

HIGH VACUUM, HIGH FLOW HOSPITAL SUCTION ASPIRATOR



Standard Clinic Plus and Hospi Plus



Clinic Plus and Hospi Plus with foot switch and electronic flow direction regulator

New innovative range of high vacuum, high flow aspirator ideal for hospitals. Pump piston type, lubrication and maintenance free. Supplied with hydrophobic 99% bacterial filter, vacuum gauge for control of vacuum and 2 autoclavable jars (2 or 4 litres) made in makrolon with 200/400 ml graduation and double security valve. Available on request 2 or 3 litre disposable liners. Range includes version with foot

TECHNICAL SPECIFICATIONS

	Hospi plus	Clinic plus
Operating voltage:	110 V or 230 V - 50/60 Hz	230 V - 50/60 Hz - 110 V on request
Maximum suction:	- 0.90 bar (675 mmHg)	- 0.90 bar (675 mmHg)
Operating cycle:	continuous	continuous
Flow:	90 l/min	60 l/min
Power:	300 VA	230 VA
Norms:	CEI 62-5 (IEC 601-1)	CEI 62-5 (IEC 601-1)
	93/42 EEC. Made in Italy	93/42 EEC. Made in Italy

Size: 460x850x420 mm
Weight: 20 kg

switch and flow direction regulator, 110 and 230 V. Four antistatic castors, two of which with brake, allow a perfect mobility. User manual in GB, FR, IT, ES, DE. See spare accessories at page 159, 166. Made in Italy.

GIMA code	CLINIC PLUS / HOSPI PLUS	Jar	Power	Foot switch	Flow direction diverter*
28194	CLINIC PLUS aspirator	2x2 l	220-230 V	-	-
28196	CLINIC PLUS aspirator	2x4 l	220-230 V	-	-
28198	CLINIC PLUS aspirator	2x4 l	220-230 V	yes	yes
28200	HOSPI PLUS aspirator	2x2 l	220-230 V	-	-
28199	HOSPI PLUS aspirator	2x2 l	110 V	-	-
28201	HOSPI PLUS aspirator	2x4 l	220-230 V	-	-
28203	HOSPI PLUS aspirator	2x2 l	220-230 V	yes	yes
28204	HOSPI PLUS aspirator	2x4 l	220-230 V	yes	yes

*Allow to direct suctioned liquids to any of the 2 jars

MAXI ASPEED HIGH FLOW ASPIRATOR FOR HOSPITAL USE



TECHNICAL SPECIFICATIONS

Operating voltage:	230 V - 50/60 Hz. Available on request 110 V - 60 Hz
Air flow:	60 or 90 l/min
Operating cycle:	continuous
Adjustable vacuum level:	0-0.90 bar (0-90 kPa)
Size:	470x580x560 mm
Weight:	15 kg (60 l), 17 kg (90 l)
MDD class:	Ila

MAXI ASPEED SURGICAL ASPIRATORS

Surgical aspirators for aspiration of body liquids in operating theatres and hospitals.

Easy to carry

Equipped with 4 antistatic wheels (2 with brake) and carrying telescopic handle.

Developed to run continuously

Made in highly heat resistant, electrically insulated plastic material in conformity with latest European safety standards. Vacuum regulator with BAR/PSI vacuometer and automatic flow direction regulator to easily switch from a jar to the other. Supplied with 2 autoclavable polycarbonate jars with safety valve (overflow protection), set of atoxic sterilizable silicone tubes, 99% antibacterial hydrophobic filters (2) and multilanguage manual (GB, FR, IT, DE, ES). Made in Italy.

GIMA code	MAXI ASPEED	Jar	Power	Foot switch	Flow direction regulator
28285	Maxi Aspeed 60 l	2x2 l	230 V	-	yes
28286	Maxi Aspeed 60 l	2x2 l	230 V	yes	yes
28288	Maxi Aspeed 60 l	2x4 l	230 V	yes	yes
28289	Maxi Aspeed 90 l	2x2 l	230 V	-	yes
28291	Maxi Aspeed 90 l	2x4 l	230 V	-	yes
28292	Maxi Aspeed 90 l	2x4 l	230 V	yes	yes

ACCESSORIES

28294	Autoclavable jar 2 l with safety valve
28295	Autoclavable jar 4 l with safety valve
28297	Hydrophobic 99% antibacterial filter
25482	Silicone tube - 8x14 mm - roll of 30m



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.

