

# DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Manufacturers SRN: TW-MF-000007258

Basic UDI-DI: 47126880500007258ABCSSGG

Medical Group: Anesthesia and breathing circuit system and accessories (Single use)

Medical Device: Anesthesia/Breathing Circuit System, Air cushion mask, PVC mask, Catheter

Mount, Rebreathing Bag, Tubing, APL valve, Connector, One-way valve, Manifold, CO2 Sampling Line

Item Code: As Attachment

Classification: Ila



*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 15986:2011, EN 62366-1:2015+AC:2015+A1:2020, EN ISO 80369-7:2017, EN ISO 5367:2023, EN ISO 5362:2019, EN ISO 5356-1:2015

Taichung, Nov 16th, 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
Anesthesia/Breathing Circuit System	70103	N/A	N/A	Hsiner
	70104	N/A	N/A	Hsiner
	70105	N/A	N/A	Hsiner
	70106	N/A	N/A	Hsiner
	70114	N/A	N/A	Hsiner
	70115	N/A	N/A	Hsiner
	70116	N/A	N/A	Hsiner
	70121	N/A	N/A	Hsiner
	70120	N/A	N/A	Hsiner
	70390	N/A	N/A	Hsiner
	70184	N/A	N/A	Hsiner
	70127	N/A	N/A	Hsiner
	70129	N/A	N/A	Hsiner
	70126	N/A	N/A	Hsiner
	70128	N/A	N/A	Hsiner
	70185	N/A	N/A	Hsiner
	70142	N/A	N/A	Hsiner
	70143	N/A	N/A	Hsiner
	70144	N/A	N/A	Hsiner
	70145	N/A	N/A	Hsiner
	70146	N/A	N/A	Hsiner
	70147	N/A	N/A	Hsiner
	70151	N/A	N/A	Hsiner
	70154	N/A	N/A	Hsiner
	70156	N/A	N/A	Hsiner
	70170	N/A	N/A	Hsiner
	70186	N/A	N/A	Hsiner
	70187	N/A	N/A	Hsiner
	70183	N/A	N/A	Hsiner
	70122	N/A	N/A	Hsiner
70123	N/A	N/A	Hsiner	

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	70124	N/A	N/A	Hsiner
	70125	N/A	N/A	Hsiner
	70159	N/A	N/A	Hsiner

