



Product Code	34439
Minimum order	1
Type	Medical device
Class	I S

UK-REP	No
CH-REP	No

RDM (NSIS)	2645421
CND	R010102
EAN/UPC	8023279344394
UMDNS	12732
PARAF	985514850
GMDN	32655

Description

GUEDEL AIRWAYS STERILE - FLEXIBLE, TRANSPARENT

Mixed assortment of 10 pieces consisting of:

- Q.ty 1 Code 34431 Guedel airway 40 mm - pink - newborn - 000
- Q.ty 1 Code 34432 Guedel airway 50 mm - blue - infant - 00
- Q.ty 1 Code 34433 Guedel airway 60 mm - black - child - 0
- Q.ty 2 Code 34434 Guedel airway 70 mm - white - boy - 1
- Q.ty 2 Code 34435 Guedel airway 80 mm - green - adults / small - 2
- Q.ty 1 Code 34436 Guedel airway 90 mm - yellow - adults / small - 3
- Q.ty 1 Code 34437 Guedel airway 100 mm - red - adults / med - 4
- Q.ty 1 Code 34438 Guedel airway 110 mm - orange - adults / large -5

Guedel airways with smooth surface and round tip for improved patient comfort.
Made in polyethylene (PE). Latex free.

EC Declaration of Conformity

Manufacturers Name:	Besmed Health Business Corp.
Manufacturers Address:	No. 5, Lane 116, Wu-Kong 2 nd 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



EC Declaration of Conformity

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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File no.: TED01-CH03-DOC-01

Date: 2024-03-21

EC Declaration of Conformity

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

Besmed Health Business Corp.
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