GIMA
PROFESSIONAL MEDICAL PRODUCTS

PALLONE RIANIMATORE MONOUSO
DISPOSABLE RESUSCITATOR BAG
INSUFFLATEUR DE REANIMATION MONOUSAGE
BALON DE REANIMACION MONOUSO
REANIMADOR DESCARTÁVEL
EINWEG-BEATMUNGSBEUTEL
ΑΝΑΖΩΟΓΟΝΗΤΗΣ ΜΙΑΣ ΧΡΗΣΗΣ
RESUSCITATOR FÖR ENGÅNGSBRUK
RESUSCITATOR DE UNICĂ FOLOSINȚĂ
ELDOBHATÓ ÚJRAÉLESZTŐ
РЕАНИМАТОР ЗА ЕДНОКРАТНА УПОТРЕБА
جهاز إنعاش يمكن التخلص منه

Manuale d'uso - User manual - Manuel de l'utilisateur - Guía de uso - Guia para utilização - - Betriebs und wartungs anweisungen - Εγχειριδιο χρησης και συντηρησης - Instruktioner för användning och underhåll - Manual de utilizare și întreținere - Kezelési és karbantartási útmutató - Инструкции за употреба и поддръжка

- تعليمات الاستخدام والصيانة

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*

ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto.*

ACHTUNG: *Die Bediener müssen das vorliegende Handbuch vor der Verwendung des Produkts sorgfältig lesen und vollständig verstehen.*

ΠΡΟΣΟΧΗ: *Οι χειριστές πρέπει να διαβάσουν προσεκτικά και πλήρως κατανοήστε το παρόν εγχειρίδιο πριν χρησιμοποιήσετε το προϊόν.*

OBSERVERA: *Operatörerna måste noggrant läsa och fullständigt förstå den här bruksanvisningen innan du använder produkten.*

ATENTIE: *Operatorii trebuie sa citeasca cu atentie si complet înțeleagеți prezentul manual înainte de a utiliza produsul.*

FIGYELEM: *A kezelőknek figyelmesen és teljesen el kell olvasniuk a termék használata előtt olvassa el a jelen kézikönyvet.*

ВНИМАНИЕ: *Операторите трябва да прочетат внимателно и изцяло разберете настоящото ръководство, преди да използвате продукта.*

تنبيه: يجب على المشغلين القراءة بعناية وبشكل كامل فهم الدليل الحالي قبل استخدام المنتج.

REF **RE-22415 (GIMA 34277) - RE-22515 (GIMA 34248) - RE-22615 (GIMA 34249)**

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District,
New Taipei City 24888, Taiwan
Made in Taiwan

EC REP
Mdi Europa Gmbh
Langenhagener Str. 71, 30855
Hannover Langenhagen, Germany

Gima S.p.A.
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

MD NON STERILE CE 0197

LATEX PHT DEHP 60°C -40°C

M34277-M-Rev.5-0724

INSTRUCTION FOR USE

PRODUCT NAME:

Besmed Disposable Resuscitator Set Model:

- RE-22415 - Single Use Resuscitator with 60 cm H2O POP-OFF, 1600 ml, Adult
- RE-22515 - Single Use Resuscitator with 40 cmH2O POP-OFF, 500 ml, Child
- RE-22615 - Single Use Resuscitator with 40 cmH2O POP-OFF, 280 ml, Infant

PRODUCT DESCRIPTION

Besmed Disposable resuscitator set are manually operated and meant as an adjunct to artificial respiration and cardiopulmonary resuscitation. The resuscitator set can be used to ventilate apnoeic patients, and augment ventilation in spontaneously breathing patients undergoing oxygen therapy. The resuscitator set come in different sizes and are designed according to different compression capacities for infants, children, and adult patients.
Technical Specification:

