






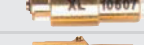






HEINE ORIGINAL BULBS

HEINE BULBS	HEINE ref.	GIMA code	Compatible with following HEINE products
 Xenon 2.5 V	035	31769	Transilluminator Finoff alpha [®] F.O. and F.O. SP Laryngoscopes - Sanalon handle Glaucostet
 Xenon 2.5 V	037	31771	K100 and Beta [®] 100, Beta [®] 100 vet otoscopes Laryngeal mirrors F.O. mini 2000 otoscope Alpha [®] and Alpha F.O. otoscopes Mini/mini 3000/Alpha/Beta tongue holders
 Xenon 2.5 V	038	31773	Miroflex ophthalmoscope HFR2 spot retinoscope Delta [®] 10 dermatoscope
 Xenon 2.5 V	041	31774	Fibrilux mini otoscope Mini 2000 combilamp Mini 2000 cliplamp Mini 1000 cliplamp
 Xenon 2.5 V	042	31780	Alpha [®] ophthalmoscope Mini 2000 ophthalmoscope Alpha [®] Focalux Mini Miroflex ophthalmoscope Mini 2000 Focalux
 Xenon 2.5 V	056	31770	Minilux otoscope Mini 2000 otoscope
 Xenon 2.5 V	057	31785	Mini 2000, Mini 3000 laryngeal mirrors
 Xenon 2.5 V	069	31781	Beta [®] 200, 200 M2, 200S ophthalmoscopes - XHL 2.5 V
 Xenon 2.5 V	077	31772	Beta [®] 200, 200 VET, 400; K 180 otoscopes Lambda 100 retinometer Delta [®] 10 plus dermatoscope
 Xenon 2.5 V	084	31782	K180 [®] ophthalmoscope - 2.5 V
 Xenon 2.5 V	105	31776	Mini 3000 F.O. otoscope
 Xenon 2.5 V	106	31777	Mini 3000 ophthalmoscope
 Xenon 2.5 V	107	31778	Mini 3000 combilamp and cliplamp - XHL 2.5 V
 Xenon 2.5 V	109	31779	Mini 3000 dermatoscope
 Xenon 2.5 V	110	31775	Mini 3000 otoscope
 Xenon 2.5 V	070	31783	Beta 200, 200 M2, 200S ophthalmoscopes - XHL 3.5V
 Xenon 2.5 V	078	31784	Beta 200, 200 Vet, K180 otoscopes lambda 100 retinometer otoscopes - XHL 3.5V

RIESTER ORIGINAL BULBS

RIESTER BULBS	RIESTER ref.	GIMA code	Bulb	Compatible with following RIESTER products
	10421	31850	Vacuum 2.7 V	Otoscope uni [®] /speculight
	10424	31851	Vacuum 2.5 V	May-ophthalmoscope uni [®]
	10487	31825	XL 3.5 V xenon	Otoscope ri-scope [®] L1
	10488	31852	Vacuum 2.7 V	Pen-scope [®] and e-scope [®] otoscope
	10489	31560	HL 2.5 V	Otoscope pen-scope [®] / ri-scope [®] L1 and e-scope [®]
	10590	31853	HL 2.5 V	Otoscope uni [®]
	10600	31854	XL 2.5 V	Otoscope ri-mini [®] , ri-scope [®] L2/L3 and e-scope [®]
	10605	31562	HL 2.5 V	Ophthalmoscope ri-mini/ ri-scope [®] L1, L2, L3, e-scope [®] , ri-derma [®]
	10607	31855	XL 3.5 V	Ri-scope [®] otoscope L2, L3
	10608	31826	XL 3.5 V	Ri-scope [®] ophthalmoscope L1, L2, L3
	14041	31561	LED 3.7 V	E-scope F.O otoscope
	14051	31563	LED 3.7 V	E-scope ophthalmoscopes



