

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
		[REDACTED]	[REDACTED]	[REDACTED]
	10254	EG010	00003434	HOFFRICHTER
		[REDACTED]	[REDACTED]	[REDACTED]
	10255	EG010	00003435	HOFFRICHTER
	10353	[REDACTED]	[REDACTED]	[REDACTED]
	10354	[REDACTED]	[REDACTED]	[REDACTED]
	10355	[REDACTED]	[REDACTED]	[REDACTED]
	10453	[REDACTED]	[REDACTED]	[REDACTED]
	10454	[REDACTED]	[REDACTED]	[REDACTED]
	10455	[REDACTED]	[REDACTED]	[REDACTED]
	10573	[REDACTED]	[REDACTED]	[REDACTED]
	10574	[REDACTED]	[REDACTED]	[REDACTED]
	10575	[REDACTED]	[REDACTED]	[REDACTED]
	11174	[REDACTED]	[REDACTED]	[REDACTED]
	11175	[REDACTED]	[REDACTED]	[REDACTED]
	11353	EG010	00003486	HOFFRICHTER
		[REDACTED]	[REDACTED]	[REDACTED]
	11354	EG010	00003487	HOFFRICHTER
		[REDACTED]	[REDACTED]	[REDACTED]
	11355	EG010	00003488	HOFFRICHTER
		[REDACTED]	[REDACTED]	[REDACTED]
	12254	[REDACTED]	[REDACTED]	[REDACTED]
12255	[REDACTED]	[REDACTED]	[REDACTED]	
12853	[REDACTED]	[REDACTED]	[REDACTED]	
12855	[REDACTED]	[REDACTED]	[REDACTED]	
CPAP Nasal Pillow Mask	13055	[REDACTED]	[REDACTED]	[REDACTED]

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

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Tubing	70243	[REDACTED]	[REDACTED]	[REDACTED]
	70253	[REDACTED]	[REDACTED]	[REDACTED]
	70241	[REDACTED]	[REDACTED]	[REDACTED]
	70242	[REDACTED]	[REDACTED]	[REDACTED]
	70246	[REDACTED]	[REDACTED]	[REDACTED]
	70247	[REDACTED]	[REDACTED]	[REDACTED]
	70262	[REDACTED]	[REDACTED]	[REDACTED]
Headgear-Class I	10200-023	[REDACTED]	[REDACTED]	[REDACTED]
	10200-043	[REDACTED]	[REDACTED]	[REDACTED]
	10229	[REDACTED]	[REDACTED]	[REDACTED]
	20001	[REDACTED]	[REDACTED]	[REDACTED]
Connector	70056	[REDACTED]	[REDACTED]	[REDACTED]
Pressure Meter	10201-001	[REDACTED]	[REDACTED]	[REDACTED]

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	NA	Hsiner
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		EG010	00003551		Hoffrichter
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	11350	NA	NA	NA	Hsiner
		A [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		EG010	00003552		Hoffrichter
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	11351	NA	NA	NA	Hsiner
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		EG010	00003498		HOFFRICHTER
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	11352	NA	NA	NA	Hsiner
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		EG010	11352		Hoffrichter
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]	

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	N/A	████	████	████
	N/A	████	████	████
	11573	NA	NA	Hsiner
	11574	NA	NA	Hsiner
	11575	NA	NA	Hsiner
	12353	NA	NA	Hsiner
	12354	NA	NA	Hsiner
	12355	NA	NA	Hsiner
	13153	NA	NA	Hsiner
	13154	NA	NA	Hsiner
	13155	NA	NA	Hsiner
		NA	NA	Hsiner
	13451	████	████	████
		████	████	████
		████	████	████
	13452	NA	NA	Hsiner
		████	████	████
		████	████	████
	13453	NA	NA	Hsiner
		████	████	████
		████	████	████
	13454	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
	14153	NA	NA	Hsiner
	14154	NA	NA	Hsiner
	14155	NA	NA	Hsiner

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
	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
	14453	NA	NA	Hsiner
	14454	NA	NA	Hsiner
	14455	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	Hsiner
	11255	NA	NA	Hsiner
	NA	████	██████████	████
	NA	████	██████████	████
	NA	████	██████████	████
	NA	████	██████████	████
	NA	EG010	00003499	Hsiner
High Flow Nasal Cannula	14952	NA	NA	Hsiner

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
		█	█	█
	14953	NA	NA	Hsiner
		█	█	█
	14954	NA	NA	Hsiner
		█	█	█
	14955	NA	NA	Hsiner
		█	█	█

