



# GIMA

## CPR MASK - pocket resuscitator

**Code:** 34218  
**Category:** Mouth to mouth resuscitaton masks  
**Unit of sale:** 1 pc.  
**Minimum order:** 1  
**Type:** Medical device  
**Class:** I  
**NSIS:** 2527128  
**CND:** R03010105  
**EAN13:** 4716770662404



**Description:** CPR MASK - pocket resuscitator

The CPR pocket mask is a non-invasive, latex free mask with an integral non-rebreathing valve and efficient filter to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation. It can be used on adult, child and infant. Supplied in a compact plastic box with a corrugated tube for an easier use.

## ORIGINAL CU, PRIMEDIC AND PROGETTI PADS

Pair	5 pairs	PEDIATRIC PADS: BRAND - MODEL	Pair	10 pairs	ADULT PADS: BRAND - MODEL
33569	-	<b>CU Medical System</b> CU-ER1, CU-ER2, CU-ER3	35345	33565	<b>CU Medical System</b> CU-ER1, CU-ER2, CU-ER3
33443	-	iPad NF 1200	33441	33441	iPad NF 1200
35345	-	CU-SP1, CU-SP2, CU-SPR	35344	35344	CU-SP1, CU-SP2
35405	-	CU-SPR (adult/pediatric)	35405	35405	CU-SPR (adult/pediatric)
35390	-	<b>Metrax-Primedic</b> HeartSave Pad, AED, AED-M, 6, 6S since S.N. 739xxxxxxx	35392	35392	<b>Metrax-Primedic</b> HeartSave Pad, AED, AED-M, 6, 6S since S.N. 739xxxxxxx
			33388	35380	HeartSave Pad, AED, AED-M, 6, 6S up to S.N. 738xxxxxxx
			35380		Defimonitor XD1, XD3, XD10, XD30, XD100, XD300, XD110, XD330
33458	33459	<b>Progetti</b> Rescue Sam, Rescue 230, Rescue Life 5.7" and 7" with cable	33458	33461	<b>Progetti</b> Rescue 230, Rescue Life 5.7" and 7"
			33420	33428	Rescue Sam with cable
				33461	

## COMPATIBLE DEFIBRILLATOR ECG THERMAL PAPER - DIFFERENT BRANDS

GIMA code	MANUFACTURER AND MODEL	Type	Width mm	Length m	Sheet	Marker	Grid*	Min. order	GIMA code	MANUFACTURER AND MODEL	Type	Width mm	Length m	Sheet	Marker	Grid*	Min. order
33099	<b>Bexen</b> Reanibex - 800	roll	106	20	-	no	or/red	10	32988	<b>Physio control</b> Life Pack 9	roll	50	30	-	no	or/red	20
33100	<b>Corplus</b> Corplus 3	roll	106	20	-	no	or/red	10	33032	Life Pack 8-9-10	roll	50	23	-	no	or/red	20
33103	<b>Hewlett Packard</b> 40457C/D,	roll	50	30	-	no	or/red	20	33033	Life Pack 11-12-15-20	roll	107	25	-	no	or/red	10
32968	<b>Mindray</b> Defi/Monitor	roll	50	20	-	no	or/red	20	32963	<b>Schiller</b> Defigard 3002	roll	50	25	-	no	or/red	20
33029	<b>BeneHeart D3, D6</b> Nihon Kohden	pack	50	100	200	no	or/red	25	32983	Defigard 6002	pack	80	70	300	yes	or/red	20
32988	<b>Philips</b> Def. TEC 5521, 5531,	roll	50	30	-	no	or/red	20	32988	<b>Welch Allyn</b> Pic-30	roll	50	30	-	no	or/red	20
33102	<b>Philips</b> Tech-8300	roll	75	25	-	no	or/red	10	33106	Defi/1400 (P/N 8000-0300)	pack	90	90	200	yes	or/red	20
33103	<b>Philips</b> Defibrillator MRX	roll	50	30	-	no	or/red	20	32964	X Series	roll	80	25	-	no	white	10
	<b>Heartstart XL</b>	roll	50	30	-	no	or/red	20	33647	R Series, X Series	roll	80	25	-	no	or/red	10

\*or/red: grid could be orange or red colour

## REANIMATION MASKS



• **34218 CPR MASK - pocket resuscitator**  
The CPR pocket mask is a non-invasive, latex free mask with an integral non-rebreathing valve and efficient filter to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation. It can be used on adult, child and infant. Supplied in a compact plastic box with a corrugated tube for an easier use.



• **34211 VENTO AIRWAYS - Poly-bag**  
• **34213 VENTO AIRWAYS - Key-holder box**  
Disposable mouth to mouth airway with a one way polycarbonate valve and non-toxic pvc protective foil to avoid any direct contact between patient and rescuer. Available in 2 versions: in poly-bag or key-holder box. Instructions in GB, IT, FR, DE.

## DEFIBRILLATION KIT

• **34219 DEFIBRILLATOR ACCESSORIES KIT**  
Pocket mask kit with accessories for reanimation and defibrillation. Kit includes:  
1 pocket mask,  
1 antiseptic wipes,  
4 vinyl gloves,  
1 disposable razor,  
3 packs of sterile gauzes.



