

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: CPAP/VPAP Nasal Mask and Accessories

Medical Device: CPAP/VPAP Nasal Mask, Nasal Pillow Mask, NIPPV Tubing, and Connector

Item Code: As Attachment

Classification: IIa



according to Rule 2 in annex IX of directive 93/42/EEC

meets the provision of the directive 93/42/EEC in consideration of the change of the directive 2007/47/EEC and its transpositions in national laws which apply to it.

Conformity assessment procedure: Directive 93/42/EEC annex II, excluding section 4; the manufacturer is fully responsible for the content of declaration of conformity.

Registration No.: 10240-2017-CE-RGC-NA-PS

Notified Body: DNV GL Nemko Presafe A/S (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

The following standards are applied for all devices:

EN 1041:2008, EN ISO 14971:2019, EN ISO 10993-1:2018, EN ISO10993-5:2009, EN ISO10993-10:2013, EN ISO 13485:2016, EN 62366:2008, EN ISO 80369-7:2017, EN ISO 17510:2020, EN ISO 5356-1:2015

Taichung, Jan. 15, 2021

Place / Date



VP of Sales and Marketing

Attachment of DoC
Device Complete List

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
CPAP Nasal Mask	10253	NA	NA	Hsiner
	10254	NA	NA	Hsiner
	10255	NA	NA	Hsiner
	10353	NA	NA	Hsiner
	10354	NA	NA	Hsiner
	10355	NA	NA	Hsiner
	10453	NA	NA	Hsiner
	10454	NA	NA	Hsiner
	10455	NA	NA	Hsiner
	10573	NA	NA	Hsiner
	10574	NA	NA	Hsiner
	10575	NA	NA	Hsiner
	10673	NA	NA	Hsiner
	10674	NA	NA	Hsiner
	10675	NA	NA	Hsiner
	10853	NA	NA	Hsiner
	10854	NA	NA	Hsiner
	10855	NA	NA	Hsiner
	11173	NA	NA	Hsiner
	11174	NA	NA	Hsiner
	11175	NA	NA	Hsiner
	11353	NA	NA	Hsiner
	11354	NA	NA	Hsiner
	11355	NA	NA	Hsiner
	11453	NA	NA	Hsiner
	11454	NA	NA	Hsiner
	11455	NA	NA	Hsiner
	12153	NA	NA	Hsiner
	12154	NA	NA	Hsiner
	12155	NA	NA	Hsiner
12253	NA	NA	Hsiner	
12254	NA	NA	Hsiner	

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	12255	NA	NA	Hsiner
	12453	NA	NA	Hsiner
	12454	NA	NA	Hsiner
	12455	NA	NA	Hsiner
	12553	NA	NA	Hsiner
	12554	NA	NA	Hsiner
	12555	NA	NA	Hsiner
	12653	NA	NA	Hsiner
	12654	NA	NA	Hsiner
	12655	NA	NA	Hsiner
	12753	NA	NA	Hsiner
	12754	NA	NA	Hsiner
	12755	NA	NA	Hsiner
	12853	NA	NA	Hsiner
	12855	NA	NA	Hsiner
	13253	NA	NA	Hsiner
	13254	NA	NA	Hsiner
	13255	NA	NA	Hsiner
	12953	NA	NA	Hsiner
	12954	NA	NA	Hsiner
	12955	NA	NA	Hsiner
CPAP Nasal Pillow Mask	11054	NA	NA	Hsiner
	11254	NA	NA	Hsiner
	13055	NA	NA	Hsiner
	11252	NA	NA	Hsiner
	12000	NA	NA	Hsiner
	12001	NA	NA	Hsiner
	12002	NA	NA	Hsiner
	12003	NA	NA	Hsiner
	12004	NA	NA	Hsiner
	12005	NA	NA	Hsiner
	12009	NA	NA	Hsiner
	12010	NA	NA	Hsiner
	12011	NA	NA	Hsiner
	12012	NA	NA	Hsiner
	12013	NA	NA	Hsiner
12014	NA	NA	Hsiner	

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	12015	NA	NA	Hsiner
	12019	NA	NA	Hsiner

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
VPAP Nasal Mask	10208	NA	NA	Hsiner
	10205	NA	NA	Hsiner
	10202	NA	NA	Hsiner
	10301	NA	NA	Hsiner
	10302	NA	NA	Hsiner
	10303	NA	NA	Hsiner
	10504	NA	NA	Hsiner
	10505	NA	NA	Hsiner
	10506	NA	NA	Hsiner
	10604	NA	NA	Hsiner
	10605	NA	NA	Hsiner
	10606	NA	NA	Hsiner
	11104	NA	NA	Hsiner
	11105	NA	NA	Hsiner
	11106	NA	NA	Hsiner
	11301	NA	NA	Hsiner
	11302	NA	NA	Hsiner
	11303	NA	NA	Hsiner
	11304	NA	NA	Hsiner
	11305	NA	NA	Hsiner
11306	NA	NA	Hsiner	
11307	NA	NA	Hsiner	
10207	NA	NA	NA	Hsiner

Device Complete List (Accessories)

