

BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)



• BUBBLE MATTRESS

Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side.

Cold-resistant -30 degrees.

Flaps length: 50+50 cm (top + bottom).

• PUMP SYSTEM

Special silent pump for an excellent pressure regulation by a knob on the front panel.

It can be hung to any kind of hospital bed frame by means of two adjustable hooks.

For use with bubble or alternating cell mattresses.

Technical Specifications

Bubble mattress:

- Total size: 200 x 90 x 7 cm
- Cell height: 7 cm (2.7")
- Material: PVC
- Thickness: 0.32 mm
- Number of cells: 130
- Suitable for persons up to: 135 kg

Pump system:

- Size: 25 x 12 x h 10 cm
- Operating voltage: 220 V, 50 Hz
- Working pressure: 40-100 mmHg
- Air output: 6-7 liter/min
- Cycle time: 6 min
- Plastic casing: Taiwan chimei ABS
- TUV-CE IEC/EN60601-1; 60601-1-2



DECLARATION OF CONFORMITY

We, undersigned GIMA S.p.A., with operational headquarters in Gessate (MI), Via Marconi 1, and registered office in Milano, Via Tommaso Grossi 2, acting as manufacturer of the medical device:

GIMA Single Registration Number (SRN):

Medical Device (Trade Name and description)	Code	Basic UDI-DI code
BUBBLE AIR MATTRESS + COMPRESSOR (28564+28565)	28566	802327900Y0333998100000PW

Risk class I (Not sterile), according to the Rule 13 Annex VIII of Regulation (EU) 2017/745 (MDR), declares, under its own responsibility, that this medical device:

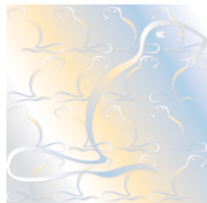
- comply with essential requirements and dispositions of Regulation (EU) 2017/745 (MDR), as from the Technical File filed at the company;
- common Specifications have not been used for the compliance of the above medical device;
- comply with directive 2011/65/EU (and subsequent amendments and integrations) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Gessate, 5/28/2021

GIMA S.p.A.

The legal Representative
(Nicola Manzoni)

A handwritten signature in black ink, appearing to read "N. Manzoni", is written over a horizontal line.



Reg. Number	10164 - A	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid Until	2024-10-14	IAF Sector	29 a

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids.

Chief Operating Officer
Giampiero Belcredi

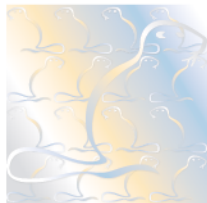
The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

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

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





Reg. Number	10164 - M	Valid From	2021-10-14
First issue date	2012-10-15	Last change date	2021-10-14
Valid until	2024-10-14		

Quality Management System Certificate
ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Management of design and production, packaging and service of:
 General non-active, non-implantable medical devices (except: injection, infusion, transfusion and dialysis; disinfecting, cleaning, rinsing; IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except: extra-corporal circulation, infusion and haemopheresis; stimulation or inhibition, rehabilitation devices and active prostheses; IVF, ART; software; medical gas supply systems and parts thereof), Monitoring devices, Devices for imaging and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices (IVD).
 Trade and service of: General non-active, non-implantable medical devices (except: IVF, ART; ingestion), Devices for wound care, Non-active dental devices and accessories (except dental implants), General active medical devices (except IVF, ART), Devices for imaging (except ionizing radiation), Monitoring devices, Devices for radiation therapy and thermo therapy (except: ionizing radiation, lithotripsy), In Vitro Diagnostic Medical Devices(IVD)

Chief Operating Officer
 Giambiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

CERTIFICATE

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



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



ANTI-DECUBITUS AIR MATTRESSES WITH PUMP - STAGE I AND II



BASIC CARE STAGE I

Flaps length: 50+50 cm (top + bottom)

EN71 MEDICAL GRADE PVC

28564

BUBBLE MATTRESS
Designed for the treatment and prevention of pressure sore stage I in short-term and domiciliary therapies. The PVC mattress is composed of 130 7 cm-high bubble cells, particularly comfortable. Fixable to bed by extra flaps on both top and bottom side. Cold-resistant -30 degrees.

PUMP SYSTEM
Special silent pump for an excellent pressure regulation by a knob on the front panel. It can be hung to any kind of hospital bed frame by means of two adjustable hooks. For use with bubble or alternating cell mattresses.