Product Name	Disposable Resuscitator Set		
Manufacturer	Besmed Health Business Corp.		
Representative Photo			
Device type	Disposable		
Patient Usage type	Single use		
Patient group	Adult	Child	Infant
Accessories	Manometer, mask, reservoir, oxygen tube, PEEP valve and connector		
Pop-Off	W/ Pop-Off		
Deliverable pressure	60 cmH_2O	40 cmH_2O	
Bag volume	1600 ml	500 ml	280 ml
Reservoir volume	2500 ml		1000 ml
Suitable patient body weight	>40 kg	11 - 40 kg	5 – 10 kg

Stroke volume range; One hand	770 ml	300 ml	160 ml
Stroke volume range; Two hands	900 ml	350 ml	190 ml
Minimum delivered volume	>600 ml	>150 ml	
Maximum cycle rate	20 breaths/min		40 breaths/min
Oxygen concentration	With reservoir: > 85% - Without reservoir: > 35%		
Dead Space	< 5.5 ml		

Material	Resuscitator body:	PVC
	Mask:	PP + TPR
	Reservoir bag:	PVC
	Oxygen tubing:	PVC
	non-rebreathing valve:	PC
	Oxygen reservoir / gas intake socket:	PC
	Duckbill / gas intake / oxygen intake valve:	PVC
	Pop-off valve:	PC, PVC, stainless steel
	Manometer:	Silicone
	PEEP valve:	PC, Silicone, Stainless Steel (for spring)
	Connector:	Silicone
Package		Non-sterile package
Operation temperature		25±5 °C, Room Temperature
Storage temperature		-40 to 60°C, 30-60% RH
Shelf Life		5 years
Specifications	Patient connection port and face mask connectors	Connection stayed intact
	Dismantling and reassembling	Proper ventilation occurred after dismantling and reassembling the device
	Patient valve function after contamination with vomitus	There is no change in the performance of the device after contamination with vomitus.

Specifications	Drop test	No function variation in the device after dropping	
	Immersion in water	There is no change in the performance of the device after immersion in water.	
	Expiratory resistance	2.07 cmH2O	
	Inspiratory resistance	3.03 cmH2O	
	Dead space and rebreathing	4.78 ml	
	Minimum delivered volume	629.23 ml	
	Pressure limitation	There is no performance deviation.	
		The resuscitator without and with reservoir bag is more than 35 % and 85 %	
	Patient valve malfunction	1.07 cmH2O	
Attestation	Test item	Guideline	Result
	Cytotoxicity	ISO 10993-5	PASS
	Skin irritation test	ISO 10993-10	PASS
	Sensitization	ISO 10993-10	PASS
	Emissions of particulate matter	ISO 18562-2	PASS
	Emissions of VOCs	ISO 18562-3	PASS

INTENDED USER:
Medical personnel received the training of respiratory care.

INTENDED USE:
Besmed Disposable resuscitator set are designed for use as an adjunct to artificial respiration and cardiopulmonary resuscitation. The resuscitator can be used to ventilate the apneic patients and to augment ventilation and oxygen delivery to the spontaneously breathing patient.

DIRECTION FOR USE:
1. Prior to use, read the Instructions, cautions, and warnings.
2. Connect the oxygen supply tubing to a regulated oxygen source.

3. Adjust the gas flow so that the reservoir expands completely during inspiration and nearly collapses as the squeeze bag refills during exhalation.
4. Prior to connection to a patient, check the function of the resuscitator, preferably attached to a test lung, by observing that the intake, reservoir, and patient valves are allowing all phases of the ventilator cycle to occur.
5. As required, connect the resuscitation mask to the patient connector.
6. Follow accepted Advance Cardiac Life Support (ACLS) or Institution-approved for ventilation.
7. Compress the squeeze bag to deliver a breath. Observe the chest rise to confirm inspiration.
8. Release pressure on the squeeze bag to allow exhalation. Observe the chest fall to confirm exhalation.
9. During ventilation, check for:
   -Signs of cyanosis
   -Adequacy of ventilation
   -Airway pressure
   -Proper function of all valves
   -Proper function of reservoir and oxygen tubing
10. Should the non-rebreathing valve become contaminated with vomiting, blood, or secretion during ventilation, disconnect the device from the patient and clear the non-rebreathing valve as follows:
    -Rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate. If the contaminate does not clear.
    -Rinse the non-rebreathing valve in water and then rapidly compress the squeeze bag to deliver several sharp breaths through the non-rebreathing valve to expel the contaminate. If the contamination still does not clear, discard the resuscitator.

