

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).

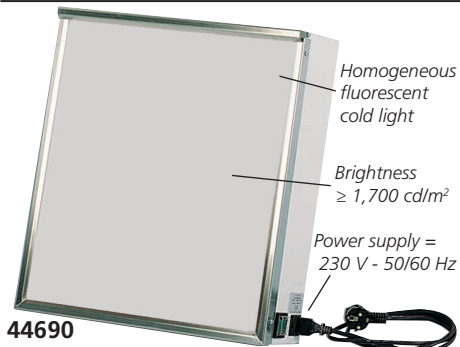
TECHNICAL SPECIFICATIONS

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.

In conformity with MDR.

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



MONOYER
3m
• 27381

MIXED DECIMAL
3m
• 27382*

ARMAGNAC
5m
• 27380

CHILDREN
3m
• 27383

ANIMALS
5m
• 27384

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	-

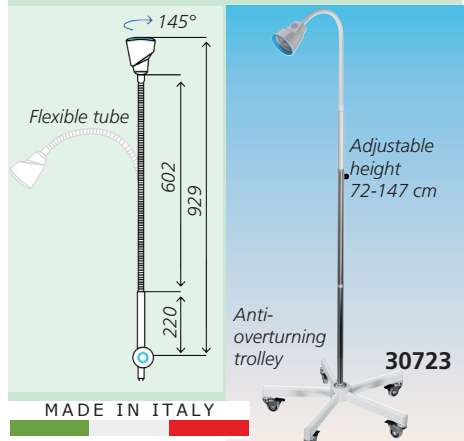
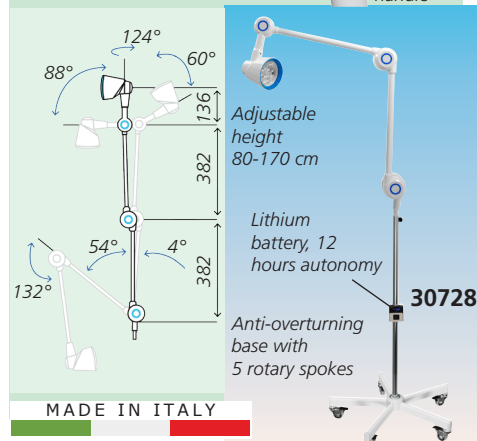
TECHNICAL SPECIFICATIONS

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

*Not suitable for Portugal

See economic optometric charts at page 273

HALOGEN AND LED LIGHTS FOR EXAMINATION AND MINOR SURGERY



ALFA-FIX AND ALFA-FLEX

Three LED light sources with coinciding lenses and polycarbonate protection shield. Thanks to three independent light sources, shadows can be reduced and provide a deep cylindrical light with highly reduced heat irradiation. Each LED integrates a resistance to ensure the continuous operation of the lamp even in the rare case of a LED fault.

Design

New design makes the lamp extremely easy to use and manoeuvre, with an additional rotation of the reflector.

Touch control

The light intensity can be adjusted through the touch button, a smooth touch of the control allows to regulate the light intensity from 4% to 100%.

Interchangeable plugs

The transformer, integrated in the plug for a lighter and smooth movement

of the arm structure, is supplied with interchangeable plugs (UK, US, EU).

Flexible arm (30723-5)

The flexible arm ensures easier light positioning and is covered with a smooth white shrink-wrap sheath for easier cleaning and disinfection.

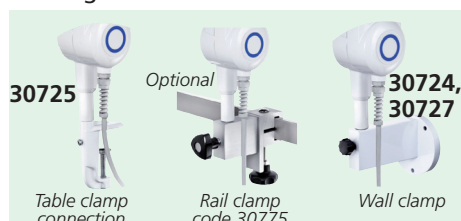
Battery kit

Included with 30728, available in 45 days for 30723 (to be purchased with light).

QR manual: GB, FR, IT, ES, PT.

GIMA code	ALFA-FIX AND ALFA-FLEX
30723	Alfa-flex LED - trolley
30724	Alfa-flex LED - wall
30725	Alfa-flex LED - table with clamp
30726	Alfa-fix LED - trolley
30727	Alfa-fix LED - wall
30728	Alfa-fix LED - trolley with battery

ACCESSORIES AND SPARE	
30766	Spare bulb Simplex - IRC 35 W for 30760-30763
30768	Spare trolley, base Ø 61 cm for Simplex and Alfaflex
30769	Spare trolley, base Ø 61 cm for Solesud2 and Alfafix
30775	Rail connection with clamp
30772	Spare glass Ø 8.5 cm for 30723-30727
30770	Spare glass Ø 12.3 cm for Solesud



