

XENON-HALOGEN OTO AND OPHTHALMOSCOPE SET



Rechargeable handle for use with 2xC batteries or rechargeable battery (34467)

• **31475 XENON-HALOGEN PARKER OTOSCOPE**
Same as PARKER Otoscope code 31440 but with halogen 2.5V bulb, and bayonet connection system. Supplied with 3 autoclavable ear funnels in a soft bag. Requires 2xC batteries (not included) or rechargeable battery.

• **31474 HALOGEN OPERATIVE PARKER OTOSCOPE**
Same as 31475 but with operative head.

• **31476 HALOGEN PARKER OPHTHALMOSCOPE**
2.5V halogen light for true tissue colour and consistent, long lasting illumination 24 colour coded lenses -25 to +40 dioptres for excellent resolution (green for +, red for -). Rubber eye brow rest to prevent scratching of eye-glasses. Illumination lens dial for clear identification of dioptre setting.

• **31477 HALOGEN OTO-OPHTHALMOSCOPE PARKER SET**
Diagnostic set including one handle, one halogen otoscope head and one halogen ophthalmoscope head, all in a plastic case.

• **31478 XENON-HALOGEN BULB FOR OTOSCOPE 2.5V**

• **31479 XENON-HALOGEN BULB FOR OPHTHALMOSCOPE 2.5V**

• **34467 RECHARGEABLE LI-ION BATTERY 2.5 V / 2,200 mAh**

• **31542 CHARGING STATION**

• **32203 "C" ALKALINE BATTERIES - blister of 2 pcs**



31474

31476

Supplied in a semi-rigid nylon bag with multi-lingual box and manual (GB, FR, IT, ES, PT, DE, GR, Arabic)



31475

31477



31476

+	1, 2, 3, 4, 5, 6, 8, 10, 12, 15, 20, 40
-	1, 2, 3, 4, 5, 6, 8, 10, 15, 20, 25

XENON-HALOGEN DIAGNOSTIC SETS IN RIGID CASES

• **31480 XENON-HALOGEN DIAGNOSTIC SET - 3.5 V**

• **31482 XENON-HALOGEN OPERATIVE DIAGNOSTIC SET - 3.5 V**

Both xenon-halogen sets are supplied in plastic rigid case containing: one rechargeable handle, one otoscope head (operative for code 31482) one ophthalmoscope head, 3 autoclavable speculum Ø 2.5, 3.5, 4.5 mm, two laryngeal mirrors (size 3 and 4), adjustable nasal speculum, bent throat lamp, tongue spatula. Should be used with 31541 + 31542.

• **31427 XENON-HALOGEN OTOSCOPE BULB 3.5V**

• **31428 XENON-HALOGEN OPHTHALMO BULB 3.5V**

• **31542 CHARGING STATION - 100-240 V - 50/60 Hz**

See details at page 261.

• **31541 RE-CHARGEABLE LI-ION BATTERY 3.5V***

*For handles sold after may 2013



Operative otoscope head



31542

31480



FIBRE OPTIC XENON-HALOGEN OTOSCOPES

• **31520 GIMALUX F.O. OTOSCOPE - black**

• **31521 GIMALUX F.O. OTOSCOPE - blue**

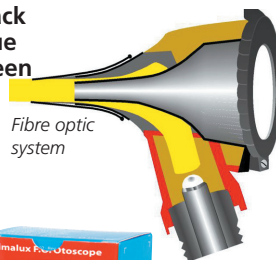
• **31522 GIMALUX F.O. OTOSCOPE - green**

High professional plastic otoscopes with extra bright halogen light provided by fibre optic system. Quality 3 times magnifying movable lens.

Output for pneumatic membrane test. Supplied with 14 single use mini speculums (7 Ø 2.5 and 7 Ø 4 mm) in a colour coordinated nylon bag. For mini ear-speculum see at page 266. All latex free.

• **34485 XENON-HALOGEN BULB 2.5V**
Old model with chrome insufflation adapter need below bulb

• **31478 XENON-HALOGEN BULB 2.5V**
for old models



Fibre optic system



Multilingual box and manual: GB, FR, IT, ES, PT, DE, GR, RO, HU, Arabic.



