

## EC Declaration of Conformity

**Manufacturers Name:** Besmed Health Business Corp.

**Manufacturers Address:** No. 5, Lane 116, Wu-Kong 2<sup>nd</sup> 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:** 4716770CT01601XX

**Name of the Device Group (s):** SILICONE MASK

**Product (MDN) code:** 1201

**European Medical Device Nomenclature (EMDN):** R020199

**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:** Besmed Silicone Mask designed to be placed over a patient's nose and/or mouth to direct anaesthetic gases to the upper airway.

**Classification:** CLASS IIa,  
**Rule 2:** Besmed Silicone Mask is a non-invasive device intended for channeling gases for the purpose of eventual introduction into the patient body.

**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 ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN 24971:2020, EN ISO 20417:2021, 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, ASTM F88, ASTM F1980-21, EN ISO 5356-1:2015.

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

Place and date (yyyy.mm.dd) of issue: Taipei, 2021.05.22

Signature:

*Sarah Lu*

*Steven Wong*

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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 [Silicone Mask]

### SILICONE MASK

Device	Reference number	Description
Silicone Mask	SM-86131	Silicone Mask, Size 3, Child Large
	SM-86132	Silicone Mask, Size 3, Child Large
	SM-86141	Silicone Mask, Size 4, Adult
	SM-86151	Silicone Mask, Size 5, Adult Large
Silicone Cushion Mask (PSF)	SM-86222	Silicone Cushion Mask, Polysulfone, Size 2
	SM-86232	Silicone Cushion Mask, Polysulfone, Size 3
	SM-86242	Silicone Cushion Mask, Polysulfone, Size 4
	SM-86252	Silicone Cushion Mask, Polysulfone, Size 5
	SM-86262	Silicone Cushion Mask, Polysulfone, Size 6
Silicone Cushion Mask (PC)	SM-86221	Silicone cushion Mask (PC) 22 mm, Size 2
	SM-86231	Silicone cushion Mask (PC) 22 mm, Size 3
	SM-86241	Silicone cushion Mask (PC) 22 mm, Size 4
	SM-86251	Silicone cushion Mask (PC) 22 mm, Size 5
	SM-86261	Silicone cushion Mask (PC) 22 mm, Size 6
Transparent Silicone Mask	SM-86503	Transparent Silicone Mask, Size 0, Infant
	SM-86513	Transparent Silicone Mask, Size 1, Infant Large
	SM-86523	Transparent Silicone Mask, Size 2, Child

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	SM-86533	Transparent Silicone Mask, 22 mm Size 3 Child Large
	SM-86543	Transparent Silicone Mask, 22 mm Size 4 Large
	SM-86553	Transparent Silicone Mask, 22 mm Size 5 Adult Large
	SM-86573	Transparent Silicone Mask, Size 00
	SM-86583	Transparent Silicone Mask, Size 000
Silicone Rendell Baker Mask W/Exhalation Valve	SM-86413	Silicone Rendell Baker Mask W/Exhalation Valve, Size #XS, 22mm
	SM-86423	Silicone Rendell Baker Mask W/Exhalation Valve, Size #S, 22mm
	SM-86433	Silicone Rendell Baker Mask W/Exhalation Valve, Size #M, 22mm
Rendell Baker Silicone Mask	SM-86303	#0 Rendell Baker Silicone Mask 22mm
	SM-86313	#1 Rendell Baker Silicone Mask 22mm
	SM-86323	#2 Rendell Baker Silicone Mask 22mm
	SM-86333	#3 Rendell Baker Silicone Mask 22mm