Hsiner Co., Ltd.
312 Jhongshan Rd. Shengang Dist, Taichung,
Taiwan 429

HSINER®

DECLARATION OF CONFORMITY

We declare under our sole responsibility that

Medical Group: Oxygen Therapy and Accessories

Medical Device: Oxygen Mask, Humidifier Bottle, Nasal Cannula, Oxygen Tubing

Item Code: As attachment

Classification: IIa

CE
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 GL NEMKO PRESAFE AS (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse71, 30855 Langenhagen, Germany

Taichung, May 27, 2019

Place / Date

Ben Lin

VP of Sales and Marketing

Product Section	Product Reference codes
Humidifier Bottle	70529、70523、70558
Oxygen Mask	30120、30121、30122、30123、30124、30125、30130、30131、30132、30133、30134、30135、30581、30591、30144、30145、30146、30147、30154、30155、30156、30157、30162、30163、30164、30165、30166、30167、30180、30181、30190、30191
Nasal Cannula	30202、30302、30203、30303、30204、30304
Oxygen Tubing	30200、30300、30245、30201、30301

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