⚠ **Warning**:

1. Do not use the resuscitator set in toxic atmospheres.
2. Do not administer supplemental oxygen in the presence of open flames.
3. This device is intended for use by qualified medical and emergency personnel trained in pulmonary ventilation and advanced cardiac life support techniques.
4. Proficiency in the assembly, disassembly, and use of this device should be demonstrated before use on a patient.
5. Always monitor airway pressure with a manometer when ventilating a patient.
6. Only qualified personnel trained in the use of Positive End Expiratory Pressure (PEEP) should level the function of the resuscitator before using it on a patient.
7. If overriding the pressure relief valve, great caution must be taken not to allow the pressure in the patient's airways to become too high.

Caution:

1. If overriding the pressure relief valve, great caution must be taken not to allow the pressure in the patient's airways to become too high.
2. Do not attempt to disassemble the pressure relief valve assembly. Disassembly will damage the component.
3. Dispose of in accordance with local regulations procedures or hospital protocol

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

نفى

LEGEND OF SYMBOLS

CE	**IT -** Dispositivo medico conforme alla Direttiva 93/42/CEE **GB -** Medical Device complies with Directive 93/42/EEC **FR -** Dispositif médical conforme à la directive 93/42 / CEE **ES -** Dispositivo médico segun a la Directiva 93/42 / CEE **PT -** Dispositivo médico em conformidade com a Diretiva 93/42/CEE **DE -** Medizinprodukt gemäß Richtlinie 93/42/CEE **C GR -** Ιατρική συσκευή σύμφωνα με την οδηγία 93/42 / CEE **HU -** Dispozitiv medical realizat în conformitate cu prevederile Directivei 93/42/CEE **RO -** Dispozitiv medical realizat în conformitate cu prevederile Directivei 93/42/CEE **SE -** Den medicintekniska produkten överensstämmer med Direktiv 93/42/EEG **BG -** Медицинско устройство, отговарящо на Директива 93/42/EEC جهاز طبي يتوافق مع التوجيه 93/42/CEE **- SA**	EC REP	**IT -** Rappresentante autorizzato nella Comunità europea **GB -** Authorized representative in the European community **FR -** Représentant autorisé dans la Communauté européenne **ES -** Representante autorizado en la Comunidad Europea **PT -** Representante autorizado na União Europeia **DE -** Autorisierter Vertreter in der EG **GR -** Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Ένωση **HU -** Meghatalmazott képviselő az Európai Közösségbenä **RO -** Reprezentant autorizat pe teritoriul Comunităţii Europene **SE -** Auktoriserad representant i Europeiska gemenskapen **BG -** Оторизиран представител в Европейската общност **SA -** ممثل معتمد في الاتحاد الأوروبي

