

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: 47126880500007258RPASY
Medical Group: CPAP/VPAP Face Mask and Accessories, CPAP/VPAP Nasal Mask and Accessories, Oxygen Therapy and Accessories, Anesthesia and breathing circuit system and accessories (Single use), Anesthesia and breathing circuit system and accessories (reusable), Resuscitator and Accessories (Single use)
Name of the Device (s): As Attachment
Product code: As Attachment
Classification: I
Conformity assessment route: according to Rule 1, 2, 5 in annex VIII 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 IX, excluding section 4; 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 14971:2019, EN ISO 10993-1:2020, EN ISO10993-5:2009,
EN ISO10993-10:2013, EN ISO 15223-1:2021, EN ISO 13485:2016/AC:2018

The following standards are applied to specific products as below:

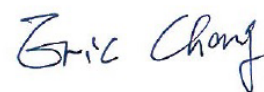
Anesthesia and Breathing Circuit System (single use): EN ISO 5356-1: 2015, Resuscitator and
Accessories (Single use): EN ISO 5356-1:2015

The following Non-Harmonized Standards are applied for all devices: IEC 62366-1:2015/AMD1:2020

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

Taichung, Nov 16, 2021

Place / Date



Eric Chang / General Manager

Attachment of DoC

Medical Group: CPAP/VPAP Face Mask and Accessories

according to Rule 1 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Headgear	C10200-023, C10200-010, A10200-011, A10200-032, C10200-035, C10200-007, C10200-043, A10200-045, A10200-049, C10200-051, 10229, 20001, 20002, 20003, C10200-112, C10200-114	Straps	13809
Silicone cushion	B10343-001,B10344-001, B10345-001, B11144-001, B11339-001, B11340-001, B11341-001, B11342-001	Masks, other	15230

Medical Group: CPAP/VPAP Nasal Mask and Accessories

according to Rule 1 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Headgear	As above	Straps	13809
Silicone cushion	B11352-001,B11351-001, B11353-001,B11354-001, B11355-001,B11349-001, B11252-001,B11253-001, B11254-001, B11255-001, B11255-003, B11153-001, B11154-001, B11155-001, B10353-001,B10354-001, B10355-001, B10353-501, B10354-501, B13753-001, B13754-001, B13755-001, B11350-001	Masks, other	15230

Medical Group: Oxygen Therapy and Accessories

according to Rule 2 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
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Water trap	30037	Ventilator Condensate Traps	18059
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Medical Group: Anesthesia and breathing circuit system and accessories (Single use)

according to Rule 1 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Clip	30016,30017,70524,70073	Fitting/Adapters, Pneumatic, Other	16797
Hook ring	A20115-101	Fitting/Adapters, Pneumatic, Other	16797

according to Rule 2 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Water trap/Bag	70520	Ventilator Condensate Traps	18059

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

according to Rule 1 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Hook	10001	Fitting/Adapters, Pneumatic, Other	16797
Test lung	70513	Simulators, Lung	12408

Medical Group: Resuscitator and Accessories (Single use)

according to Rule 1 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Case for resuscitator kit	X003001	Containers	16767
Adaptor	60100-046	Fitting/Adapters, Pneumatic, Other	16797

according to Rule 2 in annex VIII of the Regulation MDR 2017/745

Product Section	Product Type	UMDNS Description	UMDN Code
Reservoir bag	60001,60003,60004,60006,60058	Collectors	10941

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	2021.08.03	Add SRN & BUDI-DI	Michelle Hung
2.2	2021.11.16	Update Product Type	Phoebe Lu
2.3	2021.11.24	Remove unappropriated REF	Phoebe Lu