Product Section	Product Type	Internal control Code	Customer Product No.	Brand	
VPAP Nasal Mask	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	
	N/A				
	N/A				
	11401	NA	NA	NA	Hsiner
	NA				
	11402	NA	NA	NA	Hsiner
	NA				
	11403	NA	NA	NA	Hsiner
	12201	NA	NA	NA	Hsiner
	12202	NA	NA	NA	Hsiner
	12203	NA	NA	NA	Hsiner
	12401	NA	NA	NA	Hsiner
	12402	NA	NA	NA	Hsiner
	12403	NA	NA	NA	Hsiner
	12601	NA	NA	NA	Hsiner
	12602	NA	NA	NA	Hsiner
	12603	NA	NA	NA	Hsiner
	12701	NA	NA	NA	Hsiner
	12702	NA	NA	NA	Hsiner
	12703	NA	NA	NA	Hsiner
	13401	NA	NA	NA	Hsiner
	13402	NA	NA	NA	Hsiner
	13403	NA	NA	NA	Hsiner

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
		████	████	████
		████	████	██████████
		████	████	██████████
	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	[REDACTED]	[REDACTED]	[REDACTED]
Headgear-Class I	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	[REDACTED]	[REDACTED]	[REDACTED]
	C10200-007	[REDACTED]	[REDACTED]	[REDACTED]
	C10200-010	EG010	3456	HOFFRICHTER
	C10200-043	[REDACTED]	[REDACTED]	[REDACTED]
	A10200-045	[REDACTED]	[REDACTED]	[REDACTED]
	A10200-049	[REDACTED]	[REDACTED]	[REDACTED]
	10200-051	EG010	3557	HOFFRICHTER
	10229	[REDACTED]	[REDACTED]	[REDACTED]
	20001	[REDACTED]	[REDACTED]	[REDACTED]
	N/A	EG010	3514	HOFFRICHTER
	N/A	EG010	3521	HOFFRICHTER
	N/A	EG010	3523	HOFFRICHTER
	N/A	EG010	3544	HOFFRICHTER
N/A	[REDACTED]	[REDACTED]	[REDACTED]	
N/A	[REDACTED]	[REDACTED]	[REDACTED]	
Connector	N/A	[REDACTED]	[REDACTED]	[REDACTED]
Silicone cushion-Class I	B11153-001	NA	NA	Hsiner
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	B11154-001	NA	NA	Hsiner
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	B11155-001	NA	NA	Hsiner
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	B11252-001	NA	NA	Hsiner
	B11253-001	NA	NA	Hsiner
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
	B11254-001	NA	NA	Hsiner
B11255-001	NA	NA	Hsiner	
B11255-003	NA	NA	Hsiner	
B11349-001	NA	NA	Hsiner	

Product Section	Product Type	Internal control code	Customer Product No.	Brand
		████	████████	████
	B11350-001	EG010	3555	HOFFRICHTER
		████	████████	████
	B11351-001	NA	NA	Hsiner
		EG010	3519	HOFFRICHTER
		████	████████	████
	B11352-001	NA	NA	Hsiner
		EG010	3518	HOFFRICHTER
		████	████████	████
	B11353-001	NA	NA	Hsiner
	B11354-001	NA	NA	Hsiner
		████	████████	████
		EG010	3509	HOFFRICHTER
	B11355-001	NA	NA	Hsiner
		EG010	3510	HOFFRICHTER
	B10353-001	NA	NA	Hsiner
		████	████████	████
	B10353-501	NA	NA	Hsiner
		████	████████	████
	B10354-001	NA	NA	Hsiner
		████	████████	████
	B10354-501	NA	NA	Hsiner
		████	████████	████
	B10355-001	NA	NA	Hsiner
	B13753-001	NA	NA	Hsiner
	B13754-001	NA	NA	Hsiner
	B13755-001	NA	NA	Hsiner
	N/A	████	████████	████
	N/A	████	████████	████
	N/A	████	████████	████
	N/A	████	████████	████
	N/A	EG010	3508	HOFFRICHTER
	N/A	EG010	3554	HOFFRICHTER
	N/A	EG010	3555	HOFFRICHTER
Buckle-Class I	N/A	████	████████	████
	N/A	████	████████	████
	N/A	████	████████	████

Document title		Declaration of conformity	
Version	Date	Revision History	Review by
1	2019.01.31	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
1.7	2022.09.30	Add new brand of customer	Helen Cheng