

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

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: 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 AS (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse 71, 30855 Langenhagen, Germany

The following standards are applied for all devices:

EN 1041:2008, EN ISO 14971:2019, EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 15986:2011, EN ISO 13485:2016, EN 62366:2008, EN ISO 80369-7:2017, EN ISO 5367:2014, EN ISO 5362:2006, 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
Anesthesia/Breathing System	Circuit	70100	N/A	Hsiner
		70101	N/A	Hsiner
		70102	N/A	Hsiner
		70103	N/A	Hsiner
		70104	N/A	Hsiner
		70105	N/A	Hsiner
		70106	N/A	Hsiner
		70110	N/A	Hsiner
		70111	N/A	Hsiner
		70112	N/A	Hsiner
		70113	N/A	Hsiner
		70114	N/A	Hsiner
		70115	N/A	Hsiner
		70116	N/A	Hsiner
		70121	N/A	Hsiner
		70120	N/A	Hsiner
		70390	N/A	Hsiner
		70184	N/A	Hsiner
		70127	N/A	Hsiner
		70129	N/A	Hsiner
		70126	N/A	Hsiner
		70128	N/A	Hsiner
		70185	N/A	Hsiner
		70142	N/A	Hsiner
		70143	N/A	Hsiner
		70144	N/A	Hsiner
		70145	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	70146	N/A	N/A	Hsiner
	70147	N/A	N/A	Hsiner
	70150	N/A	N/A	Hsiner
	70151	N/A	N/A	Hsiner
	70152	N/A	N/A	Hsiner
	70154	N/A	N/A	Hsiner
	70156	N/A	N/A	Hsiner
	70170	N/A	N/A	Hsiner
	70171	N/A	N/A	Hsiner
	70172	N/A	N/A	Hsiner
	70186	N/A	N/A	Hsiner
	70187	N/A	N/A	Hsiner
	70188	N/A	N/A	Hsiner
	70189	N/A	N/A	Hsiner
	70183	N/A	N/A	Hsiner
	70122	N/A	N/A	Hsiner
	70123	N/A	N/A	Hsiner
	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	70509	N/A	N/A	Hsiner
	70510	N/A	N/A	Hsiner
	70511	N/A	N/A	Hsiner
	70512	N/A	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	70505	N/A	N/A	Hsiner
	70506	N/A	N/A	Hsiner
	70507	N/A	N/A	Hsiner
	70508	N/A	N/A	Hsiner
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
	70022	N/A	N/A	Hsiner
	70023	N/A	N/A	Hsiner
	70024	N/A	N/A	Hsiner
	70025	N/A	N/A	Hsiner
	70026	N/A	N/A	Hsiner
	70027	N/A	N/A	Hsiner
	70078	N/A	N/A	Hsiner
	70092	N/A	N/A	Hsiner
	70093	N/A	N/A	Hsiner
	70094	N/A	N/A	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	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
	70058	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 System	Circuit	70115	LD001	70115	Hsiner
		70146	LD001	70146	Hsiner

Device Complete List (Accessories)

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Air cushion mask	20116	ED001	20116	Hsiner
		████	████	████
	20117	ED001	20117	Hsiner
		████	████	████
	20118	████	████	████
		████	████	████
	20119	████	████	████
		████	████	████
	20120	████	████	████
	20121	████	████	████
		████	████	████
	20122	████	████	████
	20150	████	████	████
		████	████	████
	20151	AU025	20151	Hsiner
		████	████	████
		████	████	████
	20152	████	████	████
		████	████	████
		████	████	████
	20153	AU025	20153	Hsiner
		████	████	████
		████	████	████
		████	████	████
		EP001	3200003	Hsiner
	20154	████	████	████
		████	████	████
		████	████	████
		LD001	20154	Hsiner
	20155	████	████	████
		████	████	████
		████	████	████
		AU025	20155	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
		LD001	20155	Hsiner
	20156	████	████	████
		████	████████	████
		EP001	3200006	Hsiner
	20194	AK014	20194	Hsiner
	20250	████	████	████
		████	████	████
	20251	████	████	████
		████	████	████
	20252	████	████	████
		████	████	████
	20253	████	████	████
		████	████	████
		████	████	████████
	20254	████	████	████
		████	████	████
		████	████	████████
	20255	████	████	████
		████	████	████████
	20256	████	████	████
	20352	████	████	████
	20353	████	████	████
		████	████	████████
	20354	████	████	████
		████	████	████████
	20355	████	████	████
		████	████	████████
Catheter Mount	70130	AK015	70130	Hsiner
	70138	AK015	70138	Hsiner
	70338	AK015	70338	Hsiner
	70339	████	████	████
Tubing	70229	EO001	70229	Hsiner
	70512	LD001	70512	Hsiner