WELCH ALLYN BULBS

WELCH ALLYN BULBS	W. A. ref.	GIMA code	Compatible with following WELCH ALLYN products
	00200-U	32120	Anoscopes: 38800, 380, 385, 395 Illuminators: 41000, 26030 Old products: 235, 77900, 26000, 20100, 21600, 42700, 40510
	03000-U	32123	Ophthalmic: 11710, strabismoscope: 12400, episcope: 47300 Old ophthalmic: 11600, 11605, 11610 Retinoscope: 18000
	03100-U	32124	Otoscopes: 25020, 21700, 20200 Handle: 73500, holder: 28100 Illuminators: 27000, 27050, 26530, 41100, 43300 Old otoscopes: 25000, 25200, 20000
	03300-U	32125	Ophthalmic: 11511-11500
	03400-U	32126	Otoscopes: 24011-24020-24000-24031-21110/1 Handle: 73550, Illuminators: 27200-27250-41110
	03800-U	32127	Pan optic: 11810-11820-11800
	04100-U	32128	Exam light: 48400-48410
	04200-U	32129	Exam light: 48600, 48610-48625-48635, 48700
	04400-U	32130	Ophthalmoscopes: 11400-11411-11470-11475
	04700-U	32131	Laryngo: 680, 690, 692 (size 1-2) Old laryngo: 634, 664, 674, 684, 694 (check size)
	04800-U	32132	Laryngo: 680 (size 2-4), 690, 692 (size 3-4) Old laryngo: 634, 640, 664, 674, 684, 694 (check size)
	04900-U	32133	Ophthalmic: 11720, 11730, 11735, 11620, 11630
	06000-U	32134	Laryngo handles: 60813, 60814, 60713, 60815, 60803, 60804
	06500-U	32135	Macroview otoscope: 23810, 23820
	07800-U	32136	Handle: 73211, 73210, 78000, 73200

COMPATIBLE GERMAN BULBS

GIMA BULBS	GIMA code	Compatible with the following products
LARYNGOSCOPE BULBS - MADE IN GERMANY		
	34324	Gima, Riester, And, Kawe, Timesco Truphatek and most of conventional laryngoscopes in the market (generally used for blades N° 00, 0, 1)
	34325	Gima, Riester, And, Kawe, Truphatek, Timesco and most of conventional laryngoscopes in the market (generally used for blades N° 2, 3, 4)
	34485	Gima, And, Kawe and most of F.O. laryngoscopes in the market. Compatible for products that use Heine Bulb # 035
OTOSCOPE-OPHTHALMOSCOPE BULBS - MADE IN FRANCE-GERMANY		
	31795	Heine mini 3000 otoscopes
	31796	Heine mini 3000 F.O. otoscopes
	31449	Parker otoscopes and some otoscopes of Riester, Timesco and Kawe
	31446	Parker ophthalmoscope Parker diagnostic sets
	31478	Gimalux otoscopes, Kawe and Riester mini otoscopes Compatible for products that use Heine bulb #037
	31479	Parker halogen ophthalmoscope
	31428	Gima Xenon - halogen diagnostic sets - ophthalmoscope
OTO-OPHTHALMO-DERMATOSCOPE BULBS - OTHER COUNTRIES		
	31188	Gima dermatoscope Compatible for products that use Heine Bulb #038
	31427	Gima Xenon - halogen diagnostic sets - otoscope

SMART ONE PEAK FLOW-FEV1

• **33681 SMART ONE® - Peak Flow and FEV1** Manual in GB, FR, IT, ES, DE, PT, PL, RU, TR, CN
 Ideal for monitoring respiratory illnesses

and in self management of Asthma, COPD, lung transplant care, cystic fibrosis and for use in clinical trials. **Peak flow and FEV1 on your smartphone**
 Simple handheld wireless device that can be easily connected via Bluetooth to iOS and Android smartphones and tablets.

App (GB, IT) with an exclusive incentive for adult and children based on exhaled flow and volume that gives accurate and helpful results. **Graphic trend of Peak Flow and FEV1**

Measurements including option to flag any test session. Test results history with Peak Flow, traffic light health indicator, symptoms scoring and notes. Low battery consumption.

