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):	DISPOSABLE LARYNGOSCOPE SET
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R9002
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 Laryngoscope Set is a device that is intended to be used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.
Classification:	CLASS IIa, **Rule 5**: Besmed Disposable Laryngoscope Set is an invasive device with respect to the oral cavity and is short-term use.
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 15223-1:2021, ISTA 2A, UL 969:2018, ASTM F88/F88M-23, ASTM F1980-21, EN ISO 7376:2020.
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
.....
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 [Disposable Laryngoscope Set]

DISPOSABLE LARYNGOSCOPE SET

Device	Reference number	Description
Disposable Laryngoscope Set	LS-78390	Optic Handle
	LS-78490	Fiber Optic Laryngoscope Set
	LS-78200	Disposable Fiber Optic Miller, Blade Infant 0
	LS-78210	Disposable Fiber Optic Miller, Blade Child 1
	LS-78220	Disposable Fiber Optic Miller, Blade Adult 2
	LS-78230	Disposable Fiber Optic Miller, Blade large Adult 3
	LS-78120	Disposable Fiber Optic Macintosh, Blade Adult 2
	LS-78130	Disposable Fiber Optic Macintosh, Blade Adult 3
	LS-78140	Disposable Fiber Optic Macintosh, Blade Adult 4

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