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Tubing	70243	N/A	N/A	Hsiner
	70263	N/A	N/A	Hsiner
	70253	N/A	N/A	Hsiner
	70273	N/A	N/A	Hsiner
	71246	N/A	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	70240	N/A	N/A	Hsiner
	70241	N/A	N/A	Hsiner
	70242	N/A	N/A	Hsiner
	70245	N/A	N/A	Hsiner
	70246	N/A	N/A	Hsiner
	70247	N/A	N/A	Hsiner
	70260	N/A	N/A	Hsiner
	70261	N/A	N/A	Hsiner
	70262	N/A	N/A	Hsiner
Connector	70056	N/A	N/A	Hsiner
Pressure Meter	C10201-001	N/A	N/A	Hsiner
	C10201-002	N/A	N/A	Hsiner

Appendix I

Condition #1: material, element, composition, ingredient is NO CHANGE, also the related ratio is NO CHANGE

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
CPAP Nasal Mask	10253	EG010	00003440	HOFFRICHTER
	10254	EG010	00003434	HOFFRICHTER
	10255			
	10353			
	10354			
	10355			
	10453			
	10454			
	10455			
	10573			
	10574			
	10575			
	11353	EG010	00003486	HOFFRICHTER
	11354	EG010	00003487	HOFFRICHTER
	11355	EG010	00003488	HOFFRICHTER
12254				
12853				
12855				
CPAP Nasal Pillow Mask	13055			

Product Section	Product Type	Internal control Code	Customer Product No.	Brand

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
VPAP Nasal Mask	10604			
	10605			
	10606			
	11304			
	11305			
	11306			
	11307			

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Tubing	70243			
	70253			
	70241			
	70242			
	70246			
	70247			
	70262			
Connector	70056			

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Pressure Meter	10201-001			

Appendix II

Condition #2 : material, element, composition , ingredient is NO CHANGE, but the related ratio is CHANGE

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
CPAP Nasal Mask	10273	NA	NA	Hsiner
	10274	NA	NA	Hsiner
	10275	NA	NA	Hsiner
	11349	NA	NA	Hsiner
	N/A			
	11350	NA	NA	Hsiner
	11351	NA	NA	Hsiner
	N/A			
	11352	NA	NA	Hsiner
	12353	NA	NA	Hsiner
	12354	NA	NA	Hsiner
12355	NA	NA	Hsiner	

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	13153	NA	NA	Hsiner
	13154	NA	NA	Hsiner
	13155	NA	NA	Hsiner
	14153	NA	NA	Hsiner
	14154	NA	NA	Hsiner
	14155	NA	NA	Hsiner
	14453	NA	NA	Hsiner
	14454	NA	NA	Hsiner
	14455	NA	NA	Hsiner
	14253	NA	NA	Hsiner
	14254	NA	NA	Hsiner
	14255	NA	NA	Hsiner
	14349	NA	NA	Hsiner
	14350	NA	NA	Hsiner
	14351	NA	NA	Hsiner
	14352	NA	NA	Hsiner
	11573	NA	NA	Hsiner
	11574	NA	NA	Hsiner
	11575	NA	NA	Hsiner
	13653	NA	NA	Hsiner
	13654	NA	NA	Hsiner
	13655	NA	NA	Hsiner
	13753	NA	NA	Hsiner
	13754	NA	NA	Hsiner
	13755	NA	NA	Hsiner
		NA	NA	Hsiner
	13451			
		NA	NA	Hsiner
	13452			
	13453	NA	NA	Hsiner

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	13454	NA	NA	Hsiner
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	N/A			
	CPAP Nasal Pillow Mask	11253	NA	NA
11255		NA	NA	Hsiner
NA		EG010	00003499	Hsiner
NA				
NA				
NA				
NA				

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
VPAP Nasal Mask	N/A			
	N/A			
	10270	NA	NA	Hsiner
	10271	NA	NA	Hsiner
	10272	NA	NA	Hsiner

	10501	NA	NA	Hsiner
	10502	NA	NA	Hsiner
	10503	NA	NA	Hsiner
	10801	NA	NA	Hsiner
	10802	NA	NA	Hsiner
	10803	NA	NA	Hsiner
	11401	NA	NA	Hsiner
	NA			
	11402	NA	NA	Hsiner
	NA			
	11403	NA	NA	Hsiner
	12201	NA	NA	Hsiner
	12202	NA	NA	Hsiner
	12203	NA	NA	Hsiner
	12401	NA	NA	Hsiner
	12402	NA	NA	Hsiner
	12403	NA	NA	Hsiner
	12601	NA	NA	Hsiner
	12602	NA	NA	Hsiner
	12603	NA	NA	Hsiner
	12701	NA	NA	Hsiner
	12702	NA	NA	Hsiner
	12703	NA	NA	Hsiner
		NA	NA	Hsiner
	13401			
		NA	NA	Hsiner
	13402			
		NA	NA	Hsiner
	13403			
		NA	NA	Hsiner
	13404			
		NA	NA	Hsiner
	14301	NA	NA	Hsiner
	14302	NA	NA	Hsiner
	14303	NA	NA	Hsiner
	14304	NA	NA	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Tubing	N/A			
Connector	N/A			

Document title		Declaration of conformity	
Version:	Date	Revision History	Review by
1	2019.1.31	New release	Ariel Huang
1.1	2019.05.27	Update valid date and separate class I device	Phoebe Lu
1.2	2019.06.10	Add standards	Phoebe Lu
1.3	2019.09.06	Re-classification	Phoebe Lu
1.4	2020.07.31	Update regulation	Phoebe Lu
1.5	2020.12.19	Add Product No.	Cindy Hsiao
1.6	2021.01.15	Add items	Ariel Huang