New turbine flowmeter with plastic mouthpiece For personal use, easy to remove for cleaning and hygienic. Made in Italy.

• **33896 REUSABLE MOUTHPIECE - plastic - box of 10**

• **33897 DISPOSABLE MOUTHPIECE - paper - box of 100**



CE 0476

FDA 510 (K)
 Health Canada

33681



Graphic trends of Peak Flow and FEV1 which can be shared by email

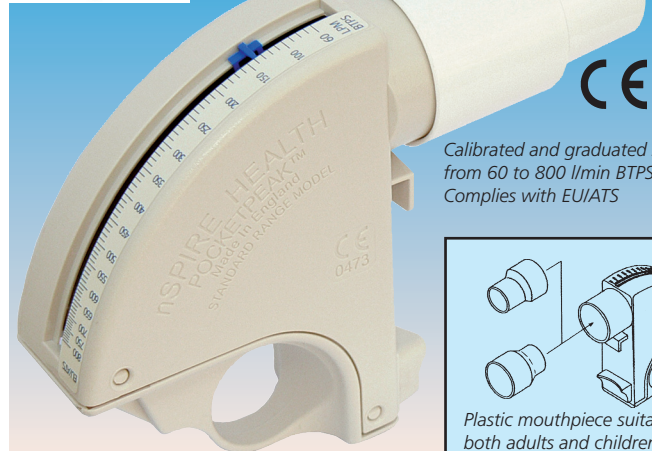


TECHNICAL SPECIFICATION	
General	
Power supply:	2 batteries AAA 1.5 V included
Autonomy:	1,000 tests
Connectivity:	Low energy Bluetooth® 4.0
Size - weight:	49x109x21 mm - 61 g (batteries included)
Mouthpieces:	Ø 30 mm (1.18 inch)
Spirometry	
Flow sensor:	bi-directional digital turbine
Flow range:	±16 L/s Flow accuracy: ±5% or 200 mL/s
Volume accuracy:	±3% or 50 ml
Measured parameters:	FEV1, PEF
Memory capacity:	the application on the smartphone memorizes data

PEAK FLOW METERS

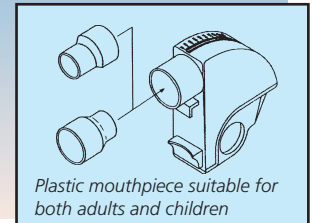


33431



CE 0473

Calibrated and graduated scale from 60 to 800 l/min BTPS
 Complies with EU/ATS



Plastic mouthpiece suitable for both adults and children

• **33431 POCKET PEAK - standard 60-800 l/min - cream**

• **33433 POCKET PEAK - low 50-400 l/min - yellow**

The Pocketpeak Peak Flow Meter is designed to provide simple and reliable home asthma management.

Lightweight and easy to use, it provides accurate and reliable measurements over time.

It is easy to clean and features a universal mouthpiece.

The EU/ATS Scale Pocket peaks will not only comply with the new European Standards but also with ATS (American Thoracic Society) Standards.

Standards range pocket peak will cover 60-800 litres/min, low range will cover 50/400 litres/min.

Package includes multilingual directions for use and peak flow diary, all packed in a cardboard box. Made in USA.

Size 86x81x30 mm.

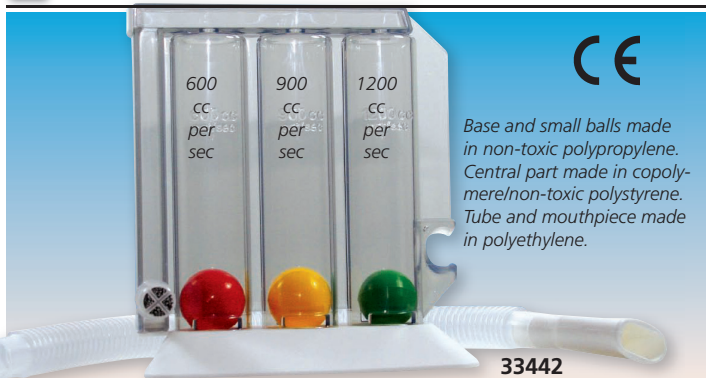
Weight 45 g. Standards: EN 13826:2003

• **33432 UNIVERSAL MOUTHPIECES - re-usable**

In plastic, sterilizable, suitable both for adults and children.

