

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: 4716770AW06101ET

Name of the Device Group (s): GUEDEL AIRWAY (NON-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 Guedel Airway (Non-Sterile) is intended to provide a clear airway through the oral cavity and the pharynx by preventing blockage by the tongue.

Classification: Class I,
Rule 5: Besmed Guedel Airway (Non-Sterile) is an invasive device and intended to provide a clear airway with respect to the oral cavity, for short term use.

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.

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

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 [Guedel Airway (Non-Sterile)]

GUEDEL AIRWAY (NON-STERILE)

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