BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan, 24888
☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
✉ : info@besmed.com 🌐 : www.besmed.com

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:

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

New Taipei City, 2021.06.24

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Sarah Lu
FUNCTION: Vice President

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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