

**BESMED HEALTH BUSINESS CORP.**

No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,  
New Taipei City, Taiwan. 24888

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✉ : info@besmed.com    🌐 : www.besmed.com

## EU Declaration of Conformity

<b>Manufacturers Name:</b>	Besmed Health Business Corp.
<b>Manufacturers Address:</b>	No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
<b>SRN (Single Registration Number) of Manufacturer:</b>	TW-MF-000007246
<b>Authorized Representative Name (if applicable):</b>	Mdi Europa GmbH
<b>Authorized Representative Address</b>	Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany
<b>SRN (Single Registration Number) of Authorized Representative:</b>	DE-AR-000006218
<b>Basic UDI-DI:</b>	4716770AW06100ER
<b>Name of the Device Group (s):</b>	AIRWAY MANAGEMENT (NON-STERILE)
<b>Product (MDN) code:</b>	1201
<b>European Medical Device Nomenclature (EMDN):</b>	R010102
<b>Conformity assessment route:</b>	Conformity assessment based on a Quality Management System and technical documentation (Annex IX of MDR 2017/745)
<b>Intended use:</b>	Besmed Airway Management is intended to provide a clear airway through the oral cavity and the pharynx by preventing blockage by the tongue.
<b>Classification:</b>	Class I, <b>Rule 5:</b> Besmed Airway Management supplied in a non-sterile condition and it is an invasive device with respect to the oral cavity, for short term use.
<b>Applicable standards or CS are applied:</b>	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 F1140, ASTM F88, ASTM F1980-21, ASTM F1608-21, EN ISO 5364:2016.

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 Besmed Health Business Corp.



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All supporting documentation is retained at the premises of the manufacturer.

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

Taipei, 2021.05.26

Signature:

Sarah Lu  
Vice President  
For and on behalf of Besmed

Steven Wong  
Regulatory Affairs Manager  
For and on behalf of Besmed

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

### AIRWAY MANAGEMENT (NON-STERILE)

Device	Reference number	Description
Airway Management (Non-sterile)	AW-61430	Guedel Airway, Size 30mm (Clear)
	AW-61440	Guedel Airway, Size 40mm (Pink)
	AW-61450	Guedel Airway, Size 50mm (Blue)
	AW-61460	Guedel Airway, Size 60mm (Black)
	AW-61470	Guedel Airway, Size 70mm (White)
	AW-61480	Guedel Airway, Size 80mm (Green)
	AW-61490	Guedel Airway, Size 90mm (Yellow)
	AW-61410	Guedel Airway, Size 100mm (Red)
	AW-61411	Guedel Airway, Size 110mm (Orange)
	AW-61412	Guedel Airway, Size 120mm (Purple)
	AW-61902	Guedel Airway Set with Case, 40mm~110mm