

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Manufacturers SRN: TW-MF-000007258

Basic UDI-DI: 47126880500007258OTASV

Medical Group: Oxygen Therapy and Accessories

Medical Device: Oxygen Mask, Humidifier Bottle, Nasal Cannula, Oxygen Tubing,

Diluter, Adjustable diluter, Oxygen adaptor, Swivel oxygen connector, Recovery kit, Oxygen Enrich kit

Item Code: As attachment

Classification: IIa

CE
2460

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 Product Assurance AS (notify body number – 2460)

Valid until: November, 12 2023

The confirmation letter reference number: 627580 covered by the formal MDR application have been received, the written agreement concluded

Extension date: December 31, 2028

EU Rep: mdi Europa

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

EU Representative SRN: DE-AR-000006218

The following standards are applied for all devices:

EN ISO 20417:2021, EN ISO 13485:2016+AC:2018+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 10993-1:2020, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 10993-5:2009, EN 62366-1:2015+AC:2015+A1:2020, EN 15986:2011, EN ISO 20789:2019, EN 13544-2 2002+A1 2009, EN 13544-3 2001+prA1 2009, EN ISO 5356-1:2015

Taichung, Dec 12th , 2023

Place / Date


VP of Sales and Marketing

Attachment of DoC

Device Complete List

Product Section	Product Type	Internal Control Code	Customer Product No.	Brand
Oxygen Mask	30120	N/A	N/A	Hsiner
	30121	N/A	N/A	Hsiner
	30122	N/A	N/A	Hsiner
	30123	N/A	N/A	Hsiner
	30124	N/A	N/A	Hsiner
	30125	N/A	N/A	Hsiner
	30130	N/A	N/A	Hsiner
	30131	N/A	N/A	Hsiner
	30132	N/A	N/A	Hsiner
	30133	N/A	N/A	Hsiner
	30134	N/A	N/A	Hsiner
	30135	N/A	N/A	Hsiner
	30581	N/A	N/A	Hsiner
	30591	N/A	N/A	Hsiner
	30144	N/A	N/A	Hsiner
	30145	N/A	N/A	Hsiner
	30146	N/A	N/A	Hsiner
	30147	N/A	N/A	Hsiner
	30154	N/A	N/A	Hsiner
	30155	N/A	N/A	Hsiner
	30156	N/A	N/A	Hsiner
	30157	N/A	N/A	Hsiner
	30162	N/A	N/A	Hsiner
	30163	N/A	N/A	Hsiner
	30164	N/A	N/A	Hsiner
	30165	N/A	N/A	Hsiner
	30166	N/A	N/A	Hsiner
	30167	N/A	N/A	Hsiner
	30180	N/A	N/A	Hsiner
	30181	N/A	N/A	Hsiner
	30190	N/A	N/A	Hsiner
	30191	N/A	N/A	Hsiner

Device Complete List (Accessories)

Product Section	Product Type	Internal Control Code	Customer Product No.	Brand
Humidifier Bottle	70529	N/A	N/A	Hsiner
	70523	N/A	N/A	Hsiner
	70558	N/A	N/A	Hsiner
Nasal Cannula	30202	N/A	N/A	Hsiner
	30203	N/A	N/A	Hsiner
	30302	N/A	N/A	Hsiner
	30303	N/A	N/A	Hsiner
	30204	N/A	N/A	Hsiner
	30304	N/A	N/A	Hsiner
	14952	N/A	N/A	Hsiner
	14953	N/A	N/A	Hsiner
	14954	N/A	N/A	Hsiner
Oxygen Tubing	14955	N/A	N/A	Hsiner
	30200	N/A	N/A	Hsiner
	30300	N/A	N/A	Hsiner
	30245	N/A	N/A	Hsiner
	30345	N/A	N/A	Hsiner
	30201	N/A	N/A	Hsiner
Diluter	30301	N/A	N/A	Hsiner
	30001	N/A	N/A	Hsiner
	30002	N/A	N/A	Hsiner
	30003	N/A	N/A	Hsiner
	30004	N/A	N/A	Hsiner
	30005	N/A	N/A	Hsiner
	30006	N/A	N/A	Hsiner
Adjustable Diluter	30007	N/A	N/A	Hsiner
	30020	N/A	N/A	Hsiner
Adaptor	30018	N/A	N/A	Hsiner
	70083	N/A	N/A	Hsiner
Connector	30038	N/A	N/A	Hsiner
	70181	N/A	N/A	Hsiner

Appendix I

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

Device Complete List

Product Section	Product Type	Internal Control Code	Customer Product No.	Brand
Oxygen Mask	30122			
	30123			
	30124			
	30125			
	30134			
	30135			
	30154			
	30164			

Accessories

Product Section	Product Type	Internal Control Code	Customer Product No.	Brand
Humidifier Bottle	70523			
	70529			
	70558			
Nasal Cannula	30202			
	30203			
	30204			
Oxygen Tubing	30245			
	30300			
Adaptor	30018			
	70083			

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
Oxygen Mask	30127	N/A	N/A	Hsiner
	30128	N/A	N/A	Hsiner
	30583	N/A	N/A	Hsiner
	30585	N/A	N/A	Hsiner
	30593	N/A	N/A	Hsiner
	30595	N/A	N/A	Hsiner
	30584	N/A	N/A	Hsiner
	30594	N/A	N/A	Hsiner
	30586	N/A	N/A	Hsiner
	30596	N/A	N/A	Hsiner
High Flow Nasal Cannula	14952	NA	NA	Hsiner
	14953	NA	NA	Hsiner
	14954	NA	NA	Hsiner
	14955	NA	NA	Hsiner

Accessories

Product Section	Product Type	Internal Control Code	Customer Product No.	Brand
Nasal Cannula	14932	N/A	N/A	Hsiner
	14933	N/A	N/A	Hsiner
	14934	N/A	N/A	Hsiner
	14935	N/A	N/A	Hsiner

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	2019.08.21	Add REF codes	Phoebe Lu
1.4	2020.07.31	Update regulation	Phoebe Lu
1.5	2021.01.15	Add Product Specification	Phoebe Lu
1.6	2022.09.30	Add new brand of customer	Helen Cheng
1.7	2023.10.19	Add SRN, Basic UDI-DI, and amend list for MDR transition period	David Lin
1.8	2023.10.18	amend list for MDR transition period	David Lin
1.9	2023.11.16	Update standard and name of NB	David Lin
2.0	2023.12.12	Correct customer product code in Appendix	David Lin