31521

31522

31520



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
- 2.5 V handles can be used with standard or rechargeable batteries
- all blades are compatible to BS EN ISO 7376 Green standard handles
- all blades are made of 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 are non magnetic

Mc INTOSH BLADES

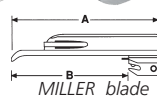
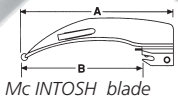
MILLER BLADES

MAXLITE

58056

58052

GIMA GREEN



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

• **31542 GIMA GREEN CHARGING STATION - 100/240 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.

Multilingual manual:
GB, FR, IT, ES

31542

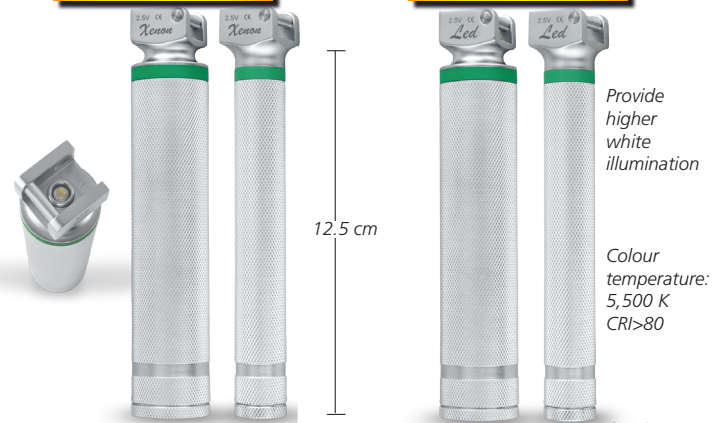


Charging station includes pediatric adaptor, wall support, UK, US and EU plug

377

HALOGEN/XENON BATTERY HANDLE

LED BATTERY HANDLE



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

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)	
34489	Pediatric rechargeable NiCa battery 3.5 V/700 mAh for 34487
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, 34487***
31541	Adult rechargeable Li-ion battery** 3.5 V for 34457, 34482, 34488****
for handles sold after may 2013 *since lot 10 ****since lot 12	
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
*LED bulb is assembled with handle in a fixed system and is not replaceable	

COMPATIBILITY HANDLE - BATTERY - BULB

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

- 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
- 2.5 V or 3.5 V 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

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

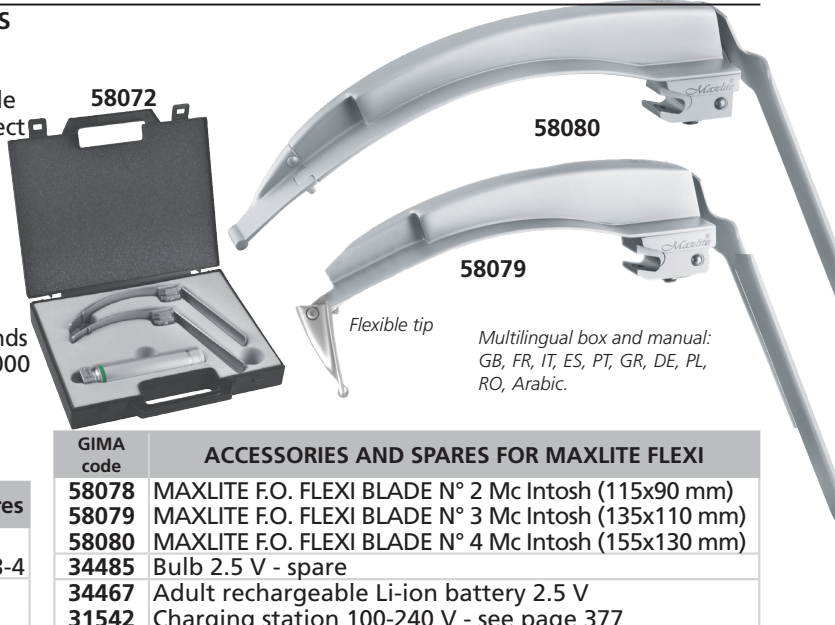
MAXLITE FLEXTIP F.O. XENON/HALOGEN OR LED SETS AND BLADES

XENON-HALOGEN OR LED F.O. FLEXTIP LARYNGOSCOPE SETS WITH INTEGRATED FIBRES FOR DIFFICULT INTUBATIONS

Deluxe set including one F.O. rechargeable handle, one or two F.O. Mc Intosh blades N° 3 or N° 3 and 4 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.