• **33410 DISPOSABLE MOUTHPIECES - box of 500**

LUNG EXERCISE DEVICE



CE

Base and small balls made in non-toxic polypropylene.
 Central part made in copolymer/non-toxic polystyrene.
 Tube and mouthpiece made in polyethylene.

33442

• **33442 RESPIROGRAM**

Device to exercise the respiration through inspiration. The respiratory-exerciser Respirogram helps the patient to recover the normal respiration after a chest or abdominal surgery.

The device is composed of: 1 base, 3 small balls different in dimension and colours, 1 transparent central part divided into 3 rooms, 1 tube and mouthpiece. Each unit packed in single box. Made in Italy. User manual: GB, IT.

• **33445 TRI-BALL® - respiratory exerciser**

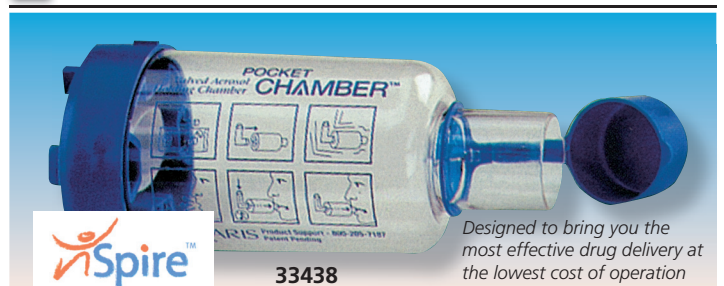
The respiratory-exerciser Tri-Ball® helps the patient to recover the normal respiration after a chest or abdominal surgery. Single patient. User manual in GB, FR, DE, IT, ES.



33445

600/900/1200 cc per sec

AEROSOL HOLDING CHAMBER



33438

Designed to bring you the most effective drug delivery at the lowest cost of operation

• **33438 POCKET CHAMBER**

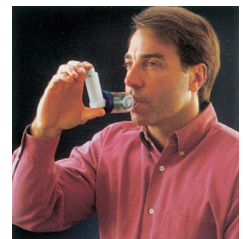
Now you can manage your asthma conveniently and effectively with a truly pocket-sized device, proven as effective as MDI chambers nearly twice its size.

The Pocket Chamber delivers a high concentration of respirable aerosol, to help provide relief from asthma symptoms while capturing large particles and reducing unwanted side-effects.

- whistle alerts patients if inspiratory rate is exceeded

- effective, affordable alternative to expensive aerosol delivery

- flexible port accepts virtually any MDI's mouthpiece



TECHNICAL SPECIFICATION

Size: 108 x 47.5 mm	Volume: 110 ml
Mouthpiece: 22 mm external Ø	Weight: 33 g
Materials: All Latex Free Silicone	Warranty: One year
User Manual: GB, FR, IT, ES, DE, PT, NL, GR, TR	Made in USA

GIMA RESUSCITATORS WITH DOUBLE STAGE VALVE



34231 Resuscitator with kit bag and facemask N° 4

GIMA RESUSCITATOR BAGS

The line offers 3 models of different size: adults, children, infants and an adult kit. All models are supplied with pressure relief valve and equipped with connector under EN 1281-1 directive for: peep valve, intubation fitting, reservoir, oxygen intake, face mask. Each resuscitator can be completely disassembled for cleaning and sterilization. Made in Italy. Autoclavable at 121°C max 20 times.