**Device Complete List (Accessories)**

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Air cushion mask	20116	N/A	N/A	Hsiner
	20117	N/A	N/A	Hsiner
	20118	N/A	N/A	Hsiner
	20119	N/A	N/A	Hsiner
	20120	N/A	N/A	Hsiner
	20121	N/A	N/A	Hsiner
	20122	N/A	N/A	Hsiner
	20149	N/A	N/A	Hsiner
	20150	N/A	N/A	Hsiner
	20151	N/A	N/A	Hsiner
	20152	N/A	N/A	Hsiner
	20153	N/A	N/A	Hsiner
	20154	N/A	N/A	Hsiner
	20155	N/A	N/A	Hsiner
	20156	N/A	N/A	Hsiner
	20190	N/A	N/A	Hsiner
	20191	N/A	N/A	Hsiner
	20192	N/A	N/A	Hsiner
	20193	N/A	N/A	Hsiner
	20194	N/A	N/A	Hsiner
	20195	N/A	N/A	Hsiner
	20196	N/A	N/A	Hsiner
	20250	N/A	N/A	Hsiner
	20251	N/A	N/A	Hsiner
	20252	N/A	N/A	Hsiner
	20253	N/A	N/A	Hsiner
	20254	N/A	N/A	Hsiner
	20255	N/A	N/A	Hsiner
	20256	N/A	N/A	Hsiner
	20350	N/A	N/A	Hsiner
	20351	N/A	N/A	Hsiner
	20352	N/A	N/A	Hsiner
	20353	N/A	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	20354	N/A	N/A	Hsiner
	20355	N/A	N/A	Hsiner
	20356	N/A	N/A	Hsiner
PVC mask	10143	N/A	N/A	Hsiner
	10144	N/A	N/A	Hsiner
	10145	N/A	N/A	Hsiner
Catheter Mount	70130	N/A	N/A	Hsiner
	70131	N/A	N/A	Hsiner
	70132	N/A	N/A	Hsiner
	70133	N/A	N/A	Hsiner
	70134	N/A	N/A	Hsiner
	70135	N/A	N/A	Hsiner
	70136	N/A	N/A	Hsiner
	70137	N/A	N/A	Hsiner
	70138	N/A	N/A	Hsiner
	70139	N/A	N/A	Hsiner
	70334	N/A	N/A	Hsiner
	70335	N/A	N/A	Hsiner
	70336	N/A	N/A	Hsiner
	70338	N/A	N/A	Hsiner
	70339	N/A	N/A	Hsiner
Tubing	70202	N/A	N/A	Hsiner
	70204	N/A	N/A	Hsiner
	70205	N/A	N/A	Hsiner
	70208	N/A	N/A	Hsiner
	70209	N/A	N/A	Hsiner
	70229	N/A	N/A	Hsiner
	70228	N/A	N/A	Hsiner
	70309-006	N/A	N/A	Hsiner
Rebreathing bag	70505	N/A	N/A	Hsiner
	70506	N/A	N/A	Hsiner
	70507	N/A	N/A	Hsiner
	70508	N/A	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Elbow Connector	70000	N/A	N/A	Hsiner
	70001	N/A	N/A	Hsiner
	70003	N/A	N/A	Hsiner
	70005	N/A	N/A	Hsiner
	70006	N/A	N/A	Hsiner
	70007	N/A	N/A	Hsiner
	70008	N/A	N/A	Hsiner
	70009	N/A	N/A	Hsiner
Wye Connector	70010	N/A	N/A	Hsiner
	70011	N/A	N/A	Hsiner
Parallel Connector	70013	N/A	N/A	Hsiner
	70062	N/A	N/A	Hsiner
Connector	70014	N/A	N/A	Hsiner
	70016	N/A	N/A	Hsiner
	70018	N/A	N/A	Hsiner
	70019	N/A	N/A	Hsiner
	70020	N/A	N/A	Hsiner
	70021	N/A	N/A	Hsiner
	70026	N/A	N/A	Hsiner
	70027	N/A	N/A	Hsiner
	70092	N/A	N/A	Hsiner
	70093	N/A	N/A	Hsiner
	70094	N/A	N/A	Hsiner
	70095	N/A	N/A	Hsiner
	70054	N/A	N/A	Hsiner
	70057	N/A	N/A	Hsiner
	70556	N/A	N/A	Hsiner
	30012	N/A	N/A	Hsiner
	30014	N/A	N/A	Hsiner
	70068	N/A	N/A	Hsiner
	70084	N/A	N/A	Hsiner
	70087	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
Anesthesia/Breathing Circuit System	70115	██████	70115	██████
	70146	██████	70146	██████
	70125	██████	70125	██████

**Device Complete List (Accessories)**

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Air cushion mask	20116	██████	20116	██████
		██████	AMVH1	██████
	20117	██████	20117	██████
		██████	AMVH2	██████
	20118	██████	AMVH3	██████
		██████	210112	██████
	20119	██████	AMVH4	██████
		██████	210113	██████
	20120	██████	AMVH5	██████
	20121	██████	AMVH6	██████
		██████	210115	██████
	20122	██████	AMVH7	██████
	20150	██████	HS2046	██████
	20151	██████	20151	██████
		██████	HS2047	██████
	20152	██████	HS2048	██████
		██████	20152	██████
	20153	██████	20153	██████
		██████	HS2049	██████
		██████	20703	██████
		██████	3200003	██████
	20154	██████	HS2050	██████
		██████	20704	██████
		██████	20154	██████
	20155	██████	HS2051	██████
		██████	20705	██████
		██████	20155	██████
		██████	20155	██████
20153 20154	██████	15807	██████	



