

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Manufacturers SRN: TW-MF-000007258

Basic UDI-DI: 47126880500007258ABCSRGE

Medical Group: Anesthesia and breathing circuit system and accessories (reusable)

Medical Device: Anesthesia/Breathing Circuit System, Silicone mask, Catheter Mount,

Rebreathing Bag, Tubing, Connector

Item Code: As Attachment

Classification: Ila


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: C548598 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, Dec 12th, 2023

Place / Date



VP of Sales and Marketing

Attachment of DoC

Product Section	Product Type	Internal Control Code	Customer's Product Code	Brand
Anesthesia/Breathing Circuit System	70320	NA	NA	Hsiner
	70340	NA	NA	Hsiner
Accessories: Silicone Mask	10110	NA	NA	Hsiner
	10111	NA	NA	Hsiner
	10112	NA	NA	Hsiner
	10113	NA	NA	Hsiner
	10114	NA	NA	Hsiner
	10115	NA	NA	Hsiner
Catheter Mount	70140	NA	NA	Hsiner
	70141	NA	NA	Hsiner
	70148	NA	NA	Hsiner
	70342	NA	NA	Hsiner
	70160	NA	NA	Hsiner
Tubing	70162	NA	NA	Hsiner
	70163	NA	NA	Hsiner
	70164	NA	NA	Hsiner
	70165	NA	NA	Hsiner
	70176	NA	NA	Hsiner
	70177	NA	NA	Hsiner
	70178	NA	NA	Hsiner
Rebreathing bag	70501	NA	NA	Hsiner
	70502	NA	NA	Hsiner
	70503	NA	NA	Hsiner
	70504	NA	NA	Hsiner
Wye Connector	70416	NA	NA	Hsiner

Appendix I

Product Section	Product Type	Internal Control Code	Customer's Product Code	Brand
Accessories: Silicone Mask	10110	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
	10111	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
	10112	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
	10113	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
	10114	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
	10115	[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]	[REDACTED]

Appendix II

Product Section	Product Type	Internal Control Code	Customer's Product Code	Brand
Accessories: Silicone Mask	NA	██████	██████	██████████
Straight Connector	70408	NA	NA	Hsiner
Elbow connector	70415	NA	NA	Hsiner

Document title		Declaration of conformity	
Version:	Date	Revision History	Review by
1	2019.1.31	New release	Ariel Huang
1.1	2019.05.30	Update valid date and separate class I device	Phoebe Lu
1.2	2019.06.11	Add standards	Phoebe Lu
1.3	2019.09.06	Re-classification	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
2.0	2023.12.12	Correct customer product code in Appendix	David Lin