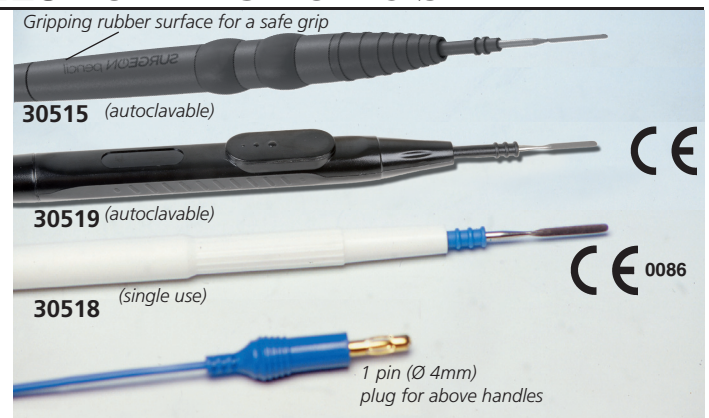


1-PIN MONOPOLAR HANDLES FOR ELECTRODES Ø 2.4 mm

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

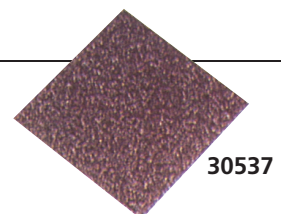
Needle handles for all GIMA Diatermo and electro-depilators

- **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



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...

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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.
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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.

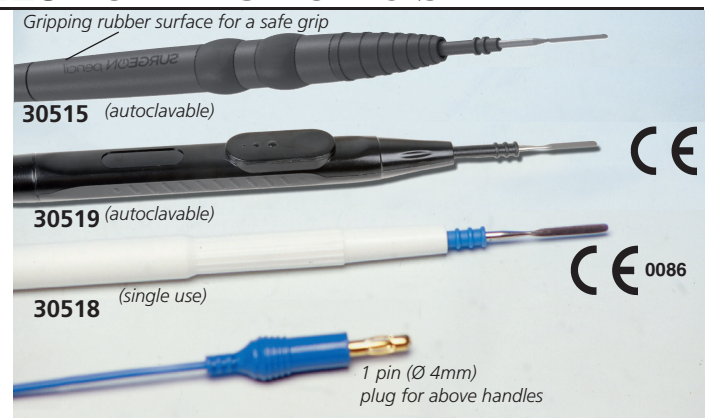


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Single-use handle without button with blade electrode with 4 mm PIN connection.



HANDLES FOR ELECTROLYSIS NEEDLES

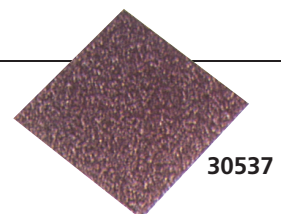
Needle handles for all GIMA Diatermo and electro-depilators

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- see electrolysis needles at page 187



ELECTRODE BRUSHES

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Disposable sterile radiopaque abrasive tip cleaner pad. Box of 100



BIPOLAR CABLES FOR MAJOR BRANDS

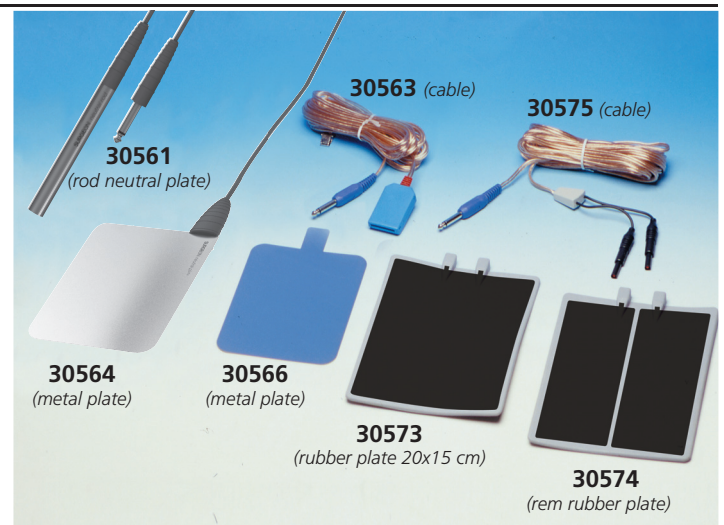
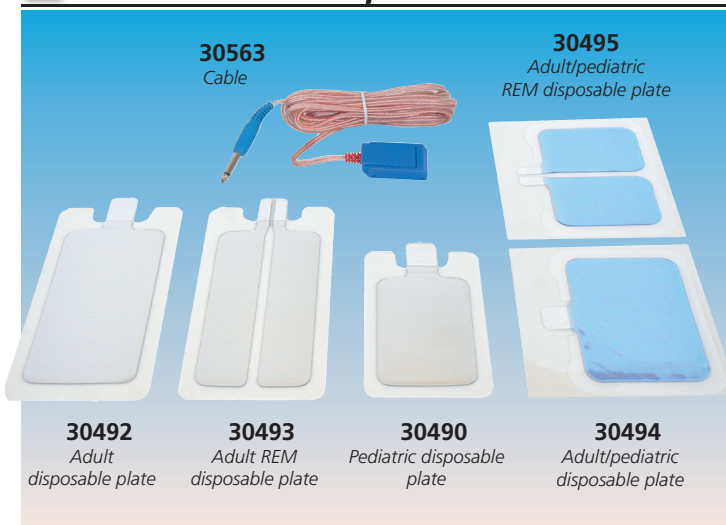