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Rebreathing bag	70507	ED001	70507	Hsiner
	70508	LD001	70508	Hsiner
Connector	70014	██████	██████	██████
		EC201	70014	Hsiner

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 System	70108	N/A	N/A	Hsiner
	70118	N/A	N/A	Hsiner
	N/A	EC003	70121-1.8PVC	Hsiner
	70155	N/A	N/A	Hsiner
	N/A	EC003	70156-1.8PVC	Hsiner
	70174	N/A	N/A	Hsiner
	70149	N/A	N/A	Hsiner
	70125-300	N/A	N/A	Hsiner
		██████	██████████	██████
	70125-180	N/A	N/A	Hsiner
		██████	██████████	██████
	N/A	██████	██████████	██████
	N/A	██████	██████████	██████
	N/A	██████	██████████	██████
	N/A	██████	██████████	██████

Device Complete List (Accessories)

Product Section	Product Type	Internal control code	Customer Product No.	Brand
Air cushion mask	20140	N/A	N/A	Hsiner
		████	████	████
		████	████	████
	20141	N/A	N/A	Hsiner
		████	████	████
		████	████	████
	20142	N/A	N/A	Hsiner
		████	████	████
		████	████	████
		LD001	20142	Hsiner
	20143	N/A	N/A	Hsiner
		████	████	████
		████	████	████
		LD001	20143	Hsiner
	20144	N/A	N/A	Hsiner
		████	████	████
		████	████	████
		LD001	20144	Hsiner
	20145	N/A	N/A	Hsiner
		████	████	████
		████	████	████
		LD001	20145	Hsiner
	20146	N/A	N/A	Hsiner
		████	████	████
		████	████	████
	20173	N/A	N/A	Hsiner
		████	████	████
	20110	N/A	N/A	Hsiner
		████	████	████

Product Section	Product Type	Internal control code	Customer Product No.	Brand
		████	████████	████
	20111	N/A	N/A	Hsiner
		████	████	████
		████	████████	████
	20112	N/A	N/A	Hsiner
		████	████	████
		████	████████	████
		████	████████	████
	20113	N/A	N/A	Hsiner
		████	████	████
		████	████████	████
		████	████████	████
	20114	N/A	N/A	Hsiner
		████	████	████
		████	████████	████
		████	████████	████
	20115	N/A	N/A	Hsiner
		████	████████	████
		████	████████	████
	20160	N/A	N/A	Hsiner
	20161	N/A	N/A	Hsiner
	20162	N/A	N/A	Hsiner
		EC201	20162	Hsiner
		████	████	████
	20163	N/A	N/A	Hsiner
		EC201	20163	Hsiner
		████	████	████
	20164	N/A	N/A	Hsiner
		EC201	20164	Hsiner
		████	████	████
	20165	N/A	N/A	Hsiner
		EC201	20165	Hsiner
		████	████	████

Product Section	Product Type	Internal control code	Customer Product No.	Brand
	20166	N/A	N/A	Hsiner
		EC201	20166	Hsiner
	N/A	██████	██████	██████████
Catheter Mount	N/A	EB004	70136	Hsiner
Elbow connector	70009	N/A	N/A	Hsiner
	N/A	EG009	HBAD03W-22M/15F-22F	HUM
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