DOC no.: FM-TCF-D001-A01-D01 Ver.: 12

EC DECLARATION OF CONFORMITY

For the following Medical device:

Disposable Aircushion Mask

(Product Group)

Classic Cushion Mask I, Classic Cushion Mask II, Rotation Mask

(Product Family)

Please see the Attachment A of Page 3.

(Size, Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance of conformity assessment **Annex II-exclusive section 4** to be certified by DNV Product Assurance AS - Veritasveien 1, 1363 Høvik, Norway (notify body number-2460).

Each kind of medical device to which the system has been applied complies with the applicable provisions of Annex I Essential requirement, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied. We declare that the DOC is issued under our sole responsibility for the product.

For the evaluation regarding the Class IIa product safety aspects, the following standards are applied:

Harmonized Standard

- EN 1041:2008
- EN 62366:2008
- EN ISO 13485:2016
- EN ISO 15223-1:2016
- EN ISO 10993-1:2009/AC:2010
- EN ISO 10993-5:2009
- EN ISO 14971:2012

Non-Harmonized Standard

- ISO 10993-10:2010
- ISO 5356-1:2015
- ISO 14644-1:2015
- ASTM F1980:2016
- ISTA-1A:2014

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The following European Authorized Representative is stated to the declaration:
Advena Ltd.
Address: Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
(Company Name/Address)

The following person is responsible for the compliance of declaration:
Foremount Enterprise Co., Ltd.
Address: No.17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City, 42944, Taiwan.
(Manufacturer Name/Address)

William Jiang / President		2023/04/20
(Name/Position)	(Legal Signature)	(Date)

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Attachment A

Product Group	Product Family	Spec	REF#	Trade name	Trade REF#	Trade model name
Disposable Aircushion Mask	Classic Cushion Mask I	#0	1210300	N/A	N/A	N/A
		#1	1210301			
		#2	1210302			
		#3	1210303			
		#4	1210304			
		#5	1210305			
	Classic Cushion Mask II	#0	1210220			
		#1	1210221			
		#2	1210222			
		#3	1210223			
		#4	1210224			
		#5	1210225			
		#0	1210230	Medline International B.V.	AMAC23010V	Air cushion masks,valve,Sz0,Neo
		#1	1210231	Medline International B.V.	AMAC23011V	Air cushion masks,valve,Sz1,Inf
		#2	1210232	Medline International B.V.	AMAC23012V	Air cushion masks,valve, Sz2,Ped

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		#3	1210233	Medline International B.V.	AMAC23013V	Air cushion masks,valve,Sz3,AduSm
		#4	1210234	Medline International B.V.	AMAC23014V	Air cushion masks,valve,Sz4,AduMed
		#5	1210235	Medline International B.V.	AMAC23015V	Air cushion masks,Sz5,AduLar
	Rotation Mask	#00	1210400-00	N/A	N/A	N/A
		#0	1210400	Medline International B.V.	AMR23020V	Rotation Mask,valve,Sz0,Neo
		#1	1210401	Medline International B.V.	AMR23021V	Rotation Mask,valve,Sz1,Inf
		#2	1210402	Medline International B.V.	AMR23022V	Rotation Mask,valve,Sz2,Ped

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		#3	1210403	Medline International B.V.	AMR23023V	Rotation Mask,valve,Sz3,AduSm
		#4	1210404	Medline International B.V.	AMR23024V	Rotation Mask,valve,Sz4,AduMed
		#5	1210405	Medline International B.V.	AMR23025V	Rotation Mask,valve,Sz5,AduLar
		#6	1210406	Medline International B.V.	AMR23026V	Rotation Mask,valve,Sz6,AduExLar

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