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):	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:	4716770AW06100XX
Name of the Device Group (s):	LARYNGEAL AIRWAY MASK (STERILE)
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R010201
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 Laryngeal Airway Mask (sterile) is a device inserted into a patient's pharynx through the mouth to provide an airway to patient needs alternative airway.
Classification:	Class IIa, **Rule 5**: Besmed Laryngeal Airway Mask (sterile) is an invasive device, which is intended to provide an alternative airway to patients.
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 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 10993-23:2021, EN ISO 11135:2014, EN ISO 15223-1:2021, UL 969:2018, ISTA 2A, ASTM F1140/F1140M-13(2020), ASTM F88/F88M-23, ASTM 1929-23, ASTM F1980-21, ASTM F1608-21, EN ISO 5364:2016.
CE certificate no.	6092261CE01

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EC Declaration of Conformity

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.

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
.....
Sarah Lu
Vice President
For and on behalf of Besmed

Steven Wong
.....
Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [Laryngeal Mask Airway (sterile)]

LARYNGEAL MASK AIRWAY (STERILE)

Device	Reference number	Description
Disposable Laryngeal Mask Airway	LA-77110	Disposable Silicone LMA, Size 1.0
	LA-77115	Disposable Silicone LMA, Size 1.5
	LA-77120	Disposable Silicone LMA, Size 2.0
	LA-77125	Disposable Silicone LMA, Size 2.5
	LA-77130	Disposable Silicone LMA, Size 3.0
	LA-77140	Disposable Silicone LMA, Size 4.0
	LA-77150	Disposable Silicone LMA, Size 5.0
Reusable Silicone Laryngeal Mask Airway	LA-77210	Laryngeal Airway-size 1.0 Reusable
	LA-77215	Laryngeal Airway-size 1.5 Reusable
	LA-77220	Laryngeal Airway-size 2.0 Reusable
	LA-77225	Laryngeal Airway-size 2.5 Reusable
	LA-77230	Laryngeal Airway-size 3.0 Reusable
	LA-77240	Laryngeal Airway-size 4.0 Reusable
	LA-77250	Laryngeal Airway-size 5.0 Reusable