- stainless steel construction, matt finish
- can be used with all Green Spec Handles
- compatible with ISO 7376 Green Standards
- channel provides improved viewing area
- 4.5 mm fibre bundle with more than 6,500 individual fibre strands
- high quality fibres ensuring excellent light transmission, 8,000 lux with 2.5V Xenon lamp, 20,000 lux with 2.5V LED lamp
- 2x"C" batteries or rechargeable batteries (not included)
- autoclavable at 134° C, approximately 2,000 times
- can sustain Plasma sterilization (Sterrad 100 NX)

GIMA code	MAXLITE FLEXTIP F.O. SETS - 2.5 V with integrated fibres	
58070	MAXLITE F.O. XENON FLEXI SET 1 blade Mc Intosh 3	
58072	MAXLITE F.O. XENON FLEXI SET 2 blades Mc Intosh 3-4	
58073	MAXLITE F.O. LED FLEXI SET 1 blade Mc Intosh 3	
34498	MAXLITE F.O. LED FLEXI SET 2 blades Mc Intosh 3-4	



58072

58080

58079

Flexible tip

Multilingual box and manual:
GB, FR, IT, ES, PT, GR, DE, PL,
RO, Arabic.

GIMA code	ACCESSORIES AND SPARES FOR MAXLITE FLEXI	
58078	MAXLITE F.O. FLEXI BLADE N° 2 Mc Intosh (115x90 mm)	
58079	MAXLITE F.O. FLEXI BLADE N° 3 Mc Intosh (135x110 mm)	
58080	MAXLITE F.O. FLEXI 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 377	

STANDARD LARYNGOSCOPE BLADES AND SETS - 2.5 V

McINTOSH BLADES

34321

34319

34318

34320

34317

MILLER BLADES

34314

34312

34311

34313

34310

OXY
connection3 YEARS
WARRANTY

34303

Standard laryngoscopes

Laringoscopes
Laryngoskop
منظار الحنجريMultilingual box
and manual: GB, FR, IT,
ES, PT, DE, PL, RO, GR, Arabic.

- Great features of the unique GIMA blades and handles
- standard 2.5 V vacuum bulb
 - light ergonomic, satin finish handle to reduce glare
 - Stainless Steel contacts guarantee long working life
 - easy sterilization ETO or steam
 - full range of Mc Intosh & Miller blades, latex free
 - ISO 7376 fittings allow use of blades with existing handles
 - set is packaged in an anti-shock case and in cardboard box
 - 2.5 V handles work with both alkaline batteries or rechargeable batteries
 - good light transmission of 3,500 LUX with 2.5 V handles
 - autoclavable up to 134° for 5 minutes (approx. 2,000 times)
 - non magnetic blades

GIMA code	STANDARD BLADES	Overall Length mm	Distal Width mm
34310	Blade N° 00 MILLER OXY - premature	65	11.5
34311	Blade N° 0 MILLER - premature/newborn	78	11.5
34312	Blade N° 1 MILLER - babies	102	11.5
34313	Blade N° 2 MILLER - adults	155	16.5
34314	Blade N° 3 MILLER - adults/large	195	16.5
34317	Blade N° 0 Mc INTOSH - newborn	80	11
34318	Blade N° 1 Mc INTOSH - babies	95	10
34319	Blade N° 2 Mc INTOSH - infants	115	12
34320	Blade N° 3 Mc INTOSH - adults	134	14
34321	Blade N° 4 Mc INTOSH - adults/large	155	14
34322	Blade N° 5 Mc INTOSH - adults/extra large	175	14

GIMA code	STANDARD RECHARGEABLE SETS (HANDLE+BLADES)
34301	Pediatric set 2 blades MILLER 0-1
34307	Pediatric set 3 blades MILLER 00-0-1
34305	Pediatric set 3 blades MILLER 0-1, Mc INTOSH 0
34306	Doctor set 3 blades MILLER 1, 2, 3 - adult handle
34302	Adult set 3 blades Mc INTOSH 2-3-4
34303	Adult set 4 blades Mc INTOSH 1-2-3-4

