

GIMA GREEN F.O. XENON/HALOGEN AND LED LARYNGOSCOPES

GIMA GREEN LARYNGOSCOPES

- maximum light transmission thanks to durable and high quality fibres
- specially designed blades for easy intubation
- matt finished to reduce glare
- autoclavable up to 134°C for 5 minutes. Blades autoclavable up to 2,000 times
- compatible to plasma sterilization
- all blades are compatible to BS EN ISO 7376 Green standard handles
- all blades are made from Austenitic Stainless steel thereby making them rust proof
- long life blades. GIMA offers 3 years Warranty
 - a large selection of power sources to use: 'AA' and 'C' type batteries or 2.5 V and 3.5 V rechargeable batteries
 - 2.5 V handles can be used with standard or rechargeable batteries
 - handles are available with 2.5 V and 3.5 V Xenon/Halogen and LED bulbs
 - all blades and handles are non magnetic

Mc INTOSH
BLADES

MILLER BLADES

MAXLITE

58056

58052

GIMA GREEN

Mc INTOSH blade

MILLER blade

Gima Green and Maxlite: Miller and Mc-Intosh blades

- Gima Green 4.0 mm Ø F.O. bundle with more than 5,500 individual fibre strands
- Miller Maxlite 3.0 mm Ø bundle with more than 5,000 individual fibre strands
- McIntosh Maxlite 4.5 mm Ø bundle with more than 6,500 individual fibre strands

High quality fibres ensuring excellent light transmission Gima Green and Miller

Maxlite: 7,000 lux with 2.5 V Xenon/Halogen lamp, 12,500 lux with 3.5 V Xenon/Halogen lamp, 18,000 lux with 2.5 LED lamp, 30,000 lux with 3.5 V LED lamp

McIntosh Maxlite: 8,000/14,000/20,000/40,000 lux

GIMA code	"GIMA MAXLITE" FIBRE OPTIC BLADES	A	B
58051	MILLER N° 0 blade - Newborn	80	55
58052	MILLER N° 1 blade - Infant	100	75
58056	Mc INTOSH N° 0 blade - Newborn	82	57
58057	Mc INTOSH N° 1 blade - Infant	93	68
58058	Mc INTOSH N° 2 blade - Child	115	90
58059	Mc INTOSH N° 3 blade - Adult	135	110
58060	Mc INTOSH N° 4 blade - Adult large	155	130
58061	Mc INTOSH N° 5 blade - Adult x-large	176	151
GIMA code	"GIMA GREEN" FIBRE OPTIC BLADES*	A	B
34460	MILLER N° 00 OXY blade - Premature	65	40
34461	MILLER N° 0 blade - Newborn	78	53
34462	MILLER N° 1 blade - Infant	102	77
34463	MILLER N° 2 blade - Child	155	130
34464	MILLER N° 3 blade - Adult	195	170
34469	Mc INTOSH N° 0 blade - Newborn	80	55
34470	Mc INTOSH N° 1 blade - Infant	92	67
34471	Mc INTOSH N° 2 blade - Child	100	75
34472	Mc INTOSH N° 3 blade - Adult	130	105
34473	Mc INTOSH N° 4 blade - Adult large	155	130
34474	Mc INTOSH N° 5 blade - Adult x-large	175	150

*equipped with detachable fibre optic light guide

F.O. LIGHT GUIDE FOR GIMA GREEN BLADES

34483	F.O. Light guide for "GIMA Green" N°3
34484	F.O. Light guide for "GIMA Green" N°4
34486	F.O. Light guide for "GIMA Green" other - specify code

- **31542 GIMA GREEN CHARGING STATION - 100/200 V - 50/60 Hz**
It can charge either 2.5 V / 3.5 V NiCa, NimH or Li-ion rechargeable batteries independently of their status of charge. Unit is designed to prevent over charging of batteries. Simultaneously charging of pediatric and adult handle.