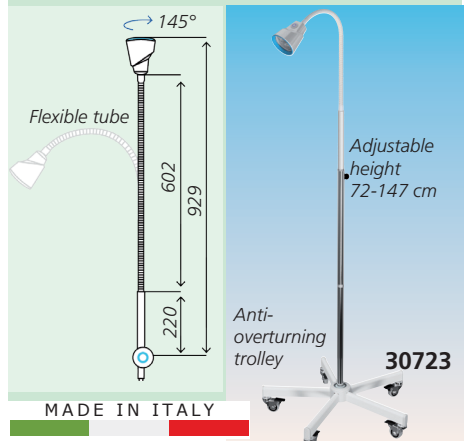
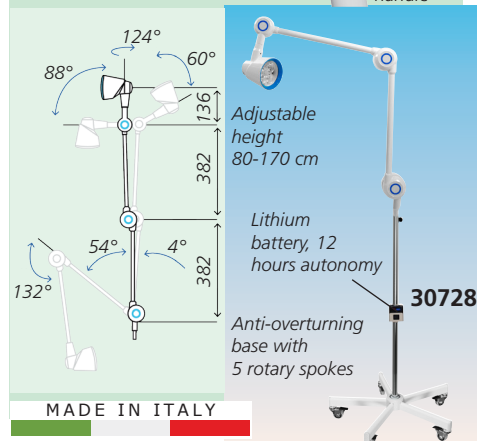
Model	ALFA-FIX	ALFA-FLEX	LUXIFLEX	LED	LED Plus
Type of lighting	LED	LED	halogen	LED	LED Plus
Consumption (Watt)	8	8	35	6.5	10
Life of the bulbs (hours)	> 60,000	> 60,000	5,000	50,000	50,000
Light intensity at 50 cm (lux)	60,000	60,000	50,000	15,000	35,000
Light intensity at 1 m (lux)	20,000	20,000	-	-	-
Colour temperature ± 5% at 1 m (K)	4,500	4,500	4,000	4,500	4,500
Colour rendering index (Ra)%	94	94	95	80	97
Light field size at 50 cm (Ø mm)	150	150	80	80	80
External Ø of the reflector (mm)	95	95	80	80	80
Colour	white	white	white	white	white
Norms	IEC 60601-1	IEC 60601-1	EN 60601-1-2		
Marks	EU 2017/745		CE 93/42		
Weight (kg)	5	5			
Operating voltage V	100-240	100-240	230	110/230	
Operating Hz	50/60	50/60		50/60	

- 30754 LUXIFLEX on trolley - halogen
 - 30756 LUXIFLEX on trolley - LED
 - 30755 LUXIFLEX PLUS on trolley - LED
- Stylish and versatile light for examination and minor surgery procedures in health-centres, clinics and hospitals. Suitable also for veterinary examinations and procedures. Class II.
- Safe low voltage operation without infrared radiation. Electronic transformer lodged at the bottom of the lamp. Flexible arm and 5 castors trolley allow easy use and movability.

- 30757 SPARE BULB LUXIFLEX - halogen



HALOGEN AND LED LIGHTS FOR EXAMINATION AND MINOR SURGERY



ALFA-FIX AND ALFA-FLEX

Three LED light sources with coinciding lenses and polycarbonate protection shield. Thanks to three independent light sources, shadows can be reduced and provide a deep cylindrical light with highly reduced heat irradiation. Each LED integrates a resistance to ensure the continuous operation of the lamp even in the rare case of a LED fault.

Design

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Touch control

The light intensity can be adjusted through the touch button, a smooth touch of the control allows to regulate the light intensity from 4% to 100%.

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Type of lighting	LED	LED	halogen	LED	LED Plus
Consumption (Watt)	8	8	35	6.5	10
Life of the bulbs (hours)	> 60,000	> 60,000	5,000	50,000	50,000
Light intensity at 50 cm (lux)	60,000	60,000	50,000	15,000	35,000
Light intensity at 1 m (lux)	20,000	20,000	-	-	-
Colour temperature ± 5% at 1 m (K)	4,500	4,500	4,000	4,500	4,500
Colour rendering index (Ra)%	94	94	95	80	97
Light field size at 50 cm (Ø mm)	150	150			
External Ø of the reflector (mm)	95	95	80	80	80
Colour	white	white	white	white	white
Norms	IEC 60601-1	IEC 60601-1	EN 60601-1-2		
Marks	EU 2017/745		CE 93/42		
Weight (kg)	5	5	110/230		
Operating voltage V	100-240	100-240	230	110/230	
Operating Hz	50/60		50/60		

- 30754 LUXIFLEX on trolley - halogen
 - 30756 LUXIFLEX on trolley - LED
 - 30755 LUXIFLEX PLUS on trolley - LED
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- 30757 SPARE BULB LUXIFLEX - halogen



GIMA STRETCHERS AND SPINAL BOARDS

CE



• **34101 GIMA STRETCHER 2 - foldable in 2**
Emergency stretcher is sturdy, but lightweight in construction, with aluminium frame and two solid iron cross-bars for heavy use. Reinforced nylon canvas, fluid repellent and non-tear.

• **34107 GIMA STRETCHER 4 - foldable in 4**
Made of strong alloy and water-tight material. Lightweight, easy to carry, foldable in 4. Length and width are foldable in 2 parts.

• **34076 BLUE STRETCHER - foldable in 2**
Lightweight, small sized, easy to carry. High-strength aluminium poles and vinyl coated waterproof nylon canvas.

