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
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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, 3511 BK Utrecht The Netherlands.
SRN (Single Registration Number) of Authorized Representative:	NL-AR-000037688
Basic UDI-DI:	4716770AW06100XX
Name of the Device Group (s):	GUEDEL AIRWAY (STERILE)
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R010102
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 Guedel Airway (sterile) is intended to provide clear airway through the oral cavity and pharynx by preventing blockage by the tounge.
Classification:	CLASS IIa, **Rule 5**: Besmed Guedel Airway (sterile) is an invasive device and intended to provide clear airway with respect to the oral cavity, for 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, ISO 5364:2016.
CE certificate no.	6092261CE01

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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 *Steven Wong*

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Sarah Lu Steven Wong
Vice President Regulatory Affairs Manager
For and on behalf of Besmed For and on behalf of Besmed

Attachment to declaration of conformity [Guedel Airway (sterile)]

GUEDEL AIRWAY (STERILE)

Device	Reference number	Description
Guedel Airway (sterile)	AW-61130	Guedel airway, 30mm, Lilac
	AW-61140	Guedel airway, 40mm, Pink
	AW-61150	Guedel airway, 50mm, Blue
	AW-61160	Guedel airway, 60mm, Black
	AW-61170	Guedel airway, 70mm, White
	AW-61180	Guedel airway, 80mm, Green
	AW-61190	Guedel airway, 90mm, Yellow
	AW-61110	Guedel airway, 100mm, Red
	AW-61111	Guedel airway, 110mm, Orange
	AW-61112	Guedel airway, 120mm, Purple
	AW-61700	Guedel Airway, 40-110mm