

EC Declaration of Conformity

Manufacturers Name: Besmed Health Business Corp.

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

SRN (Single Registration Number) of Manufacturer: TW-MF-000007246

Authorized Representative Name (if applicable): Casus Europe B.V.

Authorized Representative Address: Lange Viestraat 2b, 3511 BK Utrecht The Netherlands.

SRN (Single Registration Number) of Authorized Representative: NL-AR-000037688

Basic UDI-DI: 4716770RE02400XX

Name of the Device Group (s): MANUAL RESUSCITATOR SETS

Product (MDN) code: 1201

European Medical Device Nomenclature (EMDN): R03020201

Conformity assessment route: Conformity assessment based on a Quality Management System, and technical documentation (Annex V of MDD 93/42/EEC-M5 2007/47/EC)

Intended use: Besmed Manual Resuscitator Set are intended for use as an adjunct to artificial respiration and cardiopulmonary resuscitation. The resuscitator can be used to ventilate apnoeic patients, augment ventilation and oxygen delivery to the spontaneously breathing patients.

Classification: CLASS IIa,
Rule 2: Besmed Manual Resuscitator Set is a non-invasive devices intended for patients to augment ventilation and oxygen delivery to the spontaneously breathing patient.

Notified Body Name: TUV Rheinland LGA Products GmbH

Notified Body Address: Tillystraße 2
90431 Nuremberg
Germany

Notified Body Identification number: NB 0197

Harmonized standards or CS are applied: EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 24971:2020, EN ISO 20417:2020, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 15223-1:2021, ISTA 2A, UL-969-2018, ASTM F1980-21, EN ISO 10651-4:2023.

CE certificate no. DD 601421990001

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) MDD 93/42/EEC-M5 2007/47/EC for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by TUV Rheinland LGA Products GmbH.

EC Declaration of Conformity

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

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

Taipei, 2020-01-10

Signature:

Sarah Lu

.....

Sarah Lu

Vice President

For and on behalf of Besmed

Steven Wong

.....

Steven Wong

Regulatory Affairs Manager

For and on behalf of Besmed

Attachment to declaration of conformity [Manual Resuscitator Sets]

MANUAL RESUSCITATOR SETS

Device	Besmed Reference	Description
Disposable Resuscitator Set	RE-25433	Single Use Resuscitator with Handstrap 1600 ml W/ 60 cm H ₂ O POP-OFF, Oxygen tubing, Air cushion mask, Oxygen reservoir (2500 ml), Adult, (BE-1503)
	RE-25533	Single Use Resuscitator with Handstrap 500 ml W/ POP-OFF, Oxygen tubing, Air cushion mask, Oxygen reservoir (2500 ml), Child, (BE-1603)
	RE-25633	Single Use Resuscitator with Handstrap 280 ml W/ 40 cmH ₂ O POP-OFF, Oxygen tubing, Air cushion mask, Oxygen reservoir (1000 ml), Infant (BE-1703)
	RE-23710	Rubber Resuscitator 1700 ml W/ POP-OFF, Oxygen tubing, Mask, Oxygen reservoir (2500 ml), Adult, (BE-2401)
	RE-23720	Rubber Resuscitator 1700 ml W/ POP-OFF, Oxygen tubing, Mask, Oxygen reservoir (2500 ml), Adult, (BE-2501)
	RE-23810	Rubber Resuscitator 550 ml W/ POP-OFF, Oxygen tubing, Mask, Oxygen reservoir (2500 ml), Child (BE-2601)
	RE-23910	Rubber Resuscitator 280 ml W/ POP-OFF, Oxygen tubing, Mask, Oxygen reservoir (1000 ml), Infant, (BE-2701)
	RE-24438	Single use resuscitator 1600 ml W/O 60 cmH ₂ O POP-OFF, Oxygen tubing (2.0 m), Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult
	RE-24431	Single use resuscitator 1600 ml W/O 60 cmH ₂ O POP-OFF (W/ MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult
	RE-24433	Single use resuscitator 1600 ml W/ 60 cmH ₂ O POP-OFF (W/O MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult
	RE-24434	Single use resuscitator 1600 ml W/ 60 cmH ₂ O POP-OFF (W/ MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult

EC Declaration of Conformity

RE-24437	Single use resuscitator 1600 ml W/ 60 cmH ₂ O POP-OFF (W/O MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult
RE-23438	Single use resuscitator 1000 ml W/ 60 cmH ₂ O POP-OFF, Air cushion mask (size 5), Oxygen reservoir (2500 ml), Adult
RE-24531	Single use resuscitator 500 ml W/ 40 cmH ₂ O POP-OFF (W/ MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 3), Oxygen reservoir (2500 ml), Child
RE-24536	Single use resuscitator 500 ml W/ 40 cmH ₂ O POP-OFF (W/O MDI port), Oxygen tubing (2.0 m), Air cushion mask (size 3), Oxygen reservoir (2500 ml), Child
RE-24631	Single use resuscitator 280 ml W/ 40 cmH ₂ O POP-OFF (W/ MDI port), W/Manometer port, Oxygen tubing (2.0 m), Air cushion mask (size 1), Oxygen reservoir (1000 ml), Infant
RE-24636	Single use resuscitator 280 ml W/ 40 cmH ₂ O POP-OFF (W/O MDI port), W/Manometer port, Oxygen tubing (2.0 m), Air cushion mask (size 1), Oxygen reservoir (1000 ml), Infant
RE-28003	Single use resuscitator 180 ml W/ 40 cmH ₂ O POP-OFF, Air cushion mask (size 0), Neonate
RE-22415	Single Use Resuscitator 1600 ml W/O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult
RE-22515	Single Use Resuscitator 500 ml W/ 40 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Child
RE-22615	Single Use Resuscitator 280 ml W/ 40 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant
RE-23410	Single Use Resuscitator 1600 ml W/O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult, (BE-2401)
RE-23510	Single Use Resuscitator 500 ml W/ 40cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Child, (BE-2601)
RE-23420	Single Use Resuscitator 1600 ml W/ 60 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult, (BE-2501)
RE-23610	Single Use Resuscitator 280 ml W/ 40cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant, (BE-2701)
RE-22610	Single Use Resuscitator 280 ml W/ 40cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant
RE-22425	Single use resuscitator 1600 ml W/ 60 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult, (BE-1101)
RE-24523	Single use resuscitator 500 ml W/ 40 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Child, (BE-1201)
RE-24623	Single use resuscitator 280 ml W/ 40 cmH ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant, (BE-1301)
RE-25166	Reusable Resuscitator with Handstrap 1600 ml (W/ Manometer port), Oxygen tubing (2.0 m), Silicone mask (size 5), Oxygen reservoir (2500 ml), Adult
RE-25186	Reusable Resuscitator with Handstrap 1600 ml W/ 60 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing (2.0 m), Silicone mask (size 5), Oxygen reservoir (2500 ml), Adult

EC Declaration of Conformity

Reusable Resuscitator Set	RE-25246	Reusable Resuscitator with Handstrap 500 ml W/ 40 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing (2.0 m), Silicone mask (size 3), Oxygen reservoir (2500 ml), Child
	RE-25346	Reusable Resuscitator with Handstrap 280 ml W/ 40 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing (2.0 m), Silicone mask (size 1), Oxygen reservoir (1000 ml), Infant
	RE-24180	Reusable Resuscitator, 1600ml W/ POP-OFF, Mask, Oxygen reservoir (2500 ml), Oxygen tubing, Adult
	RE-24240	Reusable Resuscitator, 500 ml W/ POP-OFF, Mask, Oxygen reservoir (2500 ml), Oxygen tubing, Child
	RE-24340	Reusable Resuscitator, 280 ml W/ POP-OFF, Mask, Oxygen reservoir (1000 ml), Oxygen tubing, Infant
	RE-22115	Reusable Resuscitator, 1600ml, W/O POP-OFF, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-22135	Reusable Resuscitator, 1600ml, 60cm H ₂ O POP-OFF, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-22215	Reusable Resuscitator, 500 ml W/ 40 cmH ₂ O POP-OFF, Silicone mask (size 3), Oxygen reservoir (2500 ml), Child
	RE-22315	Reusable Resuscitator, 280 ml W/ 40 cmH ₂ O POP-OFF, Silicone mask (size 1), Oxygen reservoir (1000 ml), Infant
	RE-24120	Reusable Resuscitator 1600 ml (W/ Manometer port), Oxygen tubing, Silicone mask (size 5), Oxygen reservoir, Adult
	RE-24140	Reusable Resuscitator 1600 ml W/ 60 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing, Silicone mask (size 5), Oxygen reservoir, Adult
	RE-23142	Reusable Resuscitator 1000 ml W/ 60 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing, Silicone mask (size 5), Oxygen reservoir, Adult
	RE-23188	Reusable Resuscitator 1000 ml with 60 cm H ₂ O POP-OFF, Oxygen Tubing, Silicone Mask (Size 5), Oxygen Reservoir(2500ml), Adult
	RE-24166	Reusable Resuscitator 1600 ml, Oxygen Tubing, Silicone Mask (size 5), Oxygen Reservoir(2500ml), Adult
	RE-24186	Reusable Resuscitator 1600 ml with 60 cm H ₂ O POP-OFF, Oxygen Tubing, Silicone Mask (Size 5), Oxygen Reservoir(2500ml), Adult
	RE-24220	Reusable Resuscitator 500 ml W/ 40 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing, Silicone mask (size 3), Oxygen reservoir, Child
	RE-24320	Reusable Resuscitator 280 ml W/ 40 cm H ₂ O POP-OFF (W/ Manometer port), Oxygen tubing, Silicone mask (size 1), Oxygen reservoir, Infant
	RE-24246	Reusable Resuscitator 500 ml with 40 cm H ₂ O POP-OFF, Oxygen Tubing, Silicone Mask (Size 3), Oxygen Reservoir(2500ml), Child
	RE-24346	Reusable Resuscitator, 280 ml with 40 cm H ₂ O POP-OFF, Oxygen Tubing, Silicone Mask (Size 1), Oxygen Reservoir (1000 ml), Infant
	RE-22135	Reusable Resuscitator 1600 ml W/ 60 cm H ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult
	RE-22115	Reusable Resuscitator 1600 ml W/O POP-OFF, Oxygen tubing, Silicone mask (size 4), Oxygen reservoir, Adult, (BE-1401)

EC Declaration of Conformity

	RE-22215	Reusable Resuscitator 500 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Silicone mask, (size 3), Oxygen reservoir, Child
	RE-22315	Reusable Resuscitator 280 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Silicone mask, (size 1), Oxygen reservoir, Infant
	RE-27140	Reusable Resuscitator 1600 ml W/ 60 cm H ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Adult, (BE-1501)
	RE-27220	Reusable Resuscitator 500 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Child, (BE-1601)
	RE-27320	Reusable Resuscitator 280 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant, (BE-1701)
	RE-23150	Reusable Resuscitator 1700 ml, Adult
	RE-23170	Reusable Resuscitator 1600 ml W/ 60 cm H ₂ O POP-OFF, Oxygen tubing, Silicone mask (size 5), Oxygen reservoir, Adult
	RE-23230	Reusable Resuscitator 500 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Silicone mask (size 3), Oxygen reservoir, Child
	RE-23330	Reusable Resuscitator 280 ml W/ 40 cm H ₂ O POP-OFF, Oxygen tubing, Mask, Oxygen reservoir, Infant
	RE-25113	Reusable Resuscitator, 1600ml, 60cm H ₂ O POP-OFF, W/ Handstrap, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-25213	Reusable Resuscitator, 500 ml W/ 40 cmH ₂ O POP-OFF, W/ Handstrap, Silicone mask (size 3), Oxygen reservoir (2500 ml), Child
	RE-25710	Reusable Resuscitator, 1600ml, 60cm H ₂ O POP-OFF, W/ Handstrap, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-25711	Reusable Resuscitator, 500 ml W/ 40 cmH ₂ O POP-OFF, W/ Handstrap, Silicone mask (size 3), Oxygen reservoir (2500 ml), Child
	RE-25712	Reusable Resuscitator, 280 ml W/ 40 cmH ₂ O POP-OFF, W/ Handstrap, Silicone mask (size 1), Oxygen reservoir (1000 ml), Infant
Oxygen reservoir	BR-62611	PVC Oxygen reservoir 1000ml
	BR-62626	PVC Oxygen reservoir 2500ml
	BR-62725	Oxygen Reservoir, 2500 ml
	BR-62625	PVC Oxygen Reservoir, 2500 ml
	BR-62610	PVC Oxygen Reservoir, 1000 ml
	BR-62906	Oxygen Reservoir, 0.6 L
	BR-62925	Oxygen Reservoir, 2.5 L
Silicone Reservoir	BR-62320	Silicone Reservoir, 2.0 L
	BR-62310	Silicone Reservoir, 1.0 L

EC Declaration of Conformity

	BR-62305	Silicone Reservoir, 0.5 L
Disposable PEEP Valve	RE-21310	Disposable PEEP Valve, 2.5-10 cmH ₂ O, (Orange)
	RE-21320	Disposable PEEP Valve, 5-20 cmH ₂ O, (Blue)
Durable PEEP Valve	RE-21330	Durable PEEP Valve, 2-10 cm H ₂ O, ID: 30 mm
	RE-21335	Durable Peep Valve, 2-10cm H ₂ O, Orange color, OD/ID: 22m / 15F
	RE-21340	Durable Peep Valve, 5-20 cm H ₂ O, Blue color, ID: 30F
	RE-21345	Durable Peep Valve, 5-20 cm H ₂ O, Blue color, OD/ID: 22m / 15F
Disposable Pressure Manometer	RE-21460	Disposable Pressure Manometer, 60 cmH ₂ O
	RE-21470	Disposable Pressure Manometer
	RE-21450	Disposable Pressure Manometer L type, 60 cmH ₂ O
Connector	RE-21390	Connector
	RE-21391	Connector, 22M
	RE-21210	Intake Valve - All In One, OD: 25mm, ID: 6 mm
	RE-21260	Intake Valve - All In One
Non-Rebreathing Valve	RE-21135	Non-Rebreathing Valve
	RE-21171	Non - Rebreathing valve W/O POP-OFF (L TYPE) with Manometer port
	RE-21188	Non - Rebreathing valve W/ 40 cmH ₂ O POP-OFF (L TYPE) with Manometer port
	RE-21184	Non - Rebreathing valve W/ 60 cmH ₂ O POP-OFF (L TYPE) with Manometer port
Accessories	RE-21630	Oxygen Reservoir Valve