Quality highly flexible silicone bipolar cables.
Autoclavable at 134°C for minimum 20 times. 3 m long (10").

Recommended ETO sterilization for max extended life. Suitable for most generators, with connector for European or US forceps.

 30642 • 30642 BIPOLAR CABLE ADAPTOR	 Connector to forceps		 Connector to electrosurgical unit		 Connector to forceps		 Pin distance 29 mm		 Connector to forceps		 30642		 Connector to forceps		 Connector to electrosurgical unit		 Connector to forceps		 Connector to electrosurgical unit	
	GIMA Code	30632		30618		30640		30637		30643		30618+ 30642		30617		30644		30639		30638
Connector to forceps	 EU		 US		 EU		 US		 EU		 US		 EU		 US		 EU		 EU	
Compatibility brand/model	GIMA: MB 240 MB 380 VALLEY LAB, CONMED, CODMAN, OLYMPUS				GIMA: MB 120 F, MB 200 F, MB 200 D, MB 250, MB 300 D, MB 400 D LED: SURTRON 120, 200, 300, 400 VALLEY LAB, EMC, DOLLEY				GIMA: MB 122, MB 160, MB 200, MB 202				GIMA: MB 80 D, MB 120 D, MB 160 D LED: SURTRON 80, 120, 160				MARTIN BERCHTOLD AESCULAP WOLF		ERBE SELECT DOWNS SIEMENS	

SINGLE USE, METAL AND RUBBER PLATES



- 30492 DISPOSABLE GROUND PADS WITH SOLID GEL - adult
- 30490 DISPOSABLE GROUND PADS WITH SOLID GEL - pediatric
- 30493 REM DISPOSABLE GROUND PADS WITH SOLID GEL - adult
- Adult ground plate with solid gel.
- Single use plate individually packed
- 30563 CABLE FOR PLATES - 5 m
- Universal cable to connect plates (30490-30495) to diathermy.
- Safety lock with universal connection - bipolar Ø 6.3 mm plug.
- 30494 DISPOSABLE NON WOVEN GROUND PADS - adult/ped
- 30495 REM DISPOSABLE NON WOVEN GROUND PADS - adult/ped

- 30573 RUBBER PLATE 20x15 cm - without cable
- 30574 REM RUBBER PLATE 20x15 cm - without cable
- 30575 CABLE FOR RUBBER PLATES
- 30566 METAL PLATE - without cable
- 30563 CABLE FOR PLATES - 5 m
- 30559 CABLE FOR PLATES - 2.5 m
- 30564 SURGEON NEUTRAL PLATE 16x12 cm - with cable
- 30561 ROD NEUTRAL PLATE with cable

3M ELECTROSURGICAL GROUNDING PADS WITH SAFETY RING

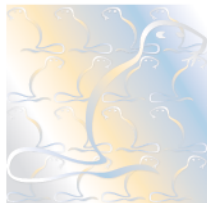
- 30496 3M 9160 SPLIT GROUNDING PAD - box of 100
 - 30497 3M 9160F SPLIT GROUNDING PAD - box of 200 (40 pouches of 5 pieces)
 - 30498 3M 9165 SPLIT GROUNDING PAD - precorded - box of 40
- The 3M 9160, and 9165 Universal Grounding Pads all have a conductor area of 15 square inches and come with the patented 3M Green Safety Ring technology which allows them to perform the same as grounding pads that are up to 33% larger in conductor area. Green Ring allows adult and pediatric use.

In addition, they have fluid resistant, non-woven backing which allows heat to pass through up to 25% faster than foam, and they have no minimum age or weight limit.



30498
(3M 9165)

30496, 30497
(3M 9160)



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
(BO)

Tel +39.051.459.3.111

Fax +39.051.763.382

E-mail: info@kiwacermet.it

www.kiwa.it

CERMET

GIMA S.p.A.

