

MEDICAL GRADE SILICONE TUBES FOR EXTERNAL USE



SILICONE TUBES for external medical use - silicone 100%
 Suitable for autoclaving (135°C - 2.2-2.5 bar) and Gamma Sterilization. Resistant to hot air up to 200°C.
 Infra-red vulcanization.
 Hours treatment at 200°C temperature in special oven.
 Anti-adherent, avoid incrustation and coagulation.
 Medical Grade - Transparent - Odourless

TECHNICAL SPECIFICATIONS

Raw material: HTV-R-401/60 S - WACKER (D)
 Colour: translucent
 Hardness: 60° ±5% Shore - DIN 53505
 Density: 1.17 g/ccm - DIN 53479A
 Tensility: 10.8 N/mm² - DIN 53504 S1
 Stretch: 490/530% - DIN 53504S1
 Tear resistance: 34-35 N/mm - ASTM D 624 B
 Reverse pull elasticity: 51% - DIN 53512
 Compression set: (22h/175°C): 30-15% - DIN 53517

Made in European Union according to: US PHARMACOPOEIA XXI
 EUROPEAN PHARMACOPEA DIN 58367 - DIN 58362 - DIN
 13098- FDA 177.2600 - BGA XV part A and B - BGA IX part B

GIMA code	Internal diameter x external diameter	Thickness mm	Minimum order
25450	1x3 mm	1 mm	roll of 100 m
25451	2x4 mm	1 mm	roll of 100 m
25452	3x5 mm	1 mm	roll of 100 m
25453	4x6 mm	1 mm	roll of 100 m
25455	6x8 mm	1 mm	roll of 30 m
25458	3x6 mm	1.5 mm	roll of 30 m
25459	4x7 mm	1.5 mm	roll of 30 m
25460	5x8 mm	1.5 mm	roll of 30 m
25461	6x9 mm	1.5 mm	roll of 30 m
25462	7x10 mm	1.5 mm	roll of 30 m
25466	4x8 mm	2 mm	roll of 30 m
25467	5x9 mm	2 mm	roll of 30 m
25468	6x10 mm	2 mm	roll of 30 m
25469	8x12 mm	2 mm	roll of 30 m
25470	10x14 mm	2 mm	roll of 30 m
25474	5x10 mm	2.5 mm	roll of 30 m
25475	7x12 mm	2.5 mm	roll of 30 m
25476	8x13 mm	2.5 mm	roll of 30 m
25477	10x15 mm	2.5 mm	roll of 30 m
25480	6x12 mm	3 mm	roll of 30 m
25481	7x13 mm	3 mm	roll of 30 m
25482	8x14 mm	3 mm	roll of 30 m
25483	9x15 mm	3 mm	roll of 30 m
25484	10x16 mm	3 mm	roll of 30 m
25485	12x18 mm	3 mm	roll of 30 m
25488	8x15 mm	3.5 mm	roll of 30 m
25491	10x20 mm	5 mm	roll of 30 m
25495		made to order	500 m

MADE TO ORDER SILICONE TUBES
 We can manufacture any size
 (minimum order 500 m - delivery 30 days)

ACCESSORIES FOR ANY SUCTION ASPIRATOR



GIMA code	STAINLESS STEEL ASPIRATION TUBES
28262	S/S Bierer Aspiration tube Ø 8 mm
28264	S/S Bierer Aspiration tube Ø 12 mm
	Supplied with removable connection cannula
28260	Set of 7 uterine aspiration cannulas for abortion: 4 cannulas with side suction end (Ø 5, 6, 8, 9 mm), 3 cannulas with front suction end (Ø 7, 10, 11 mm) and one handle

- SILICONE VACUUM SUCTION
See page 172
- SUCTION CATHETER
See page 43
- S/S FRAIZER SUCTION CANNULA
See page 34
- S/S ROSEN SUCTION CANNULA
See page 34
- S/S NOVAK SUCTION CANNULA
See page 33

BREAST PUMP - MAMILAT GIMA

• **28148 MAMILAT - BREAST PUMP - 230 V - 50 Hz**
 Easily transportable from one maternity ward to another, or for use at home. To be used for mother's milk suction. Made of highly heat-resistant, electrically insulated plastic material in conformity with the latest European safety standards. Supplied with 2 polycarbonate milk bottles (150 cc and 250 cc) antibacterial and hydrofobic filter, set of tubes 6x10 mm, breast shield, PVC air tube. Suction adjustment knob. Working time: 20 minutes ON, 40 OFF.