Product Section	Product Type	Internal control code	Customer Product No.	Brand	
	20155 20001				
	20156	██████	HS20166	██████	
		██████	3200006	██████	
	20250	██████	HS2010	██████	
		██████	322216	██████	
	20251	██████	HS2011	██████	
		██████	322217	██████	
	20252	██████	HS2012	██████	
		██████	322218	██████	
	20253	██████	HS2013	██████	
		██████	322219	██████	
		██████	20253	██████████████	
	20254	██████	HS2014	██████	
		██████	322220	██████	
		██████	20254	██████████████	
	20255	██████	HS2015	██████	
		██████	20255	██████████████	
		██████	20255	██████	
	20256	██████	HS20122	██████	
	20352	██████	322221	██████	
	20353	██████	322222	██████	
		██████	20353	██████████████	
	20354	██████	322223	██████	
		██████	20354	██████████████	
		██████	20354	██████	
	20355	██████	322224	██████	
		██████	20355	██████████████	
		██████	20355	██████	
	Catheter Mount	70339	██████	809009	██████████████
	Tubing	70229	██████	70229	██████
Rebreathing bag	70511	██████	70511	██████	
	70512	██████	70512	██████	
	70507	██████	70507	██████	

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	70508	██████	70508	██████
Connector	70014	██████	808207	██████████
		██████	70014	██████
	70020	██████	70020	██████
	70084	██████	HBAD01-22M-22F-6	██████
		██████	70084	██████

**Appendix II**

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

**Device Complete List**

Product Section	Product Type	Internal control code	Customer Product No.	Brand	
Anesthesia/Breathing Circuit System	70108	N/A	N/A	Hsiner	
	70118	N/A	N/A	Hsiner	
	70149	N/A	N/A	Hsiner	
	70155	N/A	N/A	Hsiner	
	70174	N/A	N/A	Hsiner	
	70125-300	N/A	N/A	N/A	Hsiner
		██████	198850-003000	██████	
	70125-180	N/A	N/A	Hsiner	
		██████	198853-001800	██████	
	N/A	██████	198850-001800	██████	
	N/A	██████	198851-001800	██████	
	N/A	██████	198852-001800	██████	

### Device Complete List (Accessories)

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Air cushion mask	20110	N/A	N/A	Hsiner
		██████	322100	██████
	20111	N/A	N/A	Hsiner
		██████	322101	██████
	20112	N/A	N/A	Hsiner
		██████	322102	██████
	20113	██████	210103	██████
	20114	N/A	N/A	Hsiner
		██████	302214	██████
		██████	210104	██████
	20115	N/A	N/A	Hsiner
		██████	210105	██████
	20140	N/A	N/A	Hsiner
	20141	N/A	N/A	Hsiner
	20142	N/A	N/A	Hsiner
		██████	20142	██████
	20143	N/A	N/A	Hsiner
		██████	20143	██████
	20144	N/A	N/A	Hsiner
		██████	20144	██████
	20145	N/A	N/A	Hsiner
		██████	20145	██████
	20146	N/A	N/A	Hsiner
	20160	N/A	N/A	Hsiner
		██████	20160	██████
	20161	N/A	N/A	Hsiner
		██████	20161	██████
	20162	N/A	N/A	Hsiner
		██████	20162	██████
		██████	322212	██████
20163	N/A	N/A	Hsiner	
	██████	20163	██████	

Product Section	Product Type	Internal control code	Customer Product No.	Brand
		██████	322213	██████
	20164	N/A	N/A	Hsiner
		██████	20164	██████
		██████	322214	██████
	20165	N/A	N/A	Hsiner
		██████	20165	██████
		██████	322215	██████
	20166	N/A	N/A	Hsiner
		██████	20166	██████
	20173	N/A	N/A	Hsiner
N/A	██████	15807	██████████	
Catheter Mount	N/A	██████	70136	██████
Elbow connector	70009	N/A	N/A	Hsiner
Tubing	30300-051	N/A	N/A	Hsiner
Connector	70059	N/A	N/A	Hsiner
	70522	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	2019.09.06	Add item	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	2023.08.04	Add SRN and Basic UDI-DI	Selina Wang
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