Charging station includes pediatric adaptor,
wall support, UK, US and EU plug

327

HALOGEN/XENON
BATTERY HANDLE

LED BATTERY HANDLE

Provide higher white illumination

Colour
temperature:
5,500 K
CRI>80

— Ø 1.8 cm

 $\sim \varnothing 2.7 \text{ cm}$

Xenon/Halogen and LED handles 2.5 V and 3.5 V

- closed battery compartment prevent liquid penetrating inside the battery
 - handles are supplied with lamp. Battery not included
 - solid metal handle of chromium plated metal
- Ø 2.7 cm

GIMA GREEN RECHARGEABLE BATTERY HANDLES

GIMA code	F.O. XENON/HALOGEN BATTERY HANDLES - 2.5 V
34480	Pediatric rechargeable metal handle (2xAA) - 2.5 V
34481	Adult rechargeable metal handle (2xC) - 2.5 V
34466	Pediatric rechargeable Li-Ion battery 2.5 V 1,000 mAh
34467	Adult rechargeable Li-Ion battery 2.5 V 2,200 mAh
34485	Halogen bulb 2.5 V (minimum order 6 pcs)
"GIMA GREEN" RECHARGEABLE HANDLES AND BATTERIES 3.5 V - OLD up to lot 8 (ped handle) up to lot 7 (adult handle)	
34487	Pediatric rechargeable metal handle (3.5 V) - old
34488	Adult rechargeable metal handle (3.5 V) - old
34489	Pediatric rechargeable NiCa battery 3.5 V/700 mAh for 34487
34490	Adult rechargeable NiCa battery 3.5 V/1,300 mAh for 34488
34491	Halogen Bulb 3.5 V
F.O. XENON/HALOGEN BATTERY HANDLE 3.5 V	
34456	Pediatric rechargeable metal handle (3.5 V)
34457	Adult rechargeable metal handle (3.5 V)
31540	Pediatric rechargeable Li-ion battery** 3.5 V for 34456
31541	Adult rechargeable Li-ion battery** 3.5 V for 34457, 34482
	<i>**for handles sold after may 2013</i>
34491	Halogen Bulb 3.5 V
F.O. LED BATTERY HANDLES 2.5 V AND 3.5 V	
34476	Pediatric LED rechargeable handle 2.5 V
34477	Adult LED rechargeable handle 2.5 V
34482	Adult rechargeable metal handle - LED light 3.5 V

COMPATIBILITY HANDLE - BATTERY - BULB

GIMA code	Handle		V	Battery		Rechargeable Li-ion*	Bulb
	Xenon	LED		Standard 2xAA	2xC		
34480	Ped.	-	2.5	yes	no	34466	34485
34481	Adult	-	2.5	no	yes	34467	34485
34456	Ped.	-	3.5	no	no	31540	34491
34457	Adult	-	3.5	no	no	31541	34491
34476	-	Ped.	2.5	yes	no	34466	-
34477	-	Adult	2.5	no	yes	34467	-
34482	-	Adult	3.5	no	no	31541	-

***Li-ion batteries** have twice the capacity of an equivalent size NimH batteries.

GIMA GREEN F.O. XENON/HALOGEN, LED LARYNGOSCOPE SETS



GIMA F.O. XENON/HALOGEN AND LED SETS

- Mc Intosh or Miller blades

- F.O. laryngoscopes provide cool bright illumination
- Gima Green F.O. blades with detachable fibre or Maxlite F.O. blades with integrated fibre
- Xenon/Halogen or LED F.O. rechargeable battery handle (battery not included). 2.5 V rechargeable battery handle can be used with standard or rechargeable batteries. Rechargeable battery handles should be used with charging station 31542 (not included).
- non magnetic blades and handles

LARYNGOSCOPE SET WITH F.O. BLADES

GIMA code	GIMA GREEN F.O. XENON/HALOGEN SET - 2.5 V	
34451	Pediatric set	2 blades Miller 0-1
34454	Pediatric set	3 blades Miller 0-1, Mc Intosh 0
34452	Adult set	3 blades Mc Intosh 2-3-4
34453	Adult set	4 blades Mc Intosh 1-2-3-4
34455	Doctor set	3 blades Miller 1-2-3
34485	Halogen bulb 2.5 V (minimum order 6 pcs)	
34450	Empty box without sponge	
GIMA code	GIMA GREEN F.O. LED SET - 2.5 V OR 3.5 V	
34327	Adult set	3 blades Mc Intosh 2-3-4 - 2.5 V
34328	Adult set	4 blades Mc Intosh 1-2-3-4 - 2.5 V
34329	Adult set	3 blades Mc Intosh 2-3-4 - 3.5 V
34330	Adult set	4 blades Mc Intosh 1-2-3-4 - 3.5 V

MAXLITE F.O. BLADE WITH INTEGRATED FIBRE

Built with an integrated F.O. bundle with no cavities to trap dirt or body fluids, this allowing the blade to be easily cleaned and decontaminated.



