

## DONOR ARMCHAIR

- 27557 DONOR ARMCHAIR - blue - mechanical
- 27563 DONOR ARMCHAIR - blue - electrical
- 27567 DONOR ARMCHAIR WITH WHEELS - white

Strong and stylish armchair with structure made with oval, round and square metal section tubing (legs oval tubing 50x25x1.5; central frame square tubing 30x30x1.5, cushions round tubing 20x1.5 diam.).

Structure fully coated with white epoxy powder.

High density polyurethane foam platform with wooden base covered by leatherette upholstery.

Both materials are flame resistant Class 1 IM.

Synchronized adjustment of the two cushions by a gas spring, cylinder/piston, (27557, 27567) or by a linear actuator (27563) with a push-button panel, allow a quick moving into TR/RTR position. The backrest inclination ranges from +60° to -5° in Trendelenburg position, leg rest from -80° to +5°.

The arm-rests can be height adjusted and are reclinable. When removed, they can be rotated up to 180°.

Four adjustable feet ensure maximum stability (27557 and 27563) or 4 castors, 2 with directional brake (27567) ensure mobility. Load: 150 kg. Size: 175x55xh 51 cm. Made in Italy.

- 27553 IV STAND

- 27556 COUCH ROLL HOLDER



27557



27557

White ral colour  
9003 structure,  
minimum thickness  
70/80 micron.  
Glossy finish.



WITH WHEELS



27567



27563

ELECTRICAL



## DONOR WHEELCHAIR

- 27561 DONOR WHEELCHAIR

Donor wheelchair with structure made of epoxy painted oval and round steel tube.

Backrest adjustable by gas pump.

Padded leg rest manually adjustable.

Metal footrest extractable. Armrest with articulations, manually adjustable in height.

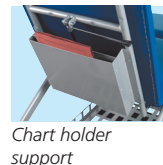
Padding made of high-density polyurethane foam, fireproof Class 1 IM. Covering made of washable, plastic material (leatherette), fireproof Class 1 IM.

Back push handle.

Mattress overall size: 166x55 cm. Carton size: 185x67xh 58 cm

Four wheels Ø 100 mm, 2 directional and 2 with brake.

Net weight: 53 kg. Gross weight: 55 kg. Maximum load: 150 kg. Supplied with blanket tray with belts to fix oxygen bottle, IV stand and chart holder support. Made in Italy.

Chart holder  
support

27561

Blanket tray with belts  
to fix oxygen bottle  
(bottle not included)

## HEIGHT ADJUSTABLE GYNAECOLOGICAL BED

- 27506 HEIGHT ADJUSTABLE GYN BED - green
- 27507 HEIGHT ADJUSTABLE GYN BED - blue
- 27496 HEIGHT ADJUSTABLE GYN BED - any colour\*

\*Available in 20 days, see below available colours

Strong and solid structure in oval tube 50x25x2 mm painted with epoxy powder, white colour.

The three sections top has high density padding, covered with washable, fire proof, leatherette material class 1 IM.

Full adjustable

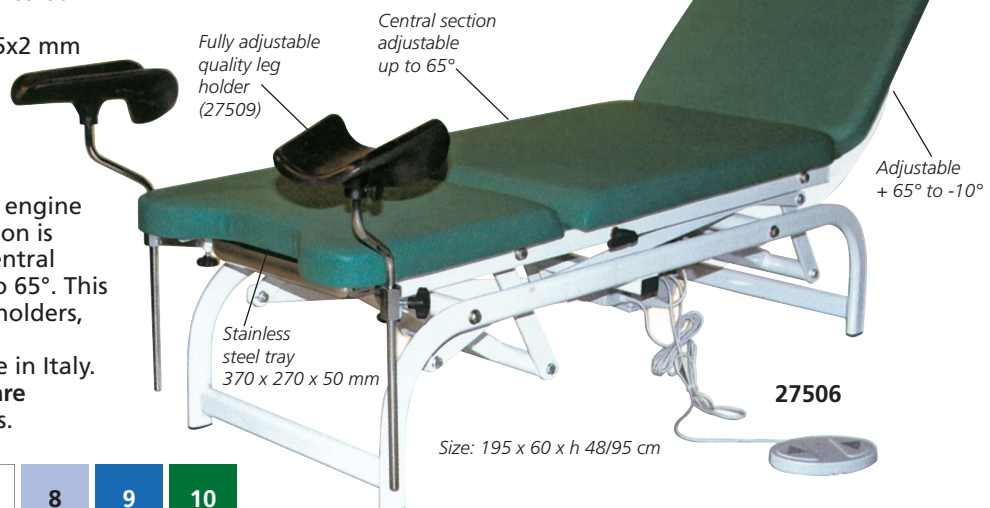
Height, up to 95 cm, is adjustable by electric engine (6000 N power) with foot control, head section is adjusted by a gas cylinder (400 N power), central section by a gas cylinder (600 N power) up to 65°. This gyn bed is supplied with 2 quality foam leg holders, stainless steel tray and couch roll holder.

