

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): Casus Europe B.V.

Authorized Representative Address Lange Viestraat 2b, Utrecht, 3511 BK, The Netherlands.

SRN (Single Registration Number) of Authorized Representative: NL-AR-000037688

Basic UDI-DI: 4716770CT01601XX

Name of the Device Group (s): DISPOSABLE CUSHION 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 Disposable Cushion Mask is designed to be placed over a patient's nose and mouth to direct anaesthetic gases to the upper airway.

Classification: CLASS IIa,
Rule 2: Besmed Disposable Cushion 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 F88-21, 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 [Disposable Cushion Mask]

DISPOSABLE CUSHION MASK

Device	Reference number	Description
Disposable Cushion Mask	CM-65204	Inflatable Air Cushion Mask W/Hook #0 Neonatal 15mm
	CM-65214	Inflatable Air Cushion Mask W/Hook #1 Infant 15mm
	CM-65224	Inflatable Air Cushion Mask W/Hook #2 Pediatric 22mm
	CM-65234	Inflatable Air Cushion Mask W/Hook #3 Small Adult 22mm
	CM-65244	Inflatable Air Cushion Mask W/Hook #4 Medium Adult 22mm
	CM-65254	Inflatable Air Cushion Mask W/Hook #5 Large Adult 22mm
	CM-65264	Inflatable Air Cushion Mask W/Hook #6 Extra Large Adult 22mm
	CM-65504	Air Cushion Mask, Horizontal Valve, Green Hook, Size 0, Neonatal
	CM-65514	Air Cushion Mask, Horizontal Valve, Pink Hook, Size 1, Infant
	CM-65524	Air Cushion Mask, Horizontal Valve, Red Hook, Size 2, Child
	CM-65534	Air Cushion Mask, Horizontal Valve, Yellow Hook, Size 3, Adult
	CM-65544	Air Cushion Mask, Horizontal Valve, White Hook, Size 4, Adult
	CM-65554	Air Cushion Mask, Horizontal Valve, Blue Hook, Size 5, Adult
	CM-65564	Air Cushion Mask, Horizontal Valve, Transparent Hook, Size 6, Adult
	CM-65404	Inflatable Air Cushion Mask W/Hook #0 Neonatal 15mm
	CM-65414	Inflatable Air Cushion Mask W/Hook #1 Infant 15mm
	CM-65424	Inflatable Air Cushion Mask W/Hook #2 Pediatric 22mm
	CM-65434	Inflatable Air Cushion Mask W/Hook #3 Small Adult 22mm

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	CM-65444	Inflatable Air Cushion Mask W/Hook #4 Medium Adult 22mm
	CM-65454	Inflatable Air Cushion Mask W/Hook #5 Large Adult 22mm
	CM-65464	Inflatable Air Cushion Mask W/Hook #6 Extra Large Adult 22mm
	CM-65402	Inflatable Air Cushion Mask W/O Hook #0 Neonatal 15mm
	CM-65412	Inflatable Air Cushion Mask W/O Hook #1 Infant 15mm
	CM-65422	Inflatable Air Cushion Mask W/O Hook #2 Pediatric 22mm
	CM-65432	Inflatable Air Cushion Mask W/O Hook #3 Small Adult 22mm
	CM-65442	Inflatable Air Cushion Mask W/O Hook #4 Medium Adult 22mm
	CM-65452	Inflatable Air Cushion Mask W/O Hook #5 Large Adult 22mm
	CM-65462	Inflatable Air Cushion Mask W/O Hook #6 Extra Large Adult 22mm
ULTRA-SMT Anesthesia Mask	CM-65800	ULTRA-SMT Anesthesia Mask Size 0 Neonatal w/o hook
	CM-65810	ULTRA-SMT Anesthesia Mask Size 1 Infant w/o hook
	CM-65820	ULTRA-SMT Anesthesia Mask Size 2 Pediatric w/o hook
	CM-65830	ULTRA-SMT Anesthesia Mask Size 3 Small Adult w/o hook
	CM-65840	ULTRA-SMT Anesthesia Mask Size 4 Medium Adult w/o hook
	CM-65850	ULTRA-SMT Anesthesia Mask Size 5 Large Adult w/o hook
	CM-65805	ULTRA-SMT Anesthesia Mask Size 0 Neonatal w hook 15mm
	CM-65815	ULTRA-SMT Anesthesia Mask Size 1 Infant w hook 15mm
	CM-65825	ULTRA-SMT Anesthesia Mask Size 2 Pediatric w hook 22mm
	CM-65835	ULTRA-SMT Anesthesia Mask Size 3 Small Adult w hook 22mm
	CM-65845	ULTRA-SMT Anesthesia Mask Size 4 Medium Adult w hook 22mm
	CM-65855	ULTRA-SMT Anesthesia Mask Size 5 Large Adult w hook 22mm
Endoscopy Mask	CM-65910	Disposable Endoscopy Mask
	CM-65912	Disposable Endoscopy Mask with 7Ft Tube & 6mm connector
Inflatable Air Cushion Mask with Horizontal Valve Part Number	CM-65504	Air Cushion Mask, Horizontal Valve, Green Hook, Size 0, Neonatal
	CM-65514	Air Cushion Mask, Horizontal Valve, Pink Hook, Size 1, Infant
	CM-65524	Air Cushion Mask, Horizontal Valve, Red Hook, Size 2, Child
	CM-65534	Air Cushion Mask, Horizontal Valve, Yellow Hook, Size 3, Adult
	CM-65544	Air Cushion Mask, Horizontal Valve, White Hook, Size 4, Adult

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	CM-65554	Air Cushion Mask, Horizontal Valve, Blue Hook, Size 5, Adult
	CM-65564	Air Cushion Mask, Horizontal Valve, Transparent Hook, Size 6, Adult

Besmed Health Business Corp.
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