

EC Declaration of Conformity


Manufacturers Name:	Besmed Health Business Corp.
Manufacturers Address:	No. 5, Lane 116, Wu-Kong 2 nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
SRN (Single Registration Number) of Manufacturer:	TW-MF-000007246
Authorized Representative Name (if applicable):	Mdi Europa GmbH
Authorized Representative Address	Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany
SRN (Single Registration Number) of Authorized Representative:	DE-AR-000006218
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.

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

Place and date (yyyy.mm.dd) of issue: Taipei, 2020-01-10
Signature:


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Sarah Lu
Vice President
For and on behalf of Besmed


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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	Gima Reference	Description
Reusable Resuscitator Set	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
	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-22115	34245	Reusable Resuscitator, 1600ml, W/O POP-OFF, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-22135	34244	Reusable Resuscitator, 1600ml, 60cm H ₂ O POP-OFF, Silicone mask (size 4), Oxygen reservoir (2500 ml), Adult
	RE-22215	34246	Reusable Resuscitator, 500 ml W/ 40 cmH ₂ O POP-OFF, Silicone mask (size 3), Oxygen reservoir (2500 ml), Child
	RE-22315	34247	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

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	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
Disposable PEEP Valve	RE-21335	-	Durable Peep Valve, 2-10cm H ₂ O, Orange color, OD/ID: 22m / 15F
	RE-21340	34227	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
Connector	RE-21391	34228	Connector, ID:22mm, OD:30mm
	RE-21260	34256	Intake Valve
Accessories	RE-21630	34279	Oxygen Reservoir Valve