

EC Declaration of Conformity

We declare under our sole responsibility that

Manufacturers Name: Hsiner Co., Ltd.
Manufacturers Address: No.312 Jhongshan Rd. Shengang Dist, Taichung City, Taiwan
Manufacturers SRN: TW-MF-000007258

EU Representative Name mdi Europa
EU Representative Address Langenhagener Strasse71, 30855 Langenhagen, Germany
EU Representative SRN: DE-AR-000006218

Basic UDI-DI: 47126880500007258OPASH
Medical Group: Oropharyngeal airway
Name of the Device (s): Berman airway, Guedel airway
Product code: As Attachment
Classification: I
Conformity assessment route: according to annex IV of the Regulation MDR 2017/745

meet the below provision of the Regulation (EU) MDR 2017/745 for medical devices

Conformity assessment procedure: Regulation (EU) MDR 2017/745 annex IV; the manufacturer is fully responsible for the content of declaration of conformity.

The following Harmonized Standards are applied for all devices:

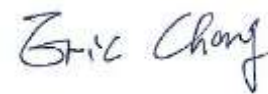
EN ISO 20417:2021, EN ISO 13485:2016+A11:2021, EN ISO 15223-1:2021

The following Non-Harmonized Standards are applied for all devices: EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO10993-5:2009, EN ISO 10993-10:2013, EN ISO 5364:2016, IEC 62366-1:2015+AMD1:2020

The following Common Specification are applied for all devices: N/A

Taichung, March 23rd, 2022

Place / Date



Eric Chang / General Manager

Attachment of DoC

Product Section	Product Type	Internal control Code	Customer Product No.	Brand
Berman airway	50002	N/A	N/A	Hsiner
	50103	N/A	N/A	Hsiner
	50104	N/A	N/A	Hsiner
	50105	N/A	N/A	Hsiner
	50106	N/A	N/A	Hsiner
	50107	N/A	N/A	Hsiner
	50108	N/A	N/A	Hsiner
	50109	N/A	N/A	Hsiner
	50110	N/A	N/A	Hsiner
	50111	N/A	N/A	Hsiner
	50112	N/A	N/A	Hsiner
Guedel airway	50001	N/A	N/A	Hsiner
		██████	██████	██████████
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	50124	N/A	N/A	Hsiner
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	50125	N/A	N/A	Hsiner
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	50126	N/A	N/A	Hsiner
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		██████	██████████	Hsiner
	50127	N/A	N/A	Hsiner
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	50128	N/A	N/A	Hsiner
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	50129	N/A	N/A	Hsiner
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Guedel airway	50130	N/A	N/A	Hsiner
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	50131	N/A	N/A	Hsiner
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	50132	N/A	N/A	Hsiner
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	50142	N/A	N/A	Hsiner
	50143	N/A	N/A	Hsiner
	50144	N/A	N/A	Hsiner
	50145	N/A	N/A	Hsiner
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	50146	N/A	N/A	Hsiner
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	50147	N/A	N/A	Hsiner
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	50148	N/A	N/A	Hsiner
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	50149	N/A	N/A	Hsiner
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	50150	N/A	N/A	Hsiner
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50151	N/A	N/A	Hsiner	
	██████	██████	██████████	
50152	N/A	N/A	Hsiner	
	██████	██████	██████████	

Document title		Declaration of conformity	
Version:	Date	Revision History	Review by
1	2019.05.30	New release	Phoebe Lu
1.1	2019.06.13	Add standard	Phoebe Lu
2	2021.04.09	Revised for MDR requirement	Michelle Hung
2.1	2021.06.15	Add SRN & BUDI-DI	Michelle Hung
2.2	2022.03.23	Correct harmonized standards	Cindy Hsiao