

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: 4716770AW06100ER

Name of the Device Group (s): AIRWAY MANAGEMENT (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 IX of MDR 2017/745).

Intended use: Besmed Airway Management (Sterile) is intended to provide a clear airway through the oral cavity and the pharynx by preventing blockage by the tongue.

Classification: Class Is,
Rule 5: Besmed Airway Management (Sterile) is supplied in a sterile condition and it's an invasive device with respect to the oral cavity.

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-2011, UL 969:2018, ASTM F1140/F1140M-13:2020, ASTM F88/F88M-21, ASTM 1929-15, ASTM F1980-21, ASTM F1608-21, EN ISO 5364:2016.

CE certificate no. 6170840CE01

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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) MDR 2017/745 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.

Place and date (yyyy.mm.dd) of issue: Taipei, 2024.03.18

Signature:

Sarah Lu

Steven Wong

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Sarah Lu
Vice President
For and on behalf of Besmed

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Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [Airway Management (Sterile)]

AIRWAY MANAGEMENT (STERILE)

Device	Reference number	Description
Airway Management (Sterile)	AW-61130	Guedel airway, 30mm, Clear
	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

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Revision log

Rev No.	Doc. No.	Reason for Change	Approval / Date
1	TED01-CH03-DOC-01	First version	Sarah Lu / 2023.04.11
2.	TED01-CH03-DOC-01	Revised Authorized Representative information	Sarah Lu / 2024.03.21