

3-PIN MONOPOLAR HANDLES FOR ELECTRODES Ø 2.4 mm

VALLEYLAB CONNECTOR HANDLES with 2 "click" push-buttons
GIMA autoclavable electrosurgery pencils with CUT-COAG switch have been studied and tested to offer maximum reliability and functionality to the operator. MB handles are provided with a 3 Pin plug Valleylab type fitting all Gima mono-bipolar Diatermo MB (120, 122, 132, 160, 200, 202, 240, 250, 380, 400) and most of bipolar electrosurgical units: Aspen Lab, ES Generator, EMC Statome, Danieli, Braun, Berchtold, Ohmeda, Ritter, Conmed, Eschmann, Bovie, Martin, Kontron, Bard, Birtcher 771, Cobi, Valleylab, Led, Erbe...

AUTOCLAVABLE HANDLES

- **30554 MB AUTOCLAVABLE HANDLE - 100 times**
Autoclavable handle with 2 large "click" push-buttons, provided with a 3 meter long silicone cable and a blade electrode. It can be autoclaved up to 100 times (electrode 20 times).
- **30545 MB AUTOCLAVABLE HANDLE - 100 times**
Same as code 30554 but with a 5 m long silicone cable
- **30550 PRIMA MB AUTOCLAVABLE HANDLE - 60 times**
Autoclavable handle with 2 large "click" push-button, provided with a 3 meter long silicone cable and a blade electrode. It can be autoclaved up to 60 times.
- **30548 STAR AUTOCLAVABLE HANDLE - 30 times**
Same as code 30554 but autoclavable up to 30 times (electrode is autoclavable up to 20 times).
- **30539 ORION PLUS AUTOCLAVABLE HANDLE - 100 times**
Same as 30554, but with a screw clamp locking system ensuring a safe contact and adapting to slightly different electrode diameters. High insulation to prevent liquid damage.
- **30536 SURGEON AUTOCLAVABLE HANDLE - 100 times**
Autoclavable, waterproof handle with ergonomic grip. Coloured ring that indicates CUT and COAG push buttons. Provided with 3 m cable and blade electrode.

SINGLE USE HANDLE

- **30551 KIRKY SINGLE-USE HANDLE - STERILE**
Single-use handle with "click" push-buttons for cut and coag. Includes blade electrode.
- **30553 GIMA SINGLE-USE HANDLE - STERILE**
Same as 30551 with 3 m cable.

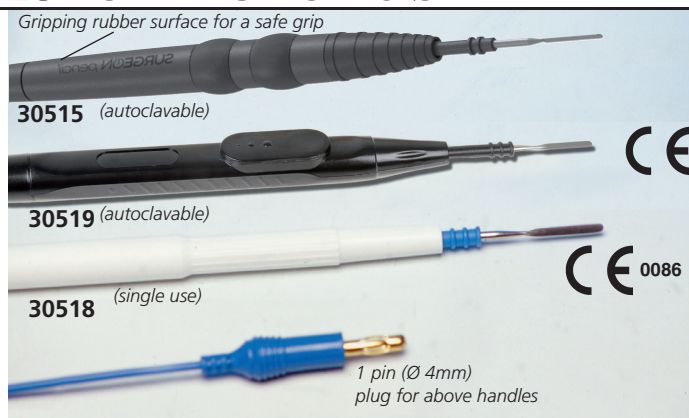


1-PIN MONOPOLAR HANDLES FOR ELECTRODES Ø 2.4 mm

1 pin plug HANDLES for diatermo 50, 80, 106, 108

These handles are provided with a 1 Pin socket (4 mm) fitting all Gima Diatermo and most of electrosurgical units in the market. These handles **do not have push-buttons**.

- **30515 SURGEON 1 PIN AUTOCLAVABLE HANDLE - 100 times**
Autoclavable, waterproof handle with ergonomic grip. Provided with 3 m cable and blade electrode
- **30519 AUTOCLAVABLE 50-80-106-108 HANDLE**
Autoclavable handle **without buttons**, provided with a 3 meter long cable and a blade electrode. It can be autoclaved up to 50 times.
- **30518 KIRKY SINGLE-USE 50-80-106-108 HANDLE - STERILE**
Single-use handle without button with blade electrode with 4 mm PIN connection.



