



Foremount Enterprise Co., Ltd.

[www.foremount.com](http://www.foremount.com)

No.17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City, 42944, Taiwan.

Tel: 886-4-25618788, Fax: 886-4-25618798

DOC no.: FM-TCF-C001-C03-D01 Ver.: 07

## EC DECLARATION OF CONFORMITY

**For the following Medical device:**

Disposable CPAP Mask

(Product Group)

NA

(Product Family)

Please see the Attachment A of Page 3.

(Size, Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance of conformity assessment **Annex II-exclusive section 4** to be certified by DNV GL Presafe AS-Veritasveien 3, N-1363 Høvik, Norway (notify body number-2460).

Each kind of medical device to which the system has been applied complies with the applicable provisions of Annex I Essential requirement, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied. We declare that the DOC is issued under our sole responsibility for the product.

For the evaluation regarding the Class IIa product safety aspects, the following standards are applied:

### **Harmonized Standard**

- EN 1041:2008
- EN 62366:2008
- EN ISO 13485:2016
- EN ISO 15223-1:2016
- EN ISO 10993-1:2009/AC:2010
- EN ISO 10993-5:2009
- EN ISO 14971:2012

### **Non-Harmonized Standard**

- ISO 10993-10:2010
- ISO 5356-1:2015
- ISO 14644-1:2015
- ASTM F1980:2016
- ISTA-1A:2014

The following European Authorized Representative is stated to the declaration:

Obelis S.A.

Address: Bd. Général Wahis 53 1030 Brussels, Belgium.

(Company Name/Address)



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The following person is responsible for the compliance of declaration:

Foremount Enterprise Co., Ltd.

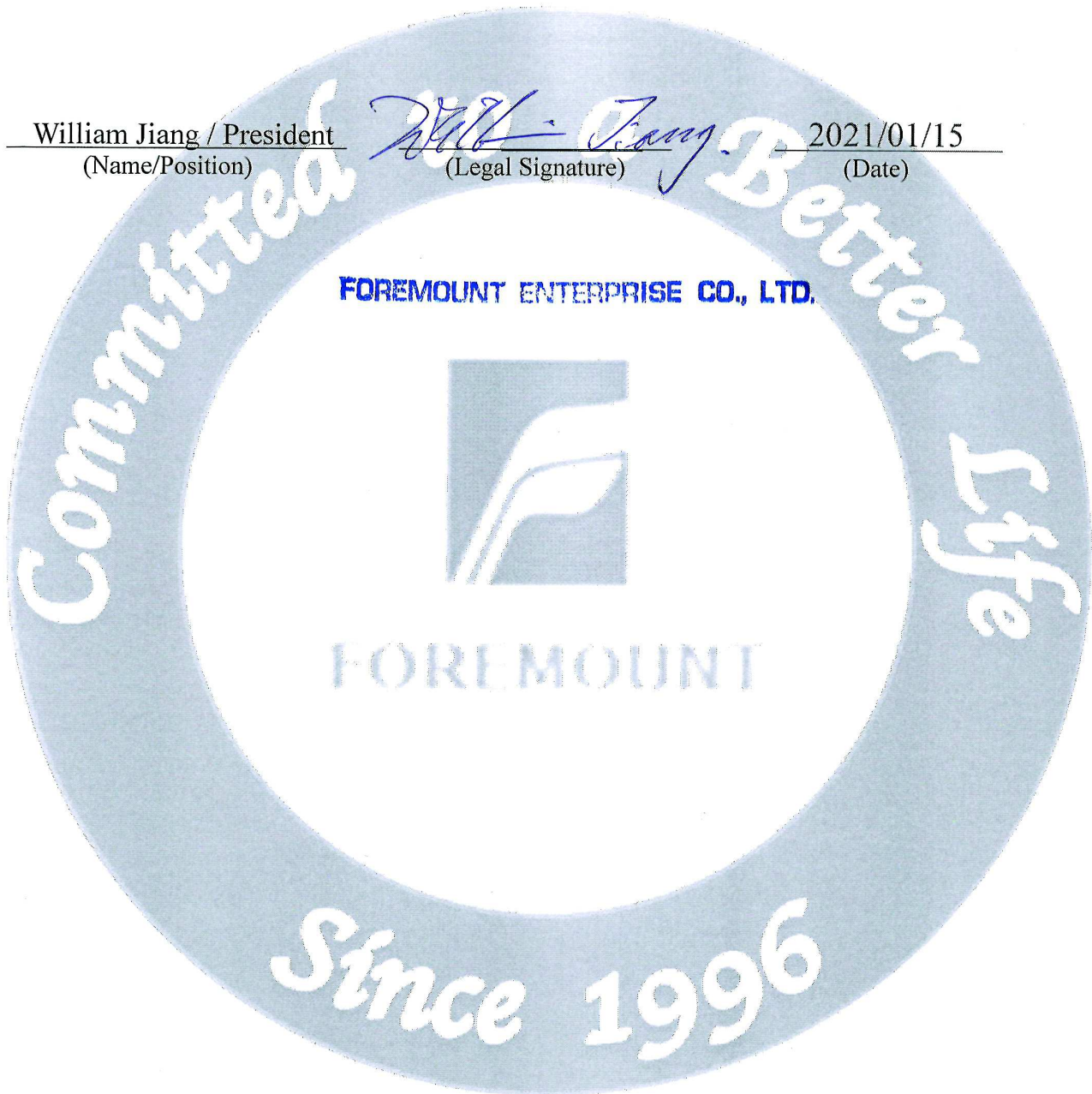
Address: No.17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City, 42944, Taiwan.

(Manufacturer Name/Address)

William Jiang / President  
(Name/Position)

*William Jiang*  
(Legal Signature)

2021/01/15  
(Date)





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Product Group	Product Family	REF	Spec
Disposable CPAP mask	NA	1410103	#3
		1410105	#5
		1410106	#6

Attachment A