GIMA code	BULBS, BATTERIES AND RECHARGEABLE HANDLES
34352	Small rechargeable handle - pediatric (2xAA) - 2.5 V
34354	Large rechargeable handle - adult (2XC) - 2.5 V
34466	Pediatric rechargeable Li-ion battery 2.5 V AA
34467	Adult rechargeable Li-ion battery 2.5 V "C"
Charging time 2.5 hours (34466), 5 hours (34467)	
31542	Charging station (including pediatric adaptor, wall support, UK, US and EU plug) 100-240 V
34324	Small Bulbs for Mc. Int. N°0 and MILLER N°00,
34325	Large Bulbs for Mc. Int. N°1,2,3,4 and MILLER N°2,3
compatible with Kawe and Riester	



34324



34325



34352 34354

DISPOSABLE F.O. LARYNGOSCOPE BLADES MILLER AND MC INTOSH

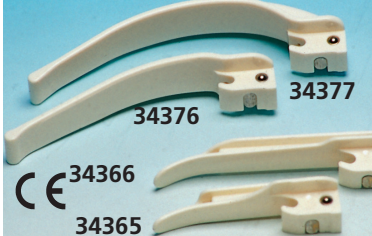
SINGLE-PATIENT USE LARYNGOSCOPE F.O. BLADES

Choice of 5 different blades: Mc Intosh N° 2, 3, 4 and Miller N° 0,1. All blades are tested for tensile strength. Individually packed, non sterile.

COMPATIBILITY WITH ALL
"GREEN" F.O. SYSTEMS

GIMA code	DISPOSABLE BLADES NON STERILE	Overall Length mm	Distal Width mm
34481	Metal handle		
34364	Plastic handle		
34365	N° 0 Miller - infant	90	22
34366	N° 1 Miller - child	100	23.3
34375	N° 2 Mc Intosh - adult small	115	34.4
34376	N° 3 Mc Intosh - adult	132	40.6
34377	N° 4 Mc Intosh - adult large	155	58.7
34359	Bulb for old plastic handle sold up to may 2016		
34358	Bulb for new plastic handle sold since june 2016		

DISPOSABLE BLADES



34366

34365

- 34381 EMERGENCY PACK: plastic handle +3 disposable blades Mc Intosh N° 2,3,4
- 34382 NYLON BAG - empty
- 34384 EMERGENCY CASE: plastic handle+6 disposable blades Miller 0,1,2 and Mc Intosh 2,3,4.



34381



34384

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).

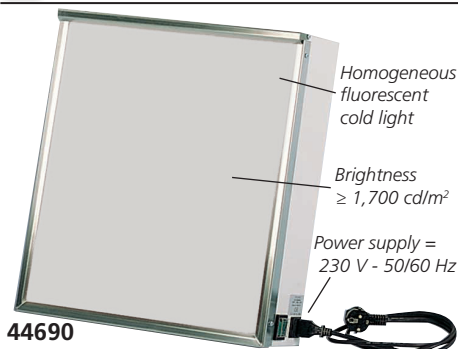
TECHNICAL SPECIFICATIONS

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



MONOYER

MIXED DECIMAL

ARMAGNAC

CHILDREN

ANIMALS

3m
• 27381

3m
• 27382*

5m
• 27380

3m
• 27383

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,...)



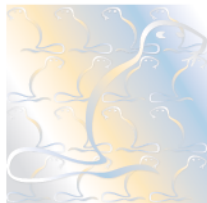
OPTOMETRIC CHARTS	Illuminated GIMA code	Not illuminated GIMA code
Armagnac - 5 m	27380	27390
Monoyer - 3 m	27381	27391
Mixed decimal - 3m	27382*	27392*
Children - 3 m	27383	27393
Animals - 5 m	27384	-
Spare Tube 700	27388	-

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



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,
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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





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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



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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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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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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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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

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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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 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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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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Data: 25/05/2021 10:15:40



Organismo Notificato n. 0476
Notified Body nr. 0476





Reg. Numero /
Reg. Number

MED 26036

Revisione /
Revision

23

Primo rilascio /
First issue date

2006-10-25

Valido da /
Valid from

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Scadenza /
Valid until

2024-05-26

Ultima modifica /
Last change date

2021-05-24

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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.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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Chief Operating Officer
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Organismo Notificato n. 0476
Notified Body nr. 0476



CERTIFICATE