HANDLES FOR ELECTROLYSIS NEEDLES

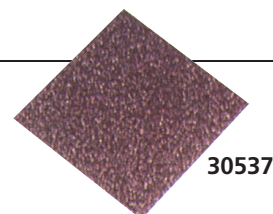
Needle handles for all GIMA Diatermo and electro-depilators

- **30552 HANDLE for electrolysis needles**
- **30415 PROFESSIONAL HANDLE for electrolysis needles**
see electrolysis needles at page 187



ELECTRODE BRUSHES

- **30537 ELECTRODE BRUSH - 50x50 mm**
Disposable sterile radiopaque abrasive tip cleaner pad. Box of 100



SPIROTEL SPIROMETERS - BLUETOOTH OPTION

- 33471 SPIROTEL with WINSPIROPRO software
- 33472 SPIROTEL with Bluetooth and WINSPIROPRO software
- 33473 SpO₂ PROBE - adult - optional
- 33410 MOUTHPIECES int Ø 2,8 x ext Ø 3, h 6.5 cm



A pocket laboratory which integrates 4 devices in one:

- spirometer with touch screen display
- triaxial accelerometer with motion analysis for therapy monitoring
- intelligent 3D oximeter with on screen results (with 33473)
- e-diary for home care symptom control.

Compatible with Qualcomm Life 2 net Hub

TECHNICAL SPECIFICATION	
Flow sensor:	Bi-directional digital turbine
Flow range:	±16L/s - ±3% or 50 mL
Dynamic resistance:	<0.5 cm H ₂ O/L/s
Measured parameters:	Flow accuracy: ±5% or 200 mL/s
	Temperature sensor: Semiconductor (0-45°C)
	Reading on spirometer: FVC, FEV1, PEF, FEF 25/75
	Reading on PC with Winspiro PRO: same parameters as Spirobank G
SpO ₂ range:	0-100% ±2% (50-100% SpO ₂)
Pulse rate range:	20-254 BPM ±2BPM or 2%
Data transmission:	USB 2.0 or Bluetooth
Memory capacity:	Up to 10,000 tests - 300 hours oximetry (only with 33473)
Power supply:	Lithium-ion 3.7 V, 1100 mAh rechargeable, for 40 hours measurements

DISPOSABLE AND RE-USABLE TURBINES FOR MIR SPIROMETERS

- 33507 DISPOSABLE TURBINE WITH INTEGRATED MOUTHPIECE - box of 60
Single patient use. Low cost and high accuracy. Individually packed to guarantee maximum hygiene. Easy to replace, no calibration needed. Compatible with GIMA codes: 33509, 33511-14, 33518-22, 33527-29, 33530, 33532, 33534.
- 33526 RE-USABLE TURBINE - bayonet
Easy to replace, no calibration needed. Compatible with GIMA codes: 33511-14, 33518, 33520-22, 33528-32, 33534.



MOUTHPIECES FOR MOST SPIROMETER BRANDS

Paper mouthpieces (disposable) and plastic mouthpieces (re-usable for most brands of spirometers and peak flow. Paper mouthpieces are packed in individual transparent pouch.



GIMA PAPER MOUTHPIECES					
GIMA code	Sizes - cm Ø int x ext x h	Suitable for	Compatibility GIMA codes	Other brands	Minimum order
33410	2.8x3x6.5	adult	33431, 33433, 33471-2, 33512-14, 33518-22, 33528-32, 33534	Micromedical Vitalograph, Mir Ferraris (Koko legend) Cardiette (Pneumos 300)	box of 500
33897					dispenser of 100
33411	2.0x2.2x6	paediatric	33411	Micromedical Vitalograph, Mir	box of 250
33412	Plastic adapter		33411	Mir	-
33506	2.6x2.8x6.5	adult	33480, 33484-7	Sibel	box of 100
33494	1.9x2.1x7	paediatric	33486, 33487	Sibel*	box of 100
33890	2.5x2.7x7	adult	-	Fukuda Sangjo, Thor	dispenser of 100
33892	2.8x3.05x7	adult	-	Cosmed (Pony model)	dispenser of 100
33898	2.8x3.05x7	adult	-	Cosmed (Pony model)	box of 500
33895	3.03x3.3	adult	-	Sensormedics, Microcard	box of 500
33899	2.42x2.6	adult	-	Sorin Lifewatch, Fukuda Denshi	box of 500
GIMA PLASTIC MOUTHPIECES					
33432	1.7x2.1x5 2.7x3x5	adult/ped	33431, 33433	Ferraris	-
33691		adult	33682-4, 6, 8	Thor	box of 10

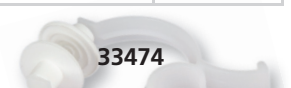
*Gimaspir A/B need adapter 33495

SPIROMETRY PAPERS

- 33492 MIR SPIROLAB PAPER - roll 112mm x 25m
Suitable also for SIBEL DATOSPIR 120 B, C, D, DATOSPIR Touch and GIMASPIR 120 models B, C, D.
- 33893 COSMED PONY PAPER - roll 57 mm x 11 m - box of 5 rolls
- 33894 COSMED PONY FX PAPER - roll 112 mm x 13m - box of 25 rolls
Compatible also with Fukuda Spirosift.
- 33250 THERMAL PAPER - roll 58 mm
Suitable for SIBEL DATOSPIR 120 A and GIMASPIR 120-A.