• **34077 WHEEL STRETCHER - foldable in 2**
Provided with wheels, outriggers and adjustable backrest. High strength aluminium poles and vinyl coated, waterproof nylon canvas. Lightweight, small sized, easy to carry.

• **34092 VALUE SPINAL BOARD**
Lightweight, strong and economic high-density PE plate. Suitable for Radiolucent MRI and CT scan. Easy-slide allows efficient and smooth movement of patients. Board floats, excellent for water rescues.

• **34083 SPINAL BOARD**
80% X-ray translucent*, washable, buoyant and impervious to all fluids. Made of linear high density polyethylene with plastic pins. Compatible with all head-immobilization devices and strapping system. CT and MRI transparent. Colour orange.
**X-ray translucence is mainly intended for the central part of the stretcher.
No translucence on the handles*

• **34022 B-BAK PIN SPINAL BOARD - yellow**
PE spinal board with Pin with robust and light structure to ensure high resistance. The 14 handles and their shape offer an easy grip, the low thickness make the application easier. Equipped with 8 plastic pins to allow easy fixing of belts with snap hook. Multilingual manual: GB, FR, IT, ES, PT, DE, GR, CZ.

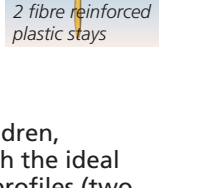
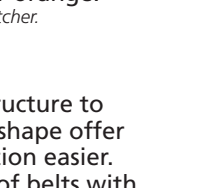
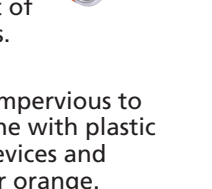
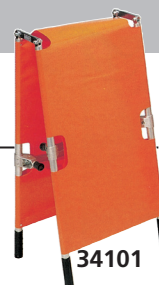
• **34097 SPINAL BOARD WITH SAFETY GLASS FIBRE PINS - orange**
Strong and lightweight high density PE spinal board, with two fibre reinforced plastic stays. Provided with glass fibre pins for better fixation of immobilisation belts. Excellent in water rescues. X-ray translucent, except 2 plastic stays.



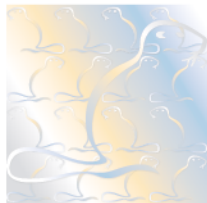
• **34023 BABY GO PEDIATRIC SPINAL BOARD**
Baby go is a professional board, designed for children, which maintains the spine in neutral position with the ideal alignment for air flow. Board has four different profiles (two each side) which guarantee the correct position of the child according to his body size (from 47 to 150 cm). Includes 2 straps to fasten head immobilizer according to child height. Multilingual manual: GB, FR, IT, ES, PT, DE, GR, CZ.

• **34024 PEDIATRIC HEAD IMMOBILIZER**
Ensure optimal immobilization of the head of children perfectly fitting their pronounced occipital prominence.

• **34025 PEDIATRIC SPIDER STRAP SYSTEM**
Multilingual manual: GB, FR, IT, ES, PT, DE, DK, NL, FI, SE, NO, LV, GR, BG, CZ, RO, RS.



TECHNICAL SPECIFICATIONS	34101 GIMA 2	34107 GIMA 4	34076 BLUE	34077 WHEEL	34092 VALUE SPINAL	34083 SPINAL	34022 SPINAL WITH PINS	34097 SPINAL WITH PINS	34023 PAED SPINAL
Open size cm:	203x50x14	221x53x16	188x45x7	188x53x21	183x43x7	184x44.5x6.5	184x40.5x4.5	183x46x5	119.5x32x4.5
Folded size cm:	96x50x17	104x19x12	94x48x10	92x53x12	-	-	-	-	-
Weight:	6 kg	5 kg	4 kg	8 kg	8 kg	7.6 kg	6 kg	7 kg	2.2 kg
Load:	120 kg	159 kg	159 kg	159 kg	159 kg	150 kg	180 kg	200 kg	30 kg



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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E-mail: info@kiwacermet.it
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

Revisione /
Revision

23

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2006-10-25

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Valid from

2021-05-24

Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 1 di / of 12

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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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

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

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
Reg. Number

MED 26036

Revisione /
Revision

23

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Valid from

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Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

Pagina / Page 2 di / of 12

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1104

Marca / Brandname:

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

Modello / Model:

Aspiratori chirurgici / Surgical aspirators

Codici / Codes:

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

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

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

Codice NANDO / NANDO codes:

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

Modello / Model:

Kit ORL sterile / Sterile ENT kit

Codici / Codes:

31456

Modello / Model:

Kit pap test / Pap smear kit

Codici / Codes:

29704

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Chief Operating Officer
Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 25/05/2021 10:11:56



Organismo Notificato n. 0476
Notified Body nr. 0476



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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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Giampiero Belcredi

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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 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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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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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Modello / Model:

Sfigmomanometri Digitali DA POLSO / DA BRACCIO / Digital 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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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 forehead multifunction thermometers

Codici / Codes:

25580 ; 25585

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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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