



# 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:** 4716770CM65810

**Name of the Device Group (s):** Disposable Anesthesia 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

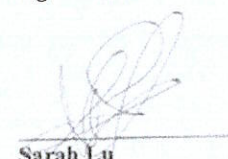
**Notified Body Identification number:** NB 0344

**harmonized standards or CS are applied:** EN 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, 2021.06.24



BESMED HEALTH BUSINESS CORP.

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Attachment to declaration of conformity [Disposable Anesthesia Mask]

### Disposable Anesthesia Mask

Device	Reference number	Description
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

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