BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan. 24888
☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
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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):	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:	4716770RE02500XX
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 sets is intended 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.
Classification:	CLASS IIa, **Rule 2**: Manual resuscitator sets 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 Nürnberg, 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 20417:2021, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2021, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 15223-1:2021, ISTA 2A, ASTM F1980-02, ISO 10651-4:2009.
CE certificate no.	DD601421990001

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.

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

Besmed Health Business Corp. DCC CONFIDENTIAL 2022120

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

Signature:

.....
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 [Manual resuscitator sets]

MANUAL RESUSCITATOR SETS

Device	Reference number	Description
Reusable resuscitator set	RE-25112	Reusable Resuscitator with Handstrap, 60 cmH_2O POP-OFF, 1600ml, Silicone Mask, Oxygen Reservoir, Oxygen Tubing, Adult
	RE-25212	Reusable Resuscitator with Handstrap, 40 cmH_2O POP-OFF, 500ml, Silicone Mask, Oxygen Reservoir, Oxygen Tubing, Child
	RE-25312	Reusable Resuscitator with Handstrap, 40 cmH_2O POP-OFF, 300ml, Silicone Mask, Oxygen Reservoir, Oxygen Tubing, Infant

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