- **34230 RESUSCITATOR BAG - with mask N°4 - adult**
With a special double stage valve at 54 m/bar. Volume 1800 cc.
- **34233 RESUSCITATOR BAG - with mask N°3 child**
With a special double stage valve at 54 m/bar. Volume 800 cc.
- **34232 RESUSCITATOR BAG - with mask N°2 - infant/newborn**
With a special double stage valve at 54 m/bar. Volume 400 cc.
- **34231 RESUSCITATOR BAG - adult with kit bag**
Same characteristic as code 34230. It is supplied with helicoidal mouth-wedge, tongue holding forceps, 3 Guedel airways (small, medium and large) oxygen tube, in a nylon bag.
- **34271 NYLON BAG - 18.5x15xh 30 cm - spare**

Double side overpressure valve at 54 m/bar avoids inconvenients in case of a regurgitation due to the presence of food in the stomach of the patient

Size 330 x Ø120 mm
Capacity = 1,800 cc



34232 Pediatric resuscitator with child facemask N° 2



34230

SILICONE TRANSPARENT AUTOCLAVABLE RESUSCITATORS

SILICONE RESUSCITATORS - latex free

Transparent resuscitators made of silicone and polysulfone fully autoclavable at 134°C.

- **34244 SILICONE RESUSCITATOR KIT - adult**
Supplied with silicone face mask N° 4, 60 cm H₂O pop-off valve, oxygen tube 2 metres, autoclavable reservoir valve and 2500 ml reservoir bag. Volume: 1,600 ml.
 - **34245 SILICONE RESUSCITATOR - adult**
Supplied with silicone face mask N° 4. Volume: 1600 ml.
 - **34246 SILICONE RESUSCITATOR - child**
Supplied with silicone face mask N° 3 and 40 cm H₂O pop-off valve. Volume: 500 ml.
 - **34247 SILICONE RESUSCITATOR - infant**
Supplied with silicone face mask N° 1 and 40 cm H₂O pop-off valve. Volume: 280 ml.
- All silicone resuscitator have multilanguage manual: GB, FR, IT, ES, PT



34245

CE 0476

All resuscitators are LATEX FREE



CE 0476

34244



CE 0476

34246



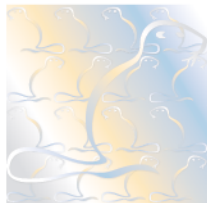
CE 0476

34247

- **34243 SILICONE RESUSCITATOR BAG KIT - adult**
Supplied with silicone face mask N° 4, 60 cm H₂O pop-off valve, oxygen tube 2 metres, autoclavable reservoir valve and 2,500 ml reservoir bag (volume: 1,600 ml), helicoidal mouth wedge (34273), tongue holding forceps, 10 Guedel airways (34439) with Cubo emergency bag (27163).



34243



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

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(BO)

Tel +39.051.459.3.111

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 / <i>Reg. Number</i>	MED 26036	Revisione / <i>Revision</i>	22
Primo rilascio / <i>First issue date</i>	2006-10-25	Valido da / <i>Valid from</i>	2016-10-24
Scadenza / <i>Valid until</i>	2021-10-24	Ultima modifica / <i>Last change date</i>	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*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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Fax +39.051.763.382
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 /
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 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

CERTIFICATE

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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CERMET



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 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

CERTIFICATE

Kiwa Cermet Italia S.p.A.
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all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

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



Organismo Notificato n. 0476
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

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

Kiwa Cermet Italia S.p.A.
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di Kiwa Italia Holding S.r.l.
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Chief Operating Officer

Giampiero Belcredi

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





Reg. Numero / <i>Reg. Number</i>	MED 26036	Revisione / <i>Revision</i>	22
Primo rilascio / <i>First issue date</i>	2006-10-25	Valido da / <i>Valid from</i>	2016-10-24
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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*

CERTIFICATE

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Organismo Notificato n. 0476
Notified Body nr. 0476

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 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 ahaed 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:*

Palloncini rianimatori in silicone / *Kit Palloncini rianimatori in silicone adulti / Silicone resuscitators / Adult silicone resuscitators kit*

Chief Operating Officer

Giampiero Belcredi

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CERTIFICATE

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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 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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