28565

MODERATE CARE STAGE I, II

Cells are fixed by means of pressure stud and can easily be replaced in case of breakage

28567

INTERCHANGEABLE CELL-MATTRESS
Recommended for the prevention and treatment of pressure sore stage I and II in medium-term and domiciliary therapies. The 20 9.5 cm-high Nylon+PVC cells provide superior comfort.

GIMA code	MATTRESSES AND PUMP
28564	Bubble mattress
28565	Pump for 28564
28566	Kit bubble mattress+pump (28564+28565)
28567	Interchangeable cell mattress
28568	Pump for 28567
28569	Kit cell mattress+pump (28567+28568)
28570	Spare cell for 28567

Manual and box in 10 languages: GB, FR, IT, ES, DE, PT, PL, HU, GR, Arabic

TECHNICAL SPECIFICATIONS - PUMP

	28565	28568
Size:	25x12xh 10 cm	
Operating voltage:	220 V, 50 Hz	
Working pressure:	40-100 mmHg	40-110 mmHg
Air output:	6-7 liter/min	6-7 liter/min
Cycle time:	6 min	12 min
Plastic casing:	Taiwan chimei ABS	
	-TUV-CE IEC/EN60601-1; 60601-1-2-	

TECHNICAL SPECIFICATIONS - MATTRESS

	28564	28567
Total size:	200x90x7 cm	200x86x9.5 cm
Cell height:	7 cm (2.7")	9.5 cm (4")
Material:	PVC	Nylon+PVC
Thickness:	0.32 mm	0.32 mm
Number of cells:	130	20+1 spare
Suitable for persons up to:	135 kg	140 kg

THERAPEUTIC ANTI-DECUBITUS MATTRESSES - STAGE III AND IV



MODERATE TO INTENSIVE CARE STAGE I, II, III

Ventilated low-air-loss cells wicks moisture away

28575

Nylon PU cover with button biocompatibility, vapor permeable & water resistant with CA117. Flame Retardant Level.

• **28575 KIT 5010 ALTERNATING PRESSURE MATTRESS + PUMP**
Valuable overlay system designed for prevention and treatment of patients at moderate to intensive risk of pressure ulcers. Pressure is periodically redistributed by inflating and deflating cells in order to mimic natural sleep movement patterns and avoid long term pressurization of tissue. Manual in: GB, IT.

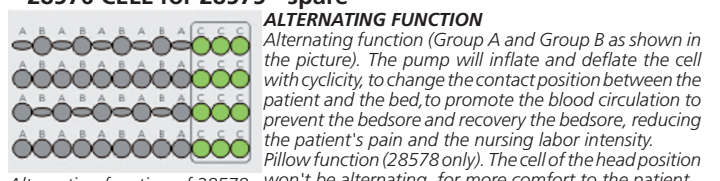
• **28576 CELL for 28575 - spare**

INTENSIVE CARE STAGE I, II, III, IV

CPR straps quickly deflate the mattress for emergencies

28578

• **28578 KIT 8050 ALTERNATING PRESSURE MATTRESS + PUMP**
Advanced systems of alternating pressure mattress. The multi-mode pump offers.



- **alternating mode:** the pressure is periodically redistributed by inflating and deflating cells in order to mimic natural sleep movement patterns and avoid long term pressurization of tissue.

- **constant static mode:** the pressure is about 2/3 lowered when compared to the same pressure level from alternating mode by means of immersion and envelopment. Visual alarms notify the caregiver unusual situation, reducing the risk of human error. Suitable for the prevention and treatment of all stages of pressure ulcers. Manual in: GB, IT.

• **28579 CELL for 28578 - spare**

TECHNICAL SPECIFICATIONS - PUMPS (28575 and 28578)

Size:	30x13.5xh 11 cm	Cell height:	12.5 cm (5")
Operating voltage:	220 V, 50 Hz	Working pressure:	55-120 mmHg
Cycle time:	12 min	Air output:	7-8 liter/min
Case material:	Flame retardant ABS		
	TUV-CE IEC/EN60601-1; 60601-1-2		

PUMP 28578 only
Static Mode, low pressure alarm, quick connector, transfer function

TECHNICAL SPECIFICATIONS - MATTRESS

	28575	28578
Total size:	200x90x12.8 cm	200x90x22 cm
Alternating	1 in 2 (group A and B)	
Cell height:	12.8 cm (5")	22 cm (8.66")
Cover material:	Nylon PU with button	Nylon+PU with cotton lining
Thickness:	0.4 mm	0.3 mm
Cells material:	nylon PVC	TPU
Suitable for persons up to:	150 kg	180 kg