• **28229 HYDROPHOBIC ANTIBACTERIAL FILTER - spare**

• **28149 SPARE KIT**

Includes two plastic bottles (125 cc and 250 cc) nipple shield, filter and tubes.

TECHNICAL SPECIFICATIONS

Regulator for suction intensity - max suction -0.33 bar
 Operating voltage: 220-230 V - 50/60 Hz - available on request 110 V - 60 Hz
 Max flow (air litres/min): 14 l/min
 Power consumption: 184 VA
 Size: 235x190x165 mm Weight: 2.2 kg
 Norms: CEI 62-5 (IEC601-1). Made in Italy

Supplied with anti-bacterial filter

5 languages manual:
 IT, GB, ES, FR, DE.



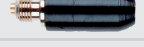




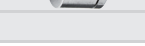



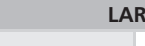


28148

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 Glaucostest
 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



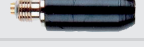




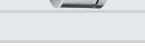



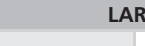
COMPATIBLE GERMAN BULBS

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

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 Glauco-test
 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
 Miroflex ophthalmoscope	038	31773	Miroflex ophthalmoscope HFR2 spot retinoscope Delta [®] 10 dermatoscope
 Fibrilux mini otoscope	041	31774	Fibrilux mini otoscope Mini 2000 combilamp Mini 2000 cliplamp Mini 1000 cliplamp
 Alpha ophthalmoscope	042	31780	Alpha [®] ophthalmoscope Mini 2000 ophthalmoscope Alpha [®] Focalux Mini Miroflex ophthalmoscope Mini 2000 Focalux
 Minilux otoscope	056	31770	Minilux otoscope Mini 2000 otoscope
 Mini 2000, Mini 3000 laryngeal mirrors	057	31785	Mini 2000, Mini 3000 laryngeal mirrors
 Beta 200, 200 M2, 200S ophthalmoscopes - XHL 2.5 V	069	31781	Beta [®] 200, 200 M2, 200S ophthalmoscopes - XHL 2.5 V
 Beta 200, 200 VET, 400, K 180 otoscopes	077	31772	Beta [®] 200, 200 VET, 400, K 180 otoscopes Lambda 100 retinometer Delta [®] 10 plus dermatoscope
 K180 ophthalmoscope - 2.5 V	084	31782	K180 [®] ophthalmoscope - 2.5 V
 Mini 3000 F.O. otoscope	105	31776	Mini 3000 F.O. otoscope
 Mini 3000 ophthalmoscope	106	31777	Mini 3000 ophthalmoscope
 Mini 3000 combilamp and cliplamp - XHL 2.5 V	107	31778	Mini 3000 combilamp and cliplamp - XHL 2.5 V
 Mini 3000 dermatoscope	109	31779	Mini 3000 dermatoscope
 Mini 3000 otoscope	110	31775	Mini 3000 otoscope
 Beta 200, 200 M2, 200S ophthalmoscopes - XHL 3.5 V	070	31783	Beta 200, 200 M2, 200S ophthalmoscopes - XHL 3.5 V
 Beta 200, 200 Vet, K180 otoscopes	078	31784	Beta 200, 200 Vet, K180 otoscopes lambda 100 retinometer otoscopes - XHL 3.5 V

