

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: 4716770CM65504

Name of the Device Group (s): Disposable Cushion Mask

Product (MDN) code: 1201

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

Intended use: The device is designed for use with manual resuscitator and anesthesia machine.

Classification: CLASS IIa, rule 2: Besmed disposable air cushion mask is connected to manual resuscitator for use as an adjunct to artificial respiration and cardiopulmonary resuscitation. Six different sizes are available, from neonate to large adult with injectable and non-injectable cushion types.

Notified Body Name: DEKRA Certification B.V.

Notified Body Address: Meander 1051 / P.O. Box 5185
6825 MJ ARNHEM / 6802 ED ARNHEM
Netherlands

Notified Body Identification number: NB 0344

harmonized standards or CS are applied: EN 20417:2021, EN ISO 15223-1:2021, EN ISO 14971:2019, EN ISO 13485:2016/AC: 2018, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013

CE certificate no.: [6092261CE01]

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. There are no significant changes in the design or intended purpose in the meaning of Article 120(3) MDR. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V.

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Place and date (yyyy.mm.dd) of issue: Taipei, 2022-08-26

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

Besmed Health Business Corp. RA CONFIDENTIAL 20220826

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Attachment to declaration of conformity [Disposable Cushion Mask]

Disposable Cushion Mask

Device	Reference number	Description
Disposable Cushion Mask	CM-65504	Air Cushion Mask, White Hook, Size 0, Neonate
	CM-65514	Air Cushion Mask, Pink Hook, Size 1, Infant
	CM-65524	Air Cushion Mask, Yellow Hook, Size 2, Child
	CM-65534	Air Cushion Mask, Red Hook, Size 3, Adult
	CM-65544	Air Cushion Mask, Green Hook, Size 4, Adult
	CM-65554	Air Cushion Mask, Blue Hook, Size 5, Adult
	CM-65564	Air Cushion Mask, Transparent Hook, Size 6, Adult
	CM-65512	Air Cushion Mask, w/o Hook, Size 1, Infant
	CM-65532	Air Cushion Mask, w/o Hook, Size 3, Adult
	CM-65552	Air Cushion Mask, w/o Hook, Size 5, Adult

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