GIMA GREEN F.O. BLADE

TECHNICAL SPECIFICATIONS - BLADES AND BULBS

	Gima Green F.O. blade	Maxlite F.O. Mc Intosh blade
Fibre light carrier:	detachable	integrated
F.O. bundle Ø:	4.0 mm	4.5 mm
Individual fibre strands:	> 5,500	> 6,500
Light transmission with 2.5 V (Xenon):	7,000 lux	8,000 lux
Light transmission with 2.5 V (LED):	18,000 lux	20,000 lux
Light transmission with 3.5 V (Xenon):	12,500 lux	14,000 lux
Light transmission with 3.5 V (LED):	30,000 lux	40,000 lux
Autoclavable at 134 °C:	2,000 times	2,000 times
LED bulb life:	50,000 hours	50,000 hours

LARYNGO SET WITH F.O. BLADES - INTEGRATED FIBRE

GIMA code	MAXLITE F.O. XENON/HALOGEN SET - 2.5 V	
34332	Pediatric set	3 blades Miller 00-0-1
34333	Adult set	3 blades Mc Intosh 1-2-3
34334	Adult set	4 blades Mc Intosh 1-2-3-4
34485	Halogen bulb 2.5 V (minimum order 6 pcs)	
GIMA code	MAXLITE F.O. LED SET - 2.5 V or 3.5 V	
34336	Pediatric set	3 blades Miller 00-0-1 - 2.5 V
34335	Adult set	3 blades Mc Intosh 2-3-4 - 2.5 V
34337	Adult set	4 blades Mc Intosh 1-2-3-4 - 2.5 V
34338	Adult set	4 blades Mc Intosh 1-2-3-4 - 3.5 V
GIMA code	BATTERIES for GIMA GREEN and MAXLITE	
34466	Pediatric rechargeable Li-ion battery 2.5 V	1,000 mAh
34467	Adult rechargeable Li-ion battery 2.5 V	2,200 mAh
31541	Adult rechargeable Li-ion battery 3.5 V*	

*Packed and shipped at half charged state

FLEXTIP F.O. XENON/HALOGEN AND LED SETS FOR DIFFICULT INTUBATIONS

F.O. SET FOR DIFFICULT INTUBATION

Deluxe boxed set including one F.O. rechargeable handle, one or two F.O. Mc Intosh blades N° 3 or N° 3 and 4, for difficult intubations and bulb. The movable blade tip facilitates lifting of the epiglottis and enables a perfect visibility of the intubation process even in case of difficult anatomical conditions. A better visibility and a lower lever force reduce the risk of injury of the larynx and the teeth. Autoclavable at 134° C.

- stainless steel construction, matt finish
- can be used with all Green Spec Handles
- compatible with ISO 7376 Green Standards
- channel provides improved viewing area
- 4.0 mm fibre bundles (GimaGreen) or 4.5 mm fibre bundle (Maxlite) for maximum light output
- 2x"C" batteries or rechargeable batteries



34492



34494

34493

GIMA code	FLEXTIP F.O. SET - 2.5 V	
34492	GIMA GREEN FLEXI F.O. SET 1 blade Mc Intosh 3	
34495	GIMA GREEN FLEXI F.O. SET 2 blades Mc Intosh 3-4	
34498	MAXLITE F.O. LED FLEXI SET 2 blades Mc Intosh 3-4 with integrated fibre	

GIMA code	ACCESSORIES AND SPARES	
34493	FLEXI F.O. BLADE N° 3 Mc Intosh (130x105 mm)	
34494	FLEXI F.O. BLADE N° 4 Mc Intosh (155x130 mm)	
34485	Bulb 2.5 V - spare	
34467	Adult rechargeable Li-ion battery 2.5 V	
31542	Charging station 100-240 V - see page 327	

GIMA RESUSCITATION KITS

- 34181 SPEED 1 RESUSCITATION KIT - UNI cylinder
- 34182 SPEED 2 RESUSCITATION KIT - NF cylinder
- 34183 SPEED 3 RESUSCITATION KIT - without cylinder
- 34180 SPEED EMPTY CASE - with sponge
- 34222 FACEMASK N° 2 - child small

First aid kits for reanimation, very useful for medical and dental rooms, sport clubs, factories, ambulances... Case made of anti-shock plastic. Size: 43 x 37 x 11 cm.