RIESTER ORIGINAL BULBS

RIESTER BULBS	RIESTER ref.	GIMA code	Bulb	Compatible with following RIESTER products
 Riester 2.7 V	10421	31850	Vacuum 2.7 V	Otoscope uni [®] /speculight
 Riester 2.7 V	10424	31851	Vacuum 2.5 V	May-ophthalmoscope uni [®]
 3.5 V xenon	10487	31825	XL 3.5 V xenon	Otoscope ri-scope [®] L1
 2.7 V	10488	31852	Vacuum 2.7 V	Pen-scope [®] and e-scope [®] otoscope
 2.5 V	10489	31560	HL 2.5 V	Otoscope pen-scope [®] / ri-scope [®] L1 and e-scope [®]
 2.5 V	10590	31853	HL 2.5 V	Otoscope uni [®]
 2.5 V	10600	31854	XL 2.5 V	Otoscope ri-mini [®] , ri-scope [®] L2/L3 and e-scope [®]
 2.5 V	10605	31562	HL 2.5 V	Ophthalmoscope ri-mini/ ri-scope [®] L1, L2, L3, e-scope [®] , ri-derma [®]
 3.5 V	10607	31855	XL 3.5 V	Ri-scope [®] otoscope L2, L3
 3.5 V	10608	31826	XL 3.5 V	Ri-scope [®] ophthalmoscope L1, L2, L3
 LED 3.7 V	14041	31561	LED 3.7 V	E-scope F.O otoscope
 LED 3.7 V	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	00200-U	32120	Anoscopes: 38800, 380, 385, 395 Illuminators: 41000, 26030 Old products: 235, 77900, 26000, 20100, 21600, 42700, 40510
 03000-U	03000-U	32123	Ophthalmic: 11710, strabismoscope: 12400, episcope: 47300 Old ophthalmic: 11600, 11605, 11610 Retinoscope: 18000
 03100-U	03100-U	32124	Otoscopes: 25020, 21700, 20200 Handle: 73500, holder: 28100 Illuminators: 27000, 27050, 26530, 41100, 43300 Old otoscopes: 25000, 25200, 20000
 03300-U	03300-U	32125	Ophthalmic: 11511-11500
 03400-U	03400-U	32126	Otoscopes: 24011-24020-24000-24031-21110/1 Handle: 73550, Illuminators: 27200-27250-41110
 03800-U	03800-U	32127	Pan optic: 11810-11820-11800
 04100-U	04100-U	32128	Exam light: 48400-48410
 04200-U	04200-U	32129	Exam light: 48600, 48610-48625-48635, 48700
 04400-U	04400-U	32130	Ophthalmoscopes: 11400-11411-11470-11475
 04700-U	04700-U	32131	Laryngo: 680, 690, 692 (size 1-2) Old laryngo: 634, 664, 674, 684, 694 (check size)
 04800-U	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	04900-U	32133	Ophthalmic: 11720, 11730, 11735, 11620, 11630
 06000-U	06000-U	32134	Laryngo handles: 60813, 60814, 60713, 60815, 60803, 60804
 06500-U	06500-U	32135	Macroview otoscope: 23810, 23820
 07800-U	07800-U	32136	Handle: 73211, 73210, 78000, 73200

