

# DECLARATION OF CONFORMITY

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We declare under our sole responsibility that

Medical Group: CPAP/VPAP Face Mask and Accessories

Medical Device: CPAP/VPAP Face Mask and Accessories

Item Code: As Attachment

Classification: Ila

The CE mark consists of two overlapping 'C' shapes, with the number '2460' positioned below them.

*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 A/S (notify body number – 2460)

Valid until: November, 12 2023

EU Rep: mdi Europa

Address: Langenhagener Strasse 71, 30855 Langenhagen, Germany

Taichung, May 24, 2019

*Place / Date*

A handwritten signature in blue ink that reads "Ben Lin".

*Vice General Manager*

**Attachment of DoC**

Product Section	Product Type
CPAP Face Mask	D150F-S, D150F-M, D150F-L
Accessories	70243 、 70263 、 70253 、 70273

Document title		Declaration of conformity	
Version:	Date	Revision History	Review by
1	2019.1.31	New release	Ariel Huang
1.1	2019.05.24	Update valid date and separate class I device	Phoebe Lu