STANDARD ACCESSORIES	SPEED 1	SPEED 2	SPEED 3
Silicone resuscitation bag - autoclavable	•	•	•
Silicone Face mask n° 4	•	•	•
Oxygen cylinder 0.5 l (empty). UNI standard	•	•	•
Oxygen cylinder 0.5 l (empty). NF standard	•	•	•
High pressure manometer	•	•	•
Guedel airways (small + medium + large)	•	•	•
Helicoidal mouthwedge + Tongue holding forceps	•	•	•
Atoxing tubing for connection to oxygen cylinder	•	•	•
Plastic case	•	•	•



34181

SPLINTER REMOVAL KIT



34190

• 34190 SPLINTER REMOVAL KIT

Includes everything to remove splinters and for first aid medications. In a polypropylene box size 235x190x43 mm:

- 1 Eye wash solution 100 ml with an eye glass
- 1 magnifying glass, 2 sterile gauze pads 18x40 cm
- 1 Professional removal pencil, 1 mirror.
- 1 stainless steel tweezers 11.5 cm

• 34192 PROFESSIONAL REMOVAL PENCIL

Small metallic splinters eye tool remover. On one side a magnetic point to remove any metallic splinter avoiding any risk for the eye. On the other side an antiabrasive nylon loop for non metallic splinters.

Small metallic splinters, eye tool remove

Anti-abrasive
nylon loop

34192

"NEODIMIO"
magnetic point

The body is made of anodised aluminium and the neoprene seals guarantee a better pencil hold. Supplied in a box and CE marked.

MEDICAL SPORT BAG



- 34135 MEDICAL SPORT BAG
- Special kit designed for first aid in sporting clubs (tennis clubs, swimming pools, gymnasium,...).

Soft nylon bag has 2 side pockets and zip closure.

Size: 470x240x190 mm
Weight: 6.5 kg

STANDARD ACCESSORIES

- | | |
|---|---|
| 1 isothermic blanket Gold/Silver 160x210 cm | 1 pack of 20 adhesive plasters 2x7 cm |
| 1 Disinfectant liquid 250 ml | 8 adhesive plasters 10x6 cm |
| 2 adhesive plasters 5 m x 2,5 cm | 1 sterile TNT bandage 60x40 cm |
| 2 pairs of sterile gloves | 1 sterile TNT bandage 60x80 cm |
| 2 VENTO mouth to mouth resuscitators | 6 sterile TNT pads 10x10 cm |
| 6 sterile gauze pads 18x40 cm | 5 instant ice packs |
| 2 instant ice sprays 150 ml | 1 hydrogen peroxide solution |
| 3 triangular TNT bandages 96x96x136 cm | 1 elastic net bandage |
| 3 Elastic bandages 6 cm | 1 haemostatic lacet |
| 3 Elastic bandages 8 cm | 1 sterile tweezers |
| 1 cotton wool pack | 5 ammonia towelettes |
| 1 pair of LISTER scissors 14,5 cm | 1 sterile saline solution bottle 250 ml |
| 2 compressive pad bandages 80x100 mm | 1 gel hands disinfectant 100 ml |
| 2 compressive pad bandages 100x120 mm | guidance leaflet 5 languages |

EYE WASH SYSTEMS

• 34889 DROP - eye wash station

Thermo-formed wall kit with all necessary items for an efficient first emergency eye wash:

- 2 sterile saline solutions of 500 ml
- 2 integrated eye cups and one mirror.

