DoC No.: FM-TD-A001-B01-D01 Ver.:3

DECLARATION OF CONFORMITY

Foremount Enterprise Co., Ltd. declares, under its sole responsibility, that the product(s) covered in this document are in conformance with the requirements of **Regulation(EU) 2017/745 of the European Parliament and of the Council of 54 April 2017 concerning Medical Devices.**

Manufacturer Name	Foremount Enterprise Co., Ltd.
Manufacturer Address	Address: No.17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City, 42944, Taiwan
Manufacturers SRN	TW-MF-000006734
Notified Body	Not Applicable
EC Certificate	Not Applicable
Product Name	Oropharyngeal Airway
Product Model Number/ Variants	“See Attached Appendix II”
Basic UDI-DI	471987189FM1XD0400DX
Intended Prupose	Oropharyngeal airway(OPA) is a medical device used to maintain or open a patient's airway. It does this by preventing the tongue from covering the epiglottis, which could prevent the person from breathing.
EMDN Code	R010102
MDR Classification	Class I Rule 5
Medical Device Regulation Assessment Route	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.
EU Authorised Representative	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN	MT-AR-000000234
Name	Joanne Shih
Title	Management Representative

Signature	 Place of Signature：Taichung, Taiwan.
Date	2024/03/18

Appendix I – Applicable Standards

Standard / CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-1:2020	Biological evaluation of medical devices Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
ISO 10993-10:2021	Biological evaluation of medical devices Part 10: Tests for skin sensitization
ISO 14644-1:2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration
ASTM F1980:2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
ISTA-1A:2014	Packaged-products weighing 150 lbs (68kg) or less
ISO 20417:2021	Medical devices Information to be supplied by the manufacturer
ISO 5364:2016	Anaesthetic and respiratory equipment Oropharyngeal airways

Appendix II – Product Listing /Schedule

Product Group	Product Family	Spec	REF#	UDI-DI	Trade name	Trade REF#	Trade model name
Oropharyngeal Airway	Berman Airway	40 mm	1110204	04719871892817	NA	NA	NA
		50 mm	1110205	04719871892831	NA	NA	NA
		60 mm	1110206	04719871892855	NA	NA	NA
		70 mm	1110207	04719871892879	NA	NA	NA
		80 mm	1110208	04719871892893	NA	NA	NA
		90 mm	1110209	04719871892916	NA	NA	NA
		100 mm	1110210	04719871892930	NA	NA	NA
		110 mm	1110211	04719871892954	NA	NA	NA
		40 mm	1111204	04719871892978	NA	NA	NA
		50 mm	1111205	04719871892992	NA	NA	NA
		60 mm	1111206	04719871893012	NA	NA	NA
		70 mm	1111207	04719871893036	NA	NA	NA
		80 mm	1111208	04719871893050	NA	NA	NA
		90 mm	1111209	04719871893074	NA	NA	NA
		100 mm	1111210	04719871893098	NA	NA	NA
		110 mm	1111211	04719871893111	NA	NA	NA
	Rigid Guedel Airway	30 mm	1110303	04719871893135	NA	NA	NA
		40 mm	1110304	04719871893159	NA	NA	NA
		50 mm	1110305	04719871893173	NA	NA	NA
		60 mm	1110306	04719871893197	NA	NA	NA
		70 mm	1110307	04719871893210	NA	NA	NA
		80 mm	1110308	04719871893234	NA	NA	NA
		90 mm	1110309	04719871893258	NA	NA	NA
		100mm	1110310	04719871893272	NA	NA	NA
		110 mm	1110311	04719871893296	NA	NA	NA
	Soft Guedel Airway	30 mm	1110403	04719871893593	Medline	SGU241030	Soft Guedel Airway,30mm, ISO3
		40 mm	1110404	04719871893616	Medline	SGU241040	Soft Guedel Airway,40mm, ISO4
		50 mm	1110405	04719871893630	Medline	SGU241050	Soft Guedel Airway,50mm, ISO5
		60 mm	1110406	04719871893654	Medline	SGU241060	Soft Guedel Airway,60mm, ISO6
		70 mm	1110407	04719871893678	Medline	SGU241070	Soft Guedel Airway,70mm, ISO7

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		80 mm	1110408	04719871893692	Medline	SGU241080	Soft Guedel Airway,80mm, ISO8
		90 mm	1110409	04719871893715	Medline	SGU241090	Soft Guedel Airway,90mm, ISO9
		100 mm	1110410	04719871893739	Medline	SGU241100	Soft Guedel Airway,100mm, ISO10
		120 mm	1110412	04719871893753	Medline	SGU241120	Soft Guedel Airway,120mm, ISO12
	Slit Guedel Airway	80 mm	1111408	04719871893777	Medline	SLT253080	Slit Guedel Airway,80mm, ISO8
		90 mm	1111409	04719871893791	Medline	SLT253090	Slit Guedel Airway,90mm, ISO9
		100 mm	1111410	04719871893814	Medline	SLT2530100	Slit Guedel Airway,100mm, ISO10

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