34219

## DAE-AED SIGNS

• **35326 DAE-AED ALUMINIUM FRONT SIGN 29x36 cm**  
• **35327 DAE-AED DOUBLE-SIDED ALUMINIUM SIGN - 34x36 cm**  
Signs in aluminium foil with thickness 5/10. Prepainted white with silkscreen in green colour. Pre-drilled for wall mounting.

35326



Signs comply with UNI EN ISO 7010:2012

35327



350 g

# CERTIFICATE

Number: 6156705

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District  
New Taipei City 24888  
Taiwan

including the implementation meets the requirements of the standard:

# ISO 13485:2016 EN ISO 13485:2016

### Scope:

Design, Development, Manufacture, Servicing, Distribution and Sales of Sterile and Non-sterile Respiratory Care, Gastroenterological (Stomach Tubing and Gastrostomy Catheter), Urological (Urine Drainage System), Gynecological (Fetal Vacuum Cup), Surgery (Drainage System) Products and Physical Medicine (TENS and Heating Pad), Active Respiratory Devices (Humidification System, Nebulizer compressor)

Certificate expiry date: 16 November 2027  
Certificate effective date: 16 November 2024  
Certified since: 24 May 2023

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# ADDENDUM

To certificate: 6156705

The management system of the organization(s) and/or location(s) of:

## Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District  
New Taipei City 24888  
Taiwan

Certified organization(s) and/or locations:

### Additional locations

### Certification Scope / Activities

Besmed Health Business Corp.  
No.2, Lane 106, Wu-Kong 3rd Rd., Wu-  
Ku District, New Taipei City 24889,  
Taiwan

Design, Development, Servicing, Distribution and Sales of  
Sterile and Non-sterile Respiratory Care, Gastroenterological  
(Stomach Tubing and Gastrostomy Catheter), Urological (Urine  
Drainage System), Gynecological (Fetal Vacuum Cup) and  
Surgery (Drainage System) Products and Physical Medicine  
(TENS and Heating Pad), Active Respiratory Devices  
(Humidification System, Nebulizer compressor)

Besmed Health Business Corp.  
No. 42, Dapumeiyuanqu 3rd Rd., Dalin  
Township, Chiayi County 62255,  
Taiwan

Manufacture of Sterile and Non-sterile Respiratory Care,  
Gastroenterological (Stomach Tubing and Gastrostomy  
Catheter), Urological (Urine Drainage System), Gynecological  
(Fetal Vacuum Cup) and Surgery (Drainage System) Products

Addendum expiry date: 16 November 2027  
Addendum effective date: 16 November 2024

## EC Declaration of Conformity

<b>Manufacturers Name:</b>	Besmed Health Business Corp.
<b>Manufacturers Address:</b>	No. 5, Lane 116, Wu-Kong 2 <sup>nd</sup> Road, Wu-Ku District, New Taipei City, Taiwan 24888
<b>SRN (Single Registration Number) of Manufacturer:</b>	TW-MF-000007246
<b>Authorized Representative Name (if applicable):</b>	Casus Europe B.V.
<b>Authorized Representative Address</b>	Lange Viestraat 2b, 3511 BK Utrecht, The Netherlands.
<b>SRN (Single Registration Number) of Authorized Representative:</b>	NL-AR-000037688
<b>Basic UDI-DI:</b>	4716770CP0600DR
<b>Name of the Device Group (s):</b>	CPR Mask
<b>Product (MDN) code:</b>	1201
<b>European Medical Device Nomenclature (EMDN):</b>	R03010201
<b>Conformity assessment route:</b>	Conformity assessment based on a Declaration of Conformity and CE Marking of Conformity (Annex IX of Regulation (EU) 2017/745)
<b>Intended use:</b>	Besmed CPR Mask is intended to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation and acts as a barrier that will direct expired air from the patient away from the user. The Besmed CPR pocket mask is a pliable facial shield that features an air-cushioned cuff equipped with an oxygen port.
<b>Classification:</b>	CLASS I, <b>Rule 2:</b> Besmed CPR Mask is a non-invasive devices that is used to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation.
<b>Harmonized standards or CS are applied:</b>	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 20417:2021, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 18561-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 15223-1:2021, ISTA 2A:2011, UL 969:2018, EN ISO 5356-1:2015, EN ISO 10651-4:2023.
<b>CE certificate no.</b>	N/A

This declaration of conformity is issued under the sole responsibility of Besmed Health Business Corp. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Besmed Health Business Corp.



## EC Declaration of Conformity

All supporting documentation is retained at the premises of the manufacturer.

Place and date (yyyy.mm.dd) of issue: Taipei, 2025.07.14

Signature:

*Sarah Lu*

*Steven Wong*

.....  
Sarah Lu  
Vice President  
For and on behalf of Besmed

.....  
Steven Wong  
Regulatory Affairs Manager  
For and on behalf of Besmed

Attachment to declaration of conformity [CPR Mask]

### CPR Mask

Device	Reference number	Description
CPR Pocket Resuscitator Set	CP-66230	CPR Pocket Resuscitator Set
	CP-66240	CPR Pocket Resuscitator Set W/Tube



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.**  
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soggetta all'attività di  
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**Certified Sites**  
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