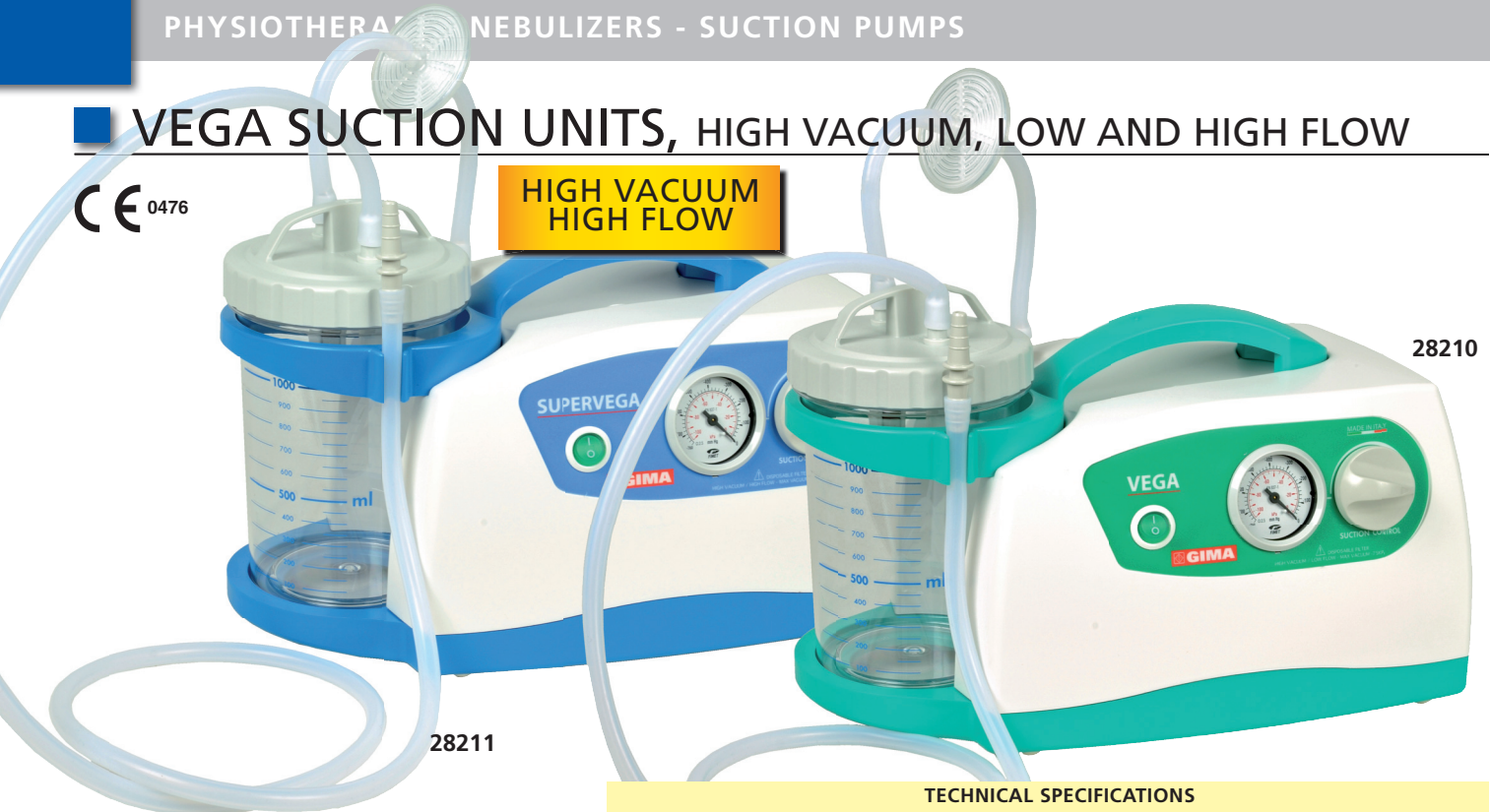
COMPATIBLE GERMAN BULBS

GIMA BULBS	GIMA code	Compatible with the following products
LARYNGOSCOPE BULBS - MADE IN GERMANY		
 Conventional laryngoscope SMALL bulb 2.7 V	34324	Gima, Riester, And, Kawe, Timesco Truphatek and most of conventional laryngoscopes in the market (generally used for blades N° 00, 0, 1)
 Conventional laryngoscope LARGE bulb 2.7 V	34325	Gima, Riester, And, Kawe, Truphatek, Timesco and most of conventional laryngoscopes in the market (generally used for blades N° 2, 3, 4)
 Xenon halogen bulb for F.O. Laryngoscope and otoscope	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		
 Xenon halogen otoscope bulb	31795	Heine mini 3000 otoscopes
 Xenon halogen F.O. otoscope bulb	31796	Heine mini 3000 F.O. otoscopes
 Otoscope bulb 2.5V	31449	Parker otoscopes and some otoscopes of Riester, Timesco and Kawe
 Ophthalmoscope bulb 2.5V	31446	Parker ophthalmoscope Parker diagnostic sets
 Xenon halogen bulb for otoscope 2.5V	31478	Gimalux otoscopes, Kawe and Riester mini otoscopes Compatible for products that use Heine bulb #037
 Halogen bulb for ophthalmoscope and dermatoscope 2.5V	31479	Parker halogen ophthalmoscope
 Xenon halogen ophthalmoscope bulbs 3.5 V	31428	Gima Xenon - halogen diagnostic sets - ophthalmoscope
OTO-OPHTHALMO-DERMATOSCOPE BULBS - OTHER COUNTRIES		
 Halogen Dermatoscope bulb 2.5 V	31188	Gima dermatoscope Compatible for products that use Heine Bulb #038
 Xenon halogen otoscope bulbs 3.5 V	31427	Gima Xenon - halogen diagnostic sets - otoscope

VEGA SUCTION UNITS, HIGH VACUUM, LOW AND HIGH FLOW



**HIGH VACUUM
HIGH FLOW**



28211

28210

VEGA SUCTION UNITS

A line of stylish, compact and reliable aspirators for small surgery. Silent, high flow and maintenance-free pumps allow long product life and durability. Recommended for nasal aspiration, oral aspiration, tracheal aspiration of body liquids (mucus, catarrh or blood) in adults or children. Equipped with vacuum regulator continuously adjustable, vacuum indicator, unbreakable 1,000 ml or 2,000 ml bottle, autoclavable at 121°C, with safety float control valve to prevent overflow. Optional bottle autoclavable at 134°C. Manufactured in electric and thermal insulated plastic body.