Maximum load: 150 kg. Weight: 70 kg. Made in Italy.

- 27509 QUALITY LEG HOLDER - couple - spare

Kit leg holder includes 2 leg holder and arms.

Suitable for 27496, 27505, 27506, 27507.



27506

Size: 195 x 60 x h 48/95 cm

Fully adjustable  
quality leg  
holder  
(27509)

Central section  
adjustable  
up to 65°

Adjustable  
+ 65° to -10°

Stainless  
steel tray  
370 x 270 x 50 mm







## MT 10 - HANDHELD IMPEDANCE TYMPANOMETER

- **33665 MT10 - HANDHELD TYMPANOMETER**
  - **33666 MT10 - HANDHELD TYMPANOMETER WITH IPSI-REFLEX**
- Professional handheld tympanometer for setting fast and reliable testing in an easy and cost effective way.

### Objective analysis

Fast and easy to operate and provides objective measures that cannot be obtained by otoscopy alone.

### Easy and fast tympanograms

Results can be obtained with little efforts and with no response required from the patient. This is especially beneficial when dealing with difficult-to-test patients or small children.

### Clinical application

Suitable for diagnostic use as tympanometer and (33666 only) reflex responses are all recorded with great detail. You can detect otitis media (a major cause of temporary or permanent hearing impairment in children), a perforated eardrum, cholesteatomas and certain neurological disorders. You can also check tympanostomy tubes and follow up on post medical treatments.

### Ipsilateral Acoustic Reflex (33666 only)

Four different reflex tests at 500, 1,000, 2,000, 4,000 Hz may be performed per ear using either fixed or automatic intensity selection. Actual reflex characteristics are displayed on the screen.

### 30 patients in memory

Can hold test results of up to 30 patients, allowing to screen a large group of patients and print out the data at a later time.

**PC-integration** with optional infrared USB interface and software. Full data-transfer to PC

- **33667 INTERFACE USB ADAPTER AND SOFTWARE BY IRDA PORT**



33669



### Interacoustics

Supplied with handle, set of 139 disposable ear-tips (mixed sizes) 4x1.5 V battery and manual in GB, DE, FR, IT, ES, SE, GR, PT, DK, FI, CZ, PL, LT, EE, HU, NL, NO, IS, RO, MK.

- **-400 to +200 daPa**
- **ipsi-reflex (33666 only)**
- **30 patient memory**
- **PC integration**



The MT10 is ergonomic to hold but also offers the possibility of using the included handle to make it even more stable and lightweight as it can rest on your arm during the measurement.

Size: 19x8x4 cm excluding probe (length with probe 22.5 cm)  
Weight 285 g without battery

- **33668 BET55 SET OF DISPOSABLE EAR-TIPS - box of 139 mixed sizes**
- **33669 SANIBEL MPTII PORTABLE THERMAL PRINTER**
- **33670 THERMAL PAPER ROLLS - box of 3**

### TECHNICAL SPECIFICATIONS

#### Tympanometry

Analysis performed: Peak compliance; peak pressure, gradient; equivalent ear canal volume  
Probe tone: 226 Hz  
Pressure levels: +200 daPa to -400 daPa  
Ear volume measurement range: 0.2 ml to 5 ml  
Sweep speed: Typically 200-300 daPa/sec; depending on ear & cavity volume  
Pressure limits (safety shut off): +600 to -800 daPa

#### Reflex measurements (33666 only)

Measurement mode: ipsilateral  
Reflex tone levels: 500 Hz, 1 kHz, 2 kHz, 4 kHz  
Four reflex levels: 100 dB with 5 dB or 10 dB steps; 95 dB, 90 dB or 85 dB with 5 dB steps  
Reflex analysis: Reflex pass/refer at each level tested; Maximum amplitude of each reflex (seen on printed report and PC report); Pressure at which reflex was performed

#### Data management

Data storage: 30 records. Any recording can be stored once the tympanogram is viewed  
Data held: Patient Initials, Tympanogram and Reflex graphs and analysis for Left and/or Right Ear, Time and Date of recording, which ears were tested, whether or not the record has been printed and sent to a PC, parameters printed and/or sent to a PC, parameters used for analysis

#### Other data

Internal backup: >30 days without main batteries fitted  
Battery Lifetime: Approx. 400 tests (Alkaline AA batteries)  
Supported printer: Martel MCP8830 or Sanibel MPTII  
Interface: Infra-red, IrDA hardware, 9600 baud  
Information printed: Space for patient and clinician's details, Tympanogram analysis parameters, Tympanogram, Reflex analysis parameters, Reflex graph, S. N. of device, Last and Next Due Calibration dates  
Safety standards: IEC 60601-1, EMC: IEC 60601-1-2  
Impedance standard: IEC 60645-5, Type 2 Tympanometer

## PA5 PEDIATRIC PORTABLE AUDIOMETER

- **33601 PA5 AUDIOMETER**
- **33602 TDH39 AUDIOMETRIC HEAD PHONE**

Paediatric portable audiometer with air conduction, free-field and visual stimulation capabilities. By means of a headphone it can be also used as a regular screening audiometer for adults. PA5 helps doctors in evaluating the auditory behaviour in neonates and infants till 24 months by means of specific tests:

### Aurolpalpebral Reflex (APR) test

APR test is a startle reflex of the eyelid elicited by relatively strong sounds that can be performed on neonates from the day of birth. It is not based on co-operation with the newborn child.

### Conditioned Orientation Response (COR) test

Based on the "Orientation Reflex", a natural reflex movement elicited by sound or visual stimulation. If the visual stimulation elicits a reflex which is conditioned by a tone, the child will look towards the visual stimulation as soon as the tone is heard. If the conditioning is effective the child will look in the direction of the sound source even before the visual stimulation is presented.

### Visual Reinforcement Audiometry (VRA) test

VRA test is an extension and modification of COR, where the cooperation with the child is less important. Not only the sound

localisation orientation reflex are accepted but also four other reactions: reflex reactions (body and face), search reactions, orientation reactions and spontaneous reactions.

**Reflex audiometry and maturation of auditory response tests**  
Different stimuli are presented in terms of intensity, frequency, duration, direction of sound in order to elicit proper reactions like waking-up, crying, astonishment, direct sound localization.



33601

Supplied with GB manual and quick guide (GB, US, DE, FR, SE, IT, PT, DK, FI, ES, GR, CZ, PL, NL, NO, EE, HU, SL).

### TECHNICAL SPECIFICATIONS

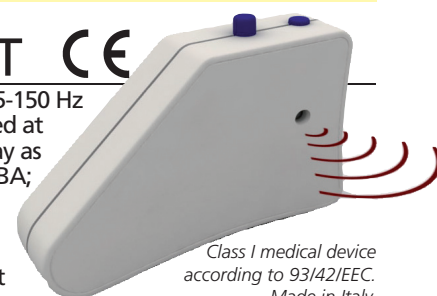
Frequencies: 500, 1,000, 2,000, 3,000, 4,000 Hz  
Stimuli: Warble tone, NB and WN  
Intensities: Distance 50 cm: 20/30-80dB HL in 10dB steps, for Warble Tone and WN 10/20-70dB for NB increases intensity by 10 dB  
Distance 16 cm: increases intensity by 10 dB  
Dimensions - weight: LxWxH: 25x7x5 cm - 360 g  
Power supply: 3AA batteries (included)

## BOEL STYLE PEDIATRIC AUDIOLOGY TEST

- **33599 GIMA AUDIOTEST - pediatric audiology test for early detection of childhood deafness**

The Boel test is a unique screening tool that tests the hearing abilities and child's response to a sound stimulus, even at an early age (between 6 to 10 months). GIMA audiotest is based on the BOEL test both for the ergonomics (designed to be held in the palm of the hand not visible to the child) and the standard sound of the bells. The two sound stimuli emitted by the audiometer reproduce a dull

low-frequency tone located at about 125-150 Hz and an acute high-frequency tone located at about 5.0-5.1 kHz in exactly the same way as the bells of the Boel test (amplitude 86dBa; 96dBa). Testing the child's response to these highly significant thresholds. Easy to use, with only two buttons for the selection of two frequencies, lightweight and battery-powered.



33599

Class I medical device according to 93/42/EEC. Made in Italy.

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### TECHNICAL SPECIFICATIONS

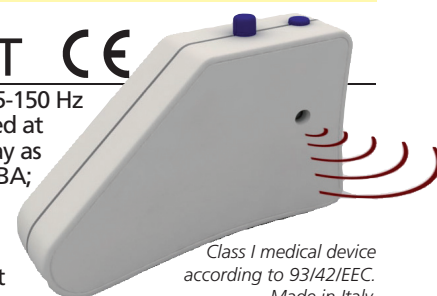
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33599

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## OXY-5 AND OXY-6 PROFESSIONAL OXIMETERS



34282



34285



34285

- 34282 OXY-5 FINGERTIP OXIMETER
- 34265 OXY-5 PEDIATRIC FINGERTIP OXIMETER
- 34285 OXY-6 COLOUR FINGERTIP OXIMETER


To monitor pulse oxygen saturation and pulse rate through patient's finger (10-22 mm finger thickness for 34282, 34285 - 8-16 mm finger thickness for 34265) in medical and hospital environments.

Main features:

- SpO<sub>2</sub> and pulse rate measurement
- bargraph of pulse rate
- perfusion index display. P.I. is a numerical value that indicates the blood perfusion condition at the sensor site. It is a relative value that varies from patient to patient and from measuring site
- high accuracy and repeatability: products are manufactured by GIMA (in P.R.C. facilities) under strong quality controls guaranteed by Italian notified body (CE 0476 CERMET)
- accuracy from the first reading in few seconds thanks to a unique noise rejection capability feature
- extra stability against motion during measurement (finger bending, Parkinson's disease, hand movement, button pressing)

- audible and visible alarms
- automatic power on and power off when finger is out
- low voltage alarm display
- 8 or 9 language manual (GB, FR, IT, ES, DE GR, PT, PL\*, Arabic)
- 50 hours working time with full batteries (30 hours for oxy-6)
- supplied in plastic case with batteries and pouch
- 4 direction adjustable display (Oxy-6 only)

- 35076 CORDURA BAG with belt loop - blue <sup>\*34265, 34282 only</sup>

TECHNICAL SPECIFICATIONS			
	RANGE	ACCURACY	RESOLUTION
Pulse rate:	30-240 bpm	± 2 bpm (2%)	1bpm
SpO <sub>2</sub> :	35%-99%	± 2% (75-99%) ± 3% (50-75%)	1%
Perfusion:	0-20%	± 0.1% (0,2-2%)	0.1%
Index:		± 0.2% (2-10%)	
Alarm:	SpO <sub>2</sub> : low limit 90% Pulse rate: low: < 50 bpm - high > 120 bpm		
Power:	1.5V (AAA size) alkaline battery x 2		
Norms:	IEC 60601-1-2 Class II 		
LCD Display:	oxygen saturation, pulse rate, low battery indicator		
Size - weight:	6.6x3.6x3.3 cm - 60 g including batteries		
Italian manufacturer (made in P.R.C.)			

## OXY-3 OXIMETER



35090

- 35090 OXY-3 OXIMETER - blister
- Easy to use pocket device, measures oxygen level and pulse rate.

Main features:

- simple operation, small & lightweight design, portable
- display SpO<sub>2</sub>, SpO<sub>2</sub> waveform, PR, Pulse bar
- low power consumption
- 2 AAA alkaline batteries included
- low battery indication, auto power off
- accommodates widest range of finger sizes from pediatric to adult
- soft silicone padding, strong slip
- resistant clip, non-invasive, no pricking
- 4 direction display
- user manual in GB, IT, ES, FR

- 35075 SILICONE COVER - light blue
- 35076 CORDURA BAG with belt loop - blue

Supplied in blister with batteries and lanyard.

35090

35075  
+  
35090

35076

## OXY-4 COLOUR OXIMETER

Size: 66x36x33 mm



35091

35092

- 35091 OXY-4 OXIMETER - blue
- 35092 OXY-4 OXIMETER - orange
- 35093 OXY-4 OXIMETER - other colour (minimum 100 pieces)

Select colour with order



Fingertip pulse oximeter to monitor pulse oxygen saturation, pulse rate, and perfusion index.

- it is light, small in size and easy to take
- accurately measures SpO<sub>2</sub> value and pulse rate value
- dual-color display of SpO<sub>2</sub>, PR, PI, Plethysmogram and pulse bar
- measuring range, SpO<sub>2</sub> 35 - 99%, Pulse rate 30 - 240 bpm
- innovative 4 directions display
- automatic power On/Off
- more than 30 hours continuous working with 2AAA alkaline batteries
- audible and visible alarm function
- battery voltage indication, low battery voltage alarm
- prevention against water ingress, drop resistant
- manual in 8 languages: GB, FR, IT, DE, ES, PT, GR, PL
- 35076 CORDURA BAG with belt loop - blue



## OXYGEN CYLINDERS: 0.5, 2, 3, 5 AND 7 LITRES



Oxygen therapy masks are produced with non toxic material, complete with adjustable elastic clip for nose and connecting tube

CE 0086



### CYLINDERS FOR OXYGEN THERAPY (empty)

Steel cylinders for therapeutic oxygen at 200 bar pressure, with valve and safety lock. These cylinders are ideal for home and hospital therapeutic use, particularly in case of desultory oxygen supply. Supplied in a sturdy plastic bag (5 and 7 l) or soft bag (2 and 3 l) with cover. Oxygen cylinders are provided with a pressure reducer with two-stage release valve (0-15 l/min) and high pressure manometer to indicate oxygen quantity in the cylinder (Code 34510/34511) and face mask (excluding 34500/34520).

GIMA code		OXYGEN CYLINDERS WITH INTEGRATED PRESSURE REDUCER				
UNI	NF	Litres	Flow	Size	Weight kg	
34500	34520*	0.5	fixed 6 l	Ø 60x400mm	2.75	-
34502	34522*	2	0/15 l	Ø110x410mm	4.5	with soft bag + cover
34503	34523*	3	0/15 l	Ø110x530mm	5.5	with soft bag + cover
34505	34525*	5	0/15 l	Ø140x550mm	9	with plastic bag + cover
34507	34527*	7	0/15 l	Ø140x680mm	11	with plastic bag + cover

### PRESSURE REDUCER with valve

9 steps for flow adjustment

Pressure reducer with valve and index flowmeter adjustable 0-12 l/min, suitable for cylinders 1 to 3 litres (code 34510/34530) and 5 to 7 litres (34511/34531). It includes two stages, release valve and high pressure manometer.

Thread cylinder connection: E25/E17 conical refill thread connection

UNI 21.7 x 1/14" or NF Ø 22.91 x 1.514

Apparatus to be connected to a cylinder without valve.

CE 0123



UNI	NF	PRESSURE REDUCERS WITH VALVE - spare
34510	34530*	Integrated pressure reducer with valve for 2/3 litres
34511	34531*	Integrated pressure reducer with valve for 5/7 litres
34539		Cover protection for cylinders 2/3/5/7 litres
GIMA code		OXYGEN THERAPY MASKS
34166		Oxygen therapy mask - adult - with tube
34167		Oxygen therapy mask - paediatric - with tube
34168		HI-Oxygen therapy mask - adult - with tube
34169		HI-Oxygen therapy mask - paediatric - with tube
34276		Disposable oxy tube - 2m - female - female
34172		Oxy glasses - nasal cannulas

\*Products not in stock, available in 15 days

## GENERAL PURPOSE CYLINDERS 5 AND 10 l AND PRESSURE REDUCERS



### DETAILS OF OXYGEN CYLINDER

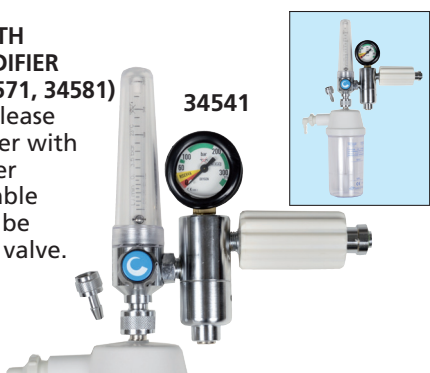


### DETAILS OF PRESSURE REDUCER WITH FLOWMETER



### PRESSURE REDUCER - WITH FLOWMETER AND HUMIDIFIER (34541, 34551, 34561, 34571, 34581)

Pressure reducer with release valve and H.P. manometer with adjustable ball flowmeter 0-15 l/min and autoclavable humidifier apparatus to be connected with cylinder valve.



### GENERAL PURPOSE CYLINDERS (empty)

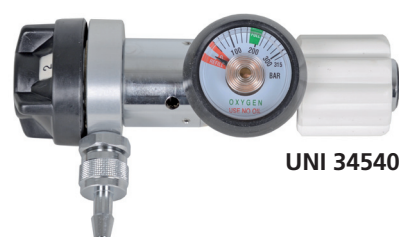
Supplied with valve. Ideal for anaesthesia apparatus, can be used with pressure reducer code 34540-34541 or other standards (NF, DIN, BRITISH STD or PIN INDEX).

GIMA code					OXYGEN CYLINDER WITH VALVE AND ACCESSORIES
UNI	NF	DIN	BULL NOSE BRITISH STD	PIN INDEX	
34545	34555*	34565*	34575*	34585*	Oxygen Cylinder 5 l with valve
34548	34558*	34568*	34578*	34588*	Oxygen Cylinder 10 l with valve
34540	34550*	34560*	34570*	34580*	Pressure reducer
34541	34551*	34561*	34571*	34581*	Pressure reducer with flowmeter and humidifier
34590	34590	34590	34590	34590	Humidifier autoclavable at 121°C

\*Products not in stock, available in 15 days

### PRESSURE REDUCER (34540, 34550, 34560, 34570, 34580)

Same as code 34541, with adjustable flow 0-15 l/min in 9 steps (1/1.5/2/3/4/6/9/12/15), LP\* port, without flowmeter and humidifier.



UNI 34540



34590

34178

- 34590 AUTOCLAVABLE HUMIDIFIER
- 34177 TROLLEY FOR OXYGEN CYLINDER - 5 l - 7 l
- 34178 TROLLEY FOR OXYGEN CYLINDER - 10 l

\*Low pressure port (for ventilators,...)





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

Via Cadriano, 23  
40057 Granarolo dell'Emilia  
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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 /  
Reg. Number

MED 26036

Revisione /  
Revision

22

Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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## Certificato CE del Sistema di Garanzia della Qualità *EC Quality Assurance System Certificate*

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema di garanzia di Qualità della Produzione dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the Production Quality Assurance System of the Organization:*

### GIMA S.p.A.

**Sede Operativa / Operational Headquarter:**

Via Marconi, 1

20060 Gessate, MI - Italia

**Sede Legale / Registered Headquarter**

Via Tommaso Grossi, 2

20121 Milano, MI - Italia

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

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

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Rif. rapporto di audit/ *Ref. audit report:* del/dated 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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Reg. Numero /  
Reg. Number

MED 26036

Revisione /  
Revision

22

Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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

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Revision

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Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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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Data: 27/04/2020 08:19:59



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Notified Body nr. 0476







Reg. Numero /  
Reg. Number

MED 26036

Revisione /  
Revision

22

Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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

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Data: 27/04/2020 08:20:27



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Notified Body nr. 0476



Reg. Numero /  
Reg. Number

MED 26036

Revisione /  
Revision

22

Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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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Data: 27/04/2020 08:20:55



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Reg. Numero /  
Reg. Number MED 26036

Primo rilascio /  
First issue date 2006-10-25

Scadenza /  
Valid until 2021-10-24

Revisione /  
Revision 22

Valido da /  
Valid from 2016-10-24

Ultima modifica /  
Last change date 2020-04-24

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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:

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

Chief Operating Officer

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22

Primo rilascio /  
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2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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

Chief Operating Officer

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2006-10-25

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Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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:

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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Chief Operating Officer  
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Data: 27/04/2020 08:22:12



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Reg. Number

MED 26036

Revisione /  
Revision

22

Primo rilascio /  
First issue date

2006-10-25

Valido da /  
Valid from

2016-10-24

Scadenza /  
Valid until

2021-10-24

Ultima modifica /  
Last change date

2020-04-24

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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

#### 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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Chief Operating Officer  
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