NOSECLIP

- 33474 NOSE CLIP

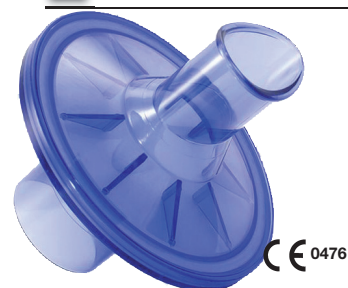


BACTERIAL FILTER

- 33525 BACTERIAL FILTER - box of 50 for MIR, Medisoft spirometers
- 33557 SPIROGUARD BACTERIAL FILTER - box of 50

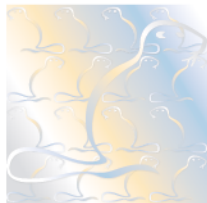
Compatibility of Spiroguard
Erich Jaeger GmbH
Ferraris Medical - P.K. Morgan
Sensormedics
Vitalograph
Masterlab and Masterscreen
Autolink-Benchmark Transflo and USA Transfer System
2200 - 2400 - 2450
Wedge-Bellow-Alpha and Escort Spirometers

BACTERIAL FILTER - MOUTHPIECE FOR MOST SPIROMETER BRANDS



BACTERIAL FILTER - MOUTHPIECE
Disposable filter with anatomical shape to prevent bacterial and viral contamination. Easy to use, direct connection to spirometer one side, patient mouthpiece other side. Suitable for most of spirometers and devices. Class II A. Individually packed in transparent bag. Made in Italy.

BACTERIAL FILTERS - MOUTHPIECES - box of 100				
GIMA code	Size - cm Ø int x ext	Compatibility with		
		GIMA codes	Other brands	
33884	2.75x3	33341, 33433, 33471-2, 33509-14, 33518-22, 33528-32, 33534	Micromedical, Vitalograph, Mir, Ferraris (koko legend), Cardiette (Pneumos 300)	
33885	2.75x3.1	-	Cosmed	
33886	2.95x3.4	-	Customed, Jaeger	
33887	3.05x3.5	-	Sensormedics, BTL, Thor, Morgan, Chest, Microgard	
33888	3.4x3.6	-	Medical Graphics	
33889	2.5x2.7	-	Fukuda Sangjo	



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

Kiwa Cermet Italia S.p.A.
 Società con socio unico,
 soggetta all'attività di
 direzione e coordinamento di
 Kiwa Italia Holding Srl
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 Fax +39.051.763.382
 E-mail: info@kiwacermet.it
 www.kiwa.it



GIMA S.p.A.
Registered Headquarters
 - Via Grossi, 2 20121 Milano Italia
Certified Sites
 - Via Marconi, 1 20060 Gessate (MI) - Italia





Reg. Numero / Reg. Number	MED 26036	Revisione / Revision	23
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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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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www.kiwacermet.it

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

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476



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

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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Organismo Notificato n. 0476
Notified Body nr. 0476

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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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

MED 26036

Revisione /
Revision

23

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Valid from

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Last change date

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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

CERTIFICATE

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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 Aneroidi / 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

CERTIFICATE

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Chief Operating Officer
Giampiero Belcredi

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Data: 25/05/2021 10:13:36



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	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 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

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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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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



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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
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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Modello / Model:

Forbici di Mayo / Forbici di Metzenbaum / Forbici Iris / Forbice ombelicale / Forbice per chirurgia orecchio di Bellucci / Pinze per medicazione standard / Pinze di Hunter-Splinter / Pinze emostatiche di Adson / Pinze emostatiche Halstead-Mosquito / Pinza per dissezione McIndoe / Pinze di Pean / Pinza di Spencer-Wells / Pinza portatamponi di Foerster / Portaghi di Hegar- Mayo / Portaghi di Crile-Wood / Mayo scissors / Metzenbaum scissors / Iris scissors / Umbilical scissors / Bellucci ear scissors / Standard dressing forceps / Hunter-Splinter forceps/ Adson haemostatic forceps/ Halstead-Mosquito dissection forceps / McIndoe dissection forceps/ Pean forceps / Spencer-Wells forceps/ Foerster polypus forceps/ Hegar-Mayo needle holder / Crile-Wood needle holder

Codici / Codes:

388xx ; 389xx

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia. Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey. L'allegato tecnico è parte integrante del presente Certificato./ The technical sheet is an integrating part of this Certificate.

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