Registered Headquarters

- Via Grossi, 2 20121 Milano Italia

Certified Sites

- Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A



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

Pagina / Page 1 di / of 9

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

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

GIMA S.p.A.

Sede Operativa / Operational Headquarter:

Via Marconi, 1

20060 Gessate, MI - Italia

Sede Legale / Registered Headquarter

Via Tommaso Grossi, 2

20121 Milano, MI - Italia

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

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

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
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E-mail: info@kiwacermet.it
www.kiwacermet.it

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



Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero /
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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

Giampiero Belcredi

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



Organismo Notificato n. 0476
Notified Body nr. 0476

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CERMET

CERTIFICATE



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Last change date

2020-04-24

Pagina / Page 3 di / of 9

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi monouso sterili per ginecologia e otorinolaringoiatria / Sterile Single use gynaecology and ENT devices

Modello / Model:

Speculum vaginale monouso sterile tache - mix / Disposable sterile vaginal speculum tache - mix

Modello / Model:

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

Modello / Model:

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

Modello / Model:

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

Modello / Model:

Tampone di trasporto in plastica sterile / Sterile plastic transport swab

Marca / Brandname:

Gimabrush Ball / Gimabrush / Gima Collector

Modello / Model:

Spazzolini cervicali monouso sterile / Sterile disposable cervical brushes

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

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

Modello / Model:

Proctoscopio adulti / Adult proctoscope

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Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476



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Reg. Number

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Valid from

2016-10-24

Scadenza /
Valid until

2021-10-24

Ultima modifica /
Last change date

2020-04-24

Pagina / Page 4 di / of 9

Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per aerosolterapia / Aerosol therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1102

Modello / Model:

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

Marca / Brandname:

EOLO / CORSIA

Modello / Model:

Aerosol professionale a pistone / Professional compressor nebulizers

Marca / Brandname:

MISTRAL

Modello / Model:

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

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

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

Codice NANDO / NANDO codes:

MD 1302, MD 0104

Marca / Brandname:

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

Modello / Model:

Sfigmomanometri Aneroidi / Aneroid Sphygmomanometers

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Chief Operating Officer
Giampiero Belcredi

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Notified Body nr. 0476



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Valid until

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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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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Modello / Model:

Pulsoximetri / Pulse oximeters

Tipologia / Medical Devices:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1302, MD 0104, MDS 7010

Marca / Brandname:

DIGIT / DIGIT KIDS FARMAMED

Modello / Model:

NUB -Termometri clinici digitali / Digital clinical thermometers

Marca / Brandname:

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

Modello / Model:

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

Marca / Brandname:

FARMAMED / LINEA F / GIMA

Modello / Model:

WATERPROOF- Termometri clinici digitali / Digital clinical thermometers

Marca / Brandname:

PBpharma /GIMA

Modello / Model:

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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per la misurazione di parametri fisiologici / Physiological parameters measuring devices

Classe di rischio / Risk class:

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

Codice NANDO / NANDO codes:

MD 1301, MD 0104

Modello / Model:

Altimetro - Plicometro - Metro per neonati / Height meter - Skinfold caliper - Baby measuring meter

Codice NANDO / NANDO codes:

MD 1301, MD 0104, MDS 7010

Modello / Model:

Bilancia pesapersona / Scales - ASTRA - FAMILY - PEGASO

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 0101

Modello / Model:

Cannule di Guedel sterili / Sterile Guedel airways

Modello / Model:

Maschera per rianimazione CPR / CPR resuscitator mask

Modello / Model:

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

Modello / Model:

Maschere laringee riutilizzabili / Reusable laryngeal airway masks

Modello / Model:

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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Dispositivi per rianimazione ed assistenza respiratoria / Respiratory care and resuscitation devices

Modello / Model:

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

Modello / Model:

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

Tipologia / Medical Devices:

Dispositivi per terapia termica / Thermic therapy devices

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

MD 1403

Modello / Model:

Ghiaccio istantaneo TNT / PE / TNT / PE instant ice cold pack

Tipologia / Medical Devices:

Kit di strumentario chirurgico monouso sterile / Sterile single use surgical instrument kit

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

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

Modello / Model:

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

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Allegato tecnico al Certificato/ Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ Identification of Medical Devices:

Tipologia / Medical Devices:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Classe di rischio / Risk class:

I s - Limitatamente agli aspetti relativi al mantenimento della sterilità / restricted to the aspects concerned the maintenance of sterile conditions

Codice NANDO / NANDO codes:

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

Modello / Model:

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

Modello / Model:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

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

Modello / Model:

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

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

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