EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10560-2017-CE-RGC-NA-PS Rev. 0.0	**PRJC-40617-2007-PRC-RGC**	**31 MARCH 2021**

This is to certify that the quality system of:

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Road., Wu-Ku District, New Taipei City 24888, Taiwan

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

Respiratory Care Products

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) 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, 15 August 2017 Error! Reference source not found.

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Sholeh Gheissar

Sholeh Gheissar

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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Project No.: **PRJC-40617-2007-PRC-RGC**
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Jurisdiction

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

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 71794-2010-CE-RGC-NA 6.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-08-15

Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Care Products	- Bubble Humidifier - Jet Nebulizer Set - Peep Valve - Guedel Airway (Sterile) - Silicone Mask - Silicone Cushion Mask - Disposable Cushion Mask - Silicone Breathing Bag - Fatal Vacuum Cup - Silicone Drainage Tube & Reservoir (Sterile) - Silicone Stomach Tubing (Sterile) - Silicone Mask One Piece - