

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: 4716770SM86513

Name of the Device Group (s): Silicone 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 made of silicone to function as an adjunct to artificial respiration and cardiopulmonary resuscitation for patients who need these types of respiratory care.

Classification: CLASS IIa, rule 2; Besmed silicone mask is connected to manual resuscitator for use as an adjunct to artificial respiration and cardiopulmonary resuscitation.

Notified Body Name: DEKRA Certification B.V.

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

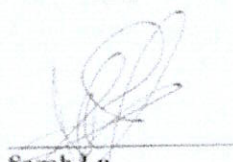
Notified Body Identification number: NB 0344

harmonized standards or CS are applied: EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 13485:2016/AC: 2018, IEC 62366-1:2015/AMD1:2020, ISO 10993-1:2018, 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. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V. All supporting documentation is retained at the premises of the manufacturer.

Signature:



Sarah Lu

FUNCTION: Vice President

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

New Taipei City, 2021.04.30

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Attachment to declaration of conformity [Silicone Mask]

Silicone Mask

Device	Reference number	Description
Silicone Mask	SM-86513	TRANSPARENT SILICONE MASK SIZE #1. Infant Large
	SM-86523	TRANSPARENT SILICONE MASK SIZE #2. Child
	SM-86533	TRANSPARENT SILICONE MASK SIZE #3. Child Large
	SM-86543	TRANSPARENT SILICONE MASK SIZE #4. Adult
	SM-86553	TRANSPARENT SILICONE MASK SIZE #5. Adult Large
	SM-86503	SILICONE MASK SIZE #0.
	SM-86131	SILICONE MASK SIZE #3. Child Large
	SM-86141	SILICONE MASK SIZE #4. Adult
	SM-86151	SILICONE MASK SIZE #5. Adult Large

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