Autoclavable and disposable collection system: In addition to standard autoclavable jar is available a disposable collection system composed by a rigid reusable container and a polyethylene disposable liner with cover, hermetically sealed, and hydrophobic, antireflux, bacterial filter operating as an overflow valve. Made in Italy.

	TECHNICAL SPECIFICATIONS		
	28209 VEGA UNO	28210 VEGA	28211 SUPERVEGA
Operating Voltage:	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz 110 V - 60 Hz (on request)	220-230 V - 50/60 Hz or 110 V - 60 Hz
Power consumption:	184 W	184 W	106 W
Bottle capacity:	1,000 ml	1,000 ml	1,000 ml or 2,000 ml
Flow (air litres/min):	15 l/min	16 l/min	40 l/min
Max suction:	-0.75 bar (563 mm/Hg)	-0.75 bar (563mm/Hg)	-0.80 bar (600mm/Hg)
Operating cycle:	continuous	continuous	continuous
Size:	25x19x16.5 cm	35x21x18 cm	35x21x18 cm
Weight:	2.2 kg	2.5 kg	3.6 kg
Norms:	93/42/ECC	93/42/ECC	93/42/ECC

GIMA code	VEGA SUCTION ASPIRATOR	Operating power	Flow
28209	Vega Uno	220-230 V - 50/60 Hz	15 l/m
28210	Vega	220-230 V - 50/60 Hz	16 l/m
28211	Super Vega 1l	220-230 V - 50/60 Hz	40 l/m
28212	Super Vega 2l	220-230 V - 50/60 Hz	40 l/m
28189	Super Vega 1l	110 V - 60 Hz	40 l/m

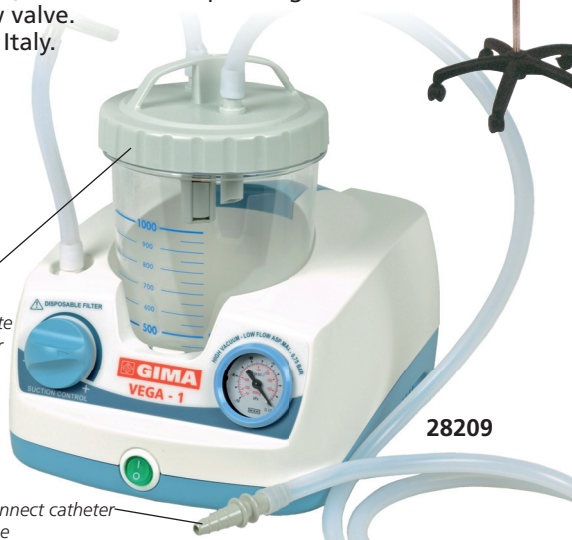


28211 + 28213



GIMA code	SPARE ACCESSORIES FOR VEGA AND TOBI LINE
28229	Hydrophobic, 99% antibacterial filter
28226	121°C autoclavable jar 1 l with cover and overflow system
28236	121°C autoclavable jar 2 l with cover and overflow system
28227	Cover and overflow valve system for 28226 and 28236
28185	134°C autoclavable jar 1 l with cover and overflow system
28186	134°C autoclavable jar 2 l with cover and overflow system
28184	Cover and overflow valve system for 28185 and 28186
28271	Disposable liner 1 l (cover + bag)
28270	Container for disposable liner 1 l
28268	Disposable liner 1 l (cover + bag) - box of 50
28273	Disposable liner 2 l (cover + bag)
28269	Disposable liner 2 l (cover + bag) - box of 50
28272	Container for disposable liner 2 l Ø 13 cm top, 9.5 cm bottom
25468	Silicone tube 6x10 mm - roll of 30 m
28252	Adaptor to connect catheter to silicone tube
	Suction catheter - see at page 43
28213	Trolley for Vega and Super Vega (not for Vega Uno)
28276	Vacuum indicator for Vega and Super Vega (not for Vega Uno)

