

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
10485-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-15495-2007-PRC-RGC

Valid Until:
27 May 2024

This is to certify that the quality system of:

Foremount Enterprise Co., Ltd.

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

For design, production and final product inspection/testing of:

RESPIRATORY CARE DEVICES

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 23 November 2020

For:
DNV GL PRESAFE AS
Notified Body No.: 2460


Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 86460-2010-CE-RGC-NA Rev. 3.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	25-08-2017
1.0	Change EU Representative	04-12-2019
2.0	Recertification	23 November 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Care Devices	Disposable AirCushion Mask - Classic Cushion Mask I - Classic Cushion Mask II - Rotation Mask Silicone Mask Airway - Berman Airway - Rigid Guedel Airway - Soft Guedel Airway Nasal Airway Bougie / Introducer Oxygen Mask Aerosol Mask High Concentration Oxygen Mask Disposable CPAP Mask Nasal Cannula Breathing Circuit Water trap Pocket Size Resuscitator Manual Resuscitator CPR Face Shield	IIa

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Foremount Enterprise Co., Ltd. - Head office	No. 17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City 42944, Taiwan
Foremount Enterprise Co., Ltd. - Factory	No. 257, Sec. 5, Changping Rd., Shengang Dist., Taichung City 42944, Taiwan

EU Representative

Name	Address
Obelis s.a.	Boulevard Général Wahis 53, 1030 Brussels Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate