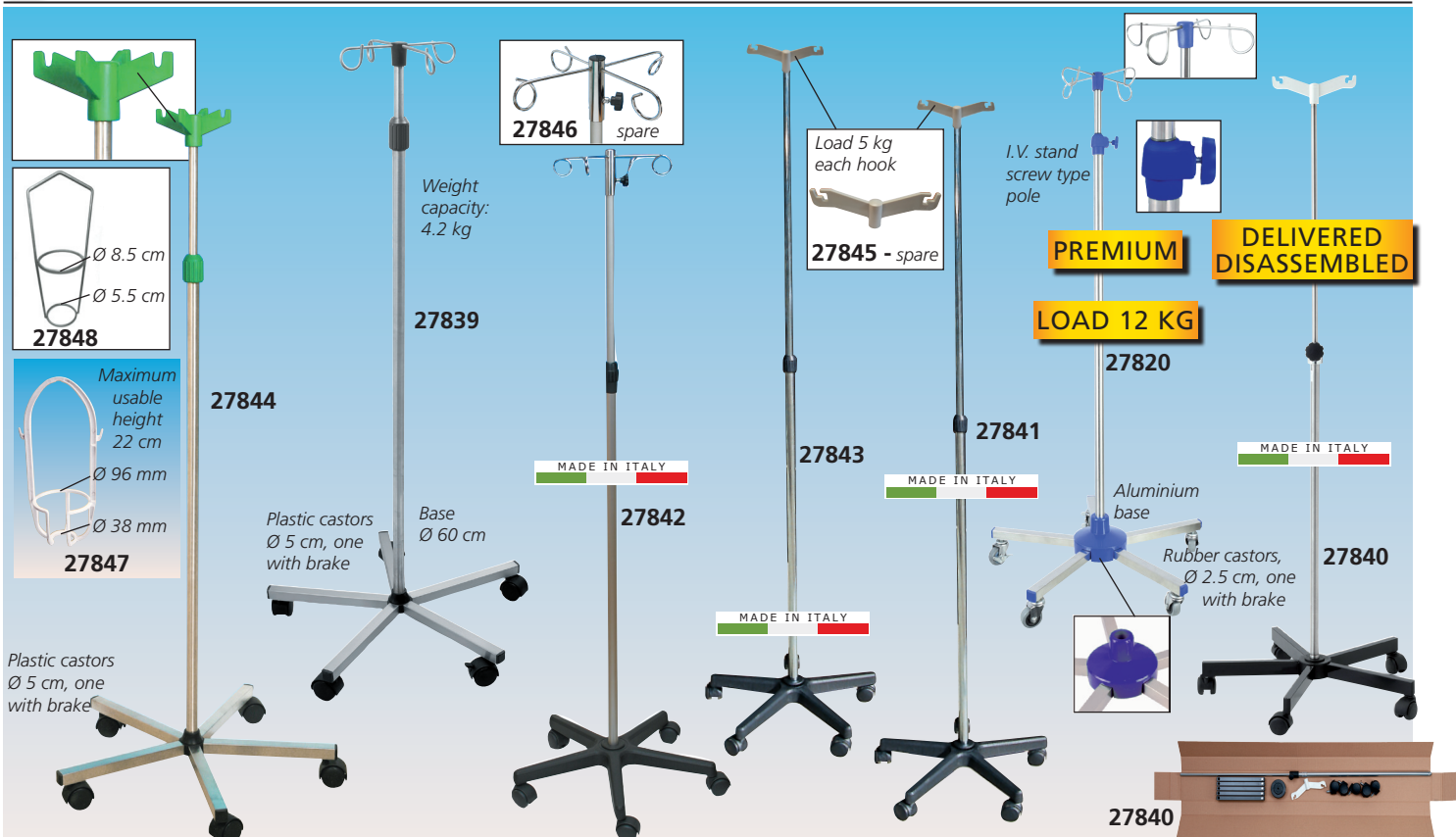


I.V. STANDS



GIMA code	IV STANDS	Adjustable height	Weight kg	Base Material	Hook		Load kg		Castors with brake
					N	Material	Per hook	Total	
27839	Stainless steel AISI 304 IV stand	160-210 cm	3.3	stainless steel	4	stainless steel	1.2	5	1
27841	Chromed-steel IV stand	160-210 cm	2.9	plastic	2	plastic	5	10	-
27842	Chromed-steel IV stand	160-210 cm	3.2	plastic	4	metal	2	8	-
27843	Aluminium IV stand	165-210 cm	2.1	plastic	2	plastic	5	10	-
27840	Epoxy painted IV stand	160-220 cm	4.0	painted steel	2	plastic	5	10	-
27844	Stainless steel AISI 304 IV stand	135-215 cm	2.9	stainless steel	4	plastic	1.2	5	1
27820	Stainless steel AISI 202 IV stand	135-215 cm	3.5	aluminium	4	stainless steel	3	12	1

ACCESSORIES FOR IV STANDS

27845	Plastic support for bottle holder - spare				2	plastic	5	10	 27849 - optional
27846	Metal support for bottle holder - spare				4	metal	2	8	
27849	Stainless steel AISI 304 support for bottle holder - optional				2	stainless steel			
27847	Plastic bottle holder - box of 40 pcs.				-				
27848	Stainless steel AISI 304 bottle holder for bottle ≥ 1 l							2.5	

INFUSION STANDS

- 27826 INFUSION STAND
 - 27829 INFUSION STAND with hydraulic pump
- Made of chrome plated steel. Four chrome plated steel hooks. Five spoke stainless steel base Ø 60 cm with castors Ø 50 mm, two with brake. In conformity with MDR.



TECHNICAL SPECIFICATIONS		
	27826	27829
Adjustable height (cm):	160-250	189-260
Load (kg)*:	30	30
Weight (kg):	10	18
Frame for infusion pump (cm):	— 39x75 —	— — —
Packaging size (cm):	— 185x18x43 —	— — —

*Load 5 kg each hook, 10 kg frame for infusion pump



HYPODERMOCLYSIS STAND

- 27857 HYPODERMOCLYSIS STAND
- Stand with hydraulic height adjustment for hypodermoclysis, for washing and surgical irrigation. Hydraulic pump with pedal for height adjustment and gripping handle for easy transport.

Stainless steel adjustable gripping handle for easy transport

LOAD 28 KG



Pedal driven shock absorbing pump. Height adjustable: 147-247 cm. Weight: 22 kg

Stainless steel base with 5 pivoting castors Ø 75 mm (2 antistatic with brake, 3 standard) and grey vipla bumpers.



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



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.
Internal software: GB, FR, DE.

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



Ergonomic to hold. Included handle make it 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

- 33667 INTERFACE USB ADAPTER AND SOFTWARE BY IRDA PORT
- 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:	IEE 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:

Auropalpebral 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.

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).



33601

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
Dimensions - weight:	Distance 16 cm: 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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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.
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Fax +39.051.763.382
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www.kiwacermet.it

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

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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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

Chief Operating Officer

Giampiero Belcredi

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Data:25/05/2021 10:11:56



Organismo Notificato n. 0476
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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 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

Chief Operating Officer
Giampiero Belcredi

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Data:25/05/2021 10:12:15



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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 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

CERTIFICATE



Reg. Numero /
Reg. Number

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Revision

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Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Codici / Codes:

28091 ; 28092

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Codici / Codes:

28097; 28105

Marca / Brandname:

MISTRAL

Modello / Model:

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

Codici / Codes:

28102

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Chief Operating Officer
Giampiero Belcredi

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

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

Codice NANDO / NANDO codes:

MD 0104

Marca / Brandname:

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

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

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

Marca / Brandname:

SIRIO

Modello / Model:

Manometro Aneroido / Aneroid manometer

Codici / Codes:

32904

Marca / Brandname:

YTON

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

Codici / Codes:

32720; 32703; 32693; 32701

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MDS 7010

Chief Operating Officer
Giampiero Belcredi

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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 per la misurazione della pressione sanguigna / Blood pressure measuring devices

Modello / Model:

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

Codici / Codes:

32926 ; 32924; 32924 SC

Modello / Model:

Sfigmomanometri Digitali SENZA MERCURIO / Digital Sphygmomanometers WITHOUT MERCURY

Codici / Codes:

32800; 32801

Marca / Brandname:

DOMINO

Modello / Model:

Sfigmomanometri Digitali / Digital Sphygmomanometers

Codici / Codes:

32803; 32804

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Codici / Codes:

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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Marca / Brandname:

DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

10980

Marca / Brandname:

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

Modello / Model:

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

Codici / Codes:

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

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Codici / Codes:

25563 ; 25562

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

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

Codici / Codes:

25580 ; 25585

Chief Operating Officer

Giampiero Belcredi

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Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	23
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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

Chief Operating Officer
Giampiero Belcredi

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Data:25/05/2021 10:14:45





Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	23
Primo rilascio / First issue date	2006-10-25	Valido da / Valid from	2021-05-24
Scadenza / Valid until	2024-05-26	Ultima modifica / Last change date	2021-05-24

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:

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



Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	23
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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:

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

Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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CERMET



Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	23
Primo rilascio / First issue date	2006-10-25	Valido da / Valid from	2021-05-24
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.

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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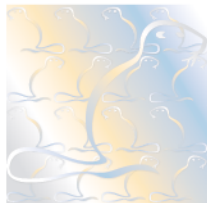
Chief Operating Officer
Giampiero Belcredi

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Data:25/05/2021 10:16:08



Organismo Notificato n. 0476
Notified Body nr. 0476





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
 Giambiero 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.

CERTIFICATE

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