• 34888 EYE WASH SOLUTION 500 ml

- sterile - spare

34889



FIRST AID FAMILY CASE



Size: 235x190x43 mm

34136

• 34136 FAMILY FIRST AID CASE

Small first aid case suitable for use anywhere and anytime: (at home or office, in the car or boat...). Made in Italy

• 34450 EMPTY CASE

STANDARD ACCESSORIES

- | | |
|--|-----------------------------------|
| 2 sterile gauze pads 18x40 cm | 3 antiseptic wipes |
| 1 pair of scissors. 1 plastic tweezers | 1 adhesive dressing 10 x 6 cm |
| 1 sterile bandage 60x40 cm | 1 gauze bandage 5 cm |
| 1 cotton wool pack 5 g | 1 adhesive plaster roll 2 cm x 1m |
| 1 pack of 10 adhesive plasters | 1 pair of protection gloves |
| 1 tissue pack 10 pcs | Guidance Leaflet 6 languages |

Case in polypropylene

Guidance in:
GB, FR, IT, ES,
DE, TR

FIRST AID CASE AND BAG



34184

Advised for offices or workshops of 2 people
Meets Italian law 388-Art. 2

• 34184 SMALL KIT - plastic case

Size: 290x215x90 mm - 1.4 kg
See content of kit at page 334

• 34188 REFILL PACK for 34184-34185-34194

• 34186 EMPTY PLASTIC CASE

290x215x90 mm

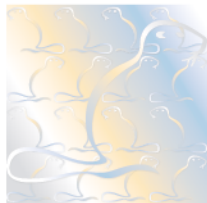
• 34185 MIZAR BAG - nylon

Size: 250x180x90 mm

Same contents as 34184 see page 334

34185





Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2020-05-06
Valid until	2021-10-14		

Previous expiry date

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 manufacturing, trade, packaging and assistance of: medical devices (DM), in vitro-diagnostic medical devices (IVD), accessories

Chief Operating Officer
Giampiero Belcredi

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

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

This certificate is composed of 1 page.

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

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CERMET

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia





Reg. Numero /
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2020-04-24

Pagina / Page 1 di / of 9

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*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Rif. rapporto di audit/ *Ref. audit report:* del/dated 08-14/11/2019

Chief Operating Officer

Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 27/04/2020 08:18:48



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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 e vasi di ricambio / Surgical aspirators and jars

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

Modello / Model:

Kit pap test / Pap smear kit

Modello / Model:

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

Modello / Model:

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

Modello / Model:

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

Chief Operating Officer

Giampiero Belcredi

Firmato digitalmente da: BELCREDI GIAMPIERO
Data: 27/04/2020 08:19:37



Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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CERMET



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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 tache - mix / Disposable sterile vaginal speculum tache - mix

Modello / Model:

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

Modello / Model:

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

Modello / Model:

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

Modello / Model:

Tampone di trasporto in plastica sterile / Sterile plastic transport swab

Marca / Brandname:

Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

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

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Chief Operating Officer
Giampiero Belcredi

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Pagina / Page 4 di / of 9

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Marca / Brandname:

MISTRAL

Modello / Model:

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

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 1302, MD 0104

Marca / Brandname:

BOSTON / BOSTON OLPRESS / BOSTON LOBIVON / BOSTON COMBISARTAN / BOSTON VALPRESSION / DALLAS / GIMATONO / LONDON / ROMA / TOKIO / TOKIO ZANTIPRESS / DAYTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Chief Operating Officer

Giampiero Belcredi

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Organismo Notificato n. 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 per la misurazione della pressione sanguigna / Blood pressure measuring devices

Marca / Brandname:

SIRIO

Modello / Model:

Manometro Aneroide / Aneroid manometer

Marca / Brandname:

YTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

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

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Marca / Brandname:

DA POLSO/WRIST - DA BRACCIO/ARM / 24 H ABPM

Modello / Model:

Sfigmomanometri Digitali Automatici / Digital Automatic Sphygmomanometers

Marca / Brandname:

YTON / DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

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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 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

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

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

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

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

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CERTIFICATE

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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

Codice NANDO / NANDO codes:

MD 1301, MD 0104, MDS 7010

Modello / Model:

Bilancia pesapersona / Scales - ASTRA - FAMILY - PEGASO

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

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Modello / Model:

Maschera per rianimazione CPR / CPR resuscitator mask

Modello / Model:

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

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Modello / Model:

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

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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 rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Modello / Model:

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

Modello / Model:

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

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

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 Ethylene oxide gas sterilization (EOG)

Modello / Model:

Kit per sutura standard / Kit per rimozione sutura / kit procedurale sutura / kit standard per parto / Standard suture pack / Suture removal pack / Suture procedure pack / Standard delivery pack

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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

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:

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

Modello / Model:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

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

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

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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