	**IT** - Importato da **GB** - Imported by **FR** - Importé par **ES** - Importado por **PT** - Importado por **GR** - Εισαγωγή από **DE** - Eingeführt von **HU** - Importálta **RO** - Importat de **SE** - Importerad av **BG** - Внесено от مستورد عن طريق **SA** -		**IT** - Fabbricante **GB** - Manufacturer **FR** - Fabricant **ES** - Fabricante **PT** - Fabricante **DE** - Hersteller **GR** - Παραγωγός **HU** - Gyártó **RO** - Producător **SE** - Tillverkare **BG** - Производител الشركة المصنعة **SA** -
	IT - Leggere le istruzioni per l'uso **GB** - Consult instructions for use **FR** - Consulter les instructions d'utilisation **ES** - Consultar las instrucciones de uso **PT** - Consulte as instruções de uso **DE** - Gebrauchsanweisung beachten **GR** - Διαβάστε προσεχτικά τις οδηγίες χρήσης **SE** - Läs bruksanvisningen **RO** - Citiți instrucțiunile de utilizare **HU** - Olvassa el a használati utasításokat **BG** - Прочетете инструкциите за употреб اقرأ بدقة وحرص تعليمات الاستخدام **SA** -		**IT** - Non utilizzare se l'imballaggio è danneggiato **GB** - Don't use if package is damaged **FR** - Ne pas utiliser si le colis est endommagé **ES** - No usar si el paquete está dañado **PT** - Não use se o pacote estiver danificado **DE** - Nicht verwenden, wenn das Paket beschädigt ist **GR** - Μην το χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη **SE** - Använd inte en förpackning som är skadad **RO** - A nu se utiliza dacă ambalajul este deteriorat **HU** - Ne használja, ha a csomagolás sérült **BG** - Да не се използва, ако опаковката е с нарушена цялост لا تستخدم في حالة تلف الحزمة **SA** -
	IT - Numero di lotto **GB** - Lot number **FR** - Numéro de lot **ES** - Número de lote **PT** - Número de lote **DE** - Chargennummer **GR** - Αριθμός παρτίδας **HU** - Tételszám **RO** - Număr de lot **SE** - Satsnummer **BG** - Номер رقم الدفعة **SA** -		**IT** - Codice prodotto **GB** - Product code **FR** - Code produit **ES** - Código producto **PT** - Código produto **DE** - Erzeugniscode **GR** - Κωδικός προϊόντος **SE** - Produktkod **RO** - Cod produs **HU** - Termékkód **BG** - Код на продукта كود المنتج **SA** -
	IT - Data di scadenza **GB** - Expiration date **FR** - Date d'échéance **ES** - Fecha de caducidad **PT** - Data de validade **DE** - Ablaufdatum **HU** - Lejárati dátum **RO** - Valabil până la data de **SE** - Utgångsdatum **BG** - Срок на годност تاريخ انتهاء الصلاحية **SA** -		**IT** - Data di fabbricazione **GB** - Date of manufacture **FR** - Date de fabrication **ES** - Fecha de fabricación **PT** - Data de fabrico **DE** - Herstellungsdatum **GR** - Ημερομηνία παραγωγής **SE** - Tillverkningsdatum **RO** - Data fabricației **HU** - Gyártás dátuma **BG** - Дата на производствоикуцрйаеv تاريخ التصنيع **SA** -
	IT - Conservare al riparo dalla luce solare **GB** - Keep away from sunlight **FR** - Á conserver à l'abri de la lumière du soleil **ES** - Conservar al amparo de la luz solar **PT** - Guardar ao abrigo da luz solar **GR** - Κρατήστε το μακριά από ηλιακή ακτινοβολία **SE** - Skyddas från soljus **RO** - A se păstra ferit de razele soarelui **HU** - Napfénytől védve tárolandó **BG** - Да се съхранява на място, защитено от слънчева светлина يحفظ بعيدًا عن ضوء الشمس **SA** -		**IT** - Conservare in luogo fresco ed asciutto **GB** - Keep in a cool, dry place **FR** - Á conserver dans un endroit frais et sec **ES** - Conservar en un lugar fresco y seco **PT** - Armazenar em local fresco e seco **GR** - Διατηρείται σε δροσερό και στεγνό περιβάλλον **SE** - Förvara på svalt och torrt ställe **RO** - A se păstra într-un loc răcoros și uscat **HU** - Száraz, hűvös helyen tárolandó **BG** - Да се съхранява на хладно и сухо място يحفظ في مكان بارد وجاف **SA** -
	**IT** - Non prodotto con lattice di gomma naturale **GB** - Not made with natural rubber latex **FR** - Non fabriqué avec du latex de caoutchouc naturel **ES** - No contiene látex de caucho natural **PT** - Sem látex de borracha natural **DE** - Ohne Naturkautschuk hergestellt **GR** - Χωρίς λάτεξ **HU** - Latex-mentes **RO** - Nu conține latex **SE** - Latexfri **BG** - Не съдържа латекс خالية من اللتيكس **SA** -		**IT** - Non contiene ftalato DEHP **GB** - No-DEHP formulation **FR** - Ne contient pas de DEHP **ES** - No contiene ftalato DEHP **PT** - Não contém ftalato DEHP **DE** - Frei von DEHP **GR** - Δεν περιέχει φθαλικό DEHP **SE** - Innehåller inte DEHP-ftalat **RO** - Conținut sau prezență de ftalați **HU** - Ftalát-mentes **BG** - Не съдържа фталати بدون الفثالات **SA** -
	IT - Limite di temperatura **GB** - Temperature limit **FR** - Limite de température **ES** - Límite de temperatur **PT** - Limite de temperatura **DE** - Temperaturgrenzwert **GR** - Διατηρείται μεταξύ -10 και 49°C **HU** - és °C között tárolandó **PL** - Przechowuj pomiędzy i °C **RO** - A se păstra la temperaturi cuprinse între și °C **SE** - Lagras mellan och °C **BG** - Да се съхранява между и °C يحفظ بين و درجة مئوية **SA** -		**IT** - Non sterile **GB** - Non-sterile **FR** - Pas stérile **ES** - No estéril **PT** - Não estéril **DE** - nicht steril **GR** - όχι αποστειρωμένο **PL** - Nie sterylne **CZ** - Nesterilní **SE** - Ej steril **FI** - Ei-steriili **SI** - Ni sterilno **SK** - Nesterilné **RO** - Nesteril **NL** - Niet steriel **HR** - Nije sterilno **HU** - Nem steril **DK** - Ikke-steril **BG** - Нестерилен **LT** - Ne sterilus **LV** - Nav sterils **EE** - Mittesteriilne ليس معقم **SA** -
	IT - Dispositivo medico **GB** - Medical Device **FR** - Dispositif médical **ES** - Producto sanitario **PT** - Dispositivo médico **DE** - Medizinprodukt **GR** - Ιατροτεχνολογικό προϊόν **PL** - Wyrób medyczny **CZ** - Zdravotnický prostředek **SE** - Medicinteknisk produkt **FI** - Lääkinnällinen laite **SI** - Medicinski pripomoček **SK** - Zdravotnícka pomôcka **RO** - Dispozitiv medical **NL** - Medisch hulpmiddel **HR** - Medicinski uređaj **HU** - Orvostechnikai eszköz **DK** - Medicinsk udstyr **BG** - Медицинско изделие **LT** - Medicininis prietaisas **LV** - Medicīniskā ierīce **EE** - Meditsiiniline seade جهاز طبي **SA** -		**IT** - Dispositivo monouso, non riutilizzare **GB** - Disposable device, do not re-use **FR** - Dispositif pour usage unique, ne pas réutiliser **ES** - Dispositivo monouso, no reutilizable **PT** - Dispositivo descartável, não reutilizar **DE** - Für einmaligen Gebrauch, nicht wiederverwenden **GR** - Προϊόν μιας χρήσεως. Μην το χρησιμοποιείται εκ νέου **SE** - Engångsanordning, får ej återanvändas **RO** - Dispozitiv de unică folosință, a nu se refolosi **HU** - Eldobható eszköz, ne használja újra **BG** - Изделие за еднократна употреба, да не се използва повторно أداة أحادية الاستخدام، لا تستخدم من جديد **SA** -