1 l polycarbonate autoclavable jar with overflow safety valve



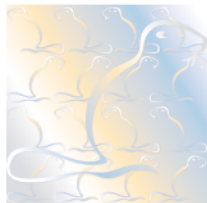
28209

28252 Adaptor to connect catheter to silicone tube

STANDARD ACCESSORIES

- Autoclavable jar (1 or 2 l) with overflow valve system
- Antibacterial and hydrophobic filter
- Set of silicone tubes 6x10 mm
- Conical connector for probes
- 6 languages user manual (GB, FR, IT, DE, ES, PT) **28229**





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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40057 Granarolo dell'Emilia
(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





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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
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www.kiwacermet.it

Rif. rapporto di audit/ *Ref. audit report:* del/dated 08-14/11/2019

Chief Operating Officer
Giampiero Belcredi

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Organismo Notificato n. 0476
Notified Body nr. 0476



Reg. Numero / <i>Reg. Number</i>	MED 26036	Revisione / <i>Revision</i>	22
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Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate*

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*

Dispositivi attivi per l'aspirazione di sostanze e liquidi / *Active substances and liquids suctioning devices*

Classe di rischio / *Risk class:*

II a

Codice NANDO / *NANDO codes:*

MD 1104

Marca / *Brandname:*

VEGA / SUPER VEGA / TOBI / SUPER TOBI / TOBI CLINIC / TOBI HOSPITAL / CLINIC PLUS / HOSPI PLUS

Modello / *Model:*

Aspiratori chirurgici e vasi di ricambio / *Surgical aspirators and jars*

Tipologia / *Medical Devices:*

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

Classe di rischio / *Risk class:*

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

Codice NANDO / *NANDO codes:*

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

Modello / *Model:*

Kit ORL sterile / *Sterile ENT kit*

Modello / *Model:*

Kit pap test / *Pap smear kit*

Modello / *Model:*

Spatula cervicale monouso sterile in plastica o legno / *Disposable sterile plastic or wooden cervical spatula*

Modello / *Model:*

Speculum vaginale monouso sterile perno centrale - mix / *Disposable sterile vaginal speculum central pin - mix*

Modello / *Model:*

Speculum vaginale monouso sterile perno centrale - piccolo, medio, grande / *Disposable sterile vaginal speculum central pin - small, medium, large*

Chief Operating Officer

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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

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Reg. Numero / <i>Reg. Number</i>	MED 26036	Revisione / <i>Revision</i>	22
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Allegato tecnico al Certificato/ *Technical sheet enclosed to the Certificate*

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*

Dispositivi per aerosolterapia / *Aerosol therapy devices*

Classe di rischio / *Risk class:*

II a

Codice NANDO / *NANDO codes:*

MD 1102

Modello / *Model:*

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

Marca / *Brandname:*

EOLO / CORSIA

Modello / *Model:*

Aerosol professionale a pistone / *Professional compressor nebulizers*

Marca / *Brandname:*

MISTRAL

Modello / *Model:*

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

Tipologia / *Medical Devices:*

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

Classe di rischio / *Risk class:*

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

Codice NANDO / *NANDO codes:*

MD 1302, MD 0104

Marca / *Brandname:*

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

Modello / *Model:*

Sfigmomanometri Aneroidi / *Aneroid Sphygmomanometers*

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Chief Operating Officer

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Organismo Notificato n. 0476
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Reg. Numero /
Reg. Number MED 26036

Revisione /
Revision 22

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First issue date 2006-10-25

Valido da /
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Valid until 2021-10-24

Ultima modifica /
Last change date 2020-04-24

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CERTIFICATE

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 ahaed multifunction thermometers

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 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

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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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Chief Operating Officer
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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:

Strumentario chirurgico monouso sterile / Sterile single use surgical instrument

Classe di rischio / Risk class:

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

Codice NANDO / NANDO codes:

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

Modello / Model:

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

Modello / Model:

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

Classe di rischio / Risk class:

II a

Codice NANDO / NANDO codes:

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

Modello / Model:

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

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

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Chief Operating Officer
Giampiero Belcredi

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