators on the protectors verify steam or EO gas processing.



Scissors
not included



35965



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

Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

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

Management of design and production, packaging and service of:

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

Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

Chief Operating Officer
Giampiero Belcredi

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

This certificate is composed of 1 page.

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

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www.kiwa.it

CERMET

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) - Italia





Reg. Numero /
Reg. Number

MED 26036

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Revision

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Valid from

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2024-05-26

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2021-05-24

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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 / Registered Headquarter

Via Tommaso Grossi, 2
20121 Milano, MI - Italia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato V, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex V, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*
Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / *Sterile Single use gynaecology and ENT devices*
Dispositivi per aerosolterapia / *Aerosol therapy devices*
Dispositivi per la misurazione della pressione sanguigna / *Blood pressure measuring devices*
Dispositivi per la misurazione della saturazione di ossigeno / *Oxygen saturation measuring devices*
Dispositivi per la misurazione della temperatura corporea / *Body temperature measuring devices*
Dispositivi per la misurazione di parametri fisiologici / *Physiological parameters measuring devices*
Dispositivi per rianimazione ed assistenza respiratoria / *Respiratory care and resuscitation devices*
Dispositivi per terapia termica / *Thermic therapy devices*
Kit di strumentario chirurgico monouso sterile / *Sterile single use surgical instrument kit*
Strumentario chirurgico monouso sterile / *Sterile single use surgical instrument*

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

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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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:

Dispositivi attivi per l'aspirazione di sostanze e liquidi / Active substances and liquids suctioning devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1104

Marca / Brandname:

VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

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

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
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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:

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

Modello / Model:

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

Codici / Codes:

29745 ; 29748-29749

Modello / Model:

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

Codici / Codes:

29991

Modello / Model:

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

Codici / Codes:

29946 ; 29947 ; 29948

Modello / Model:

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

Codici / Codes:

29987

Modello / Model:

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

Codici / Codes:

29995

Modello / Model:

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

Codici / Codes:

29986

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Chief Operating Officer
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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Modello / Model:

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

Codici / Codes:

29983; 29984 ; 29985 ; 29976; 29977, 29978

Modello / Model:

Tampone di trasporto in plastica sterile / Sterile plastic transport swab

Codici / Codes:

29753

Marca / Brandname:

Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Codici / Codes:

29735 ;29736 ; 29737

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Proctoscopio adulti / Adult proctoscope

Codici / Codes:

25957

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Chief Operating Officer
Giampiero Belcredi

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Codici / Codes:

28091 ; 28092

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / Brandname:

MISTRAL

Modello / Model:

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

Codici / Codes:

28102

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 0104

Marca / Brandname:

BOSTON / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TECNICO PROFEXIONAL / DAYTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

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

Marca / Brandname:

SIRIO

Modello / Model:

Manometro Aneroido / Aneroid manometer

Codici / Codes:

32904

Marca / Brandname:

YTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

32720; 32703; 32693; 32701

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MDS 7010

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Tipologia / Medical Devices:

Dispositivi per la misurazione della pressione sanguigna / Blood pressure measuring devices

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital Sphygmomanometers WRIST / ARM

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / Brandname:

DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / Medical Devices:

Dispositivi per la misurazione della saturazione di ossigeno / Oxygen saturation measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione della temperatura corporea / Body temperature measuring devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Marca / Brandname:

DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / Brandname:

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

Modello / Model:

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

Codici / Codes:

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

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

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

Codici / Codes:

25580 ; 25585

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione di parametri fisiologici / Physiological parameters measuring devices

Classe di rischio / Risk class:

I m - Limitatamente agli aspetti relativi ai requisiti metrologici / restricted to the aspects concerned the metrological requirements

Codice NANDO / NANDO codes:

MD 1301, MD 0104

Modello / Model:

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

Codici / Codes:

27335 ; 27344; 27331

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0101, MDS 7006 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Codici / Codes:

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

Modello / Model:

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

Codici / Codes:

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

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Codici / Codes:

34424; 34425, 34426, 34427, 34428, 34429

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Modello / Model:

Palloni rianimatori in silicone / Kit Palloni rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit

Codici / Codes:

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

Modello / Model:

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

Codici / Codes:

34257; 34258; 34275; 34279

Modello / Model:

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

Codici / Codes:

34227 ; 34228 ; 34259 ; 34256

Tipologia / Medical Devices:

Dispositivi per terapia termica / Thermic therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack

Codici / Codes:

34110 ; 34111

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Kit di strumentario chirurgico monouso sterile / Sterile single use surgical instrument kit

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

38950 ; 38951

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

Modello / Model:

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

Codici / Codes:

388xx

Modello / Model:

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

Codici / Codes:

388xx

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0106, MDS 7006 Radiation

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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:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Modello / Model:

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

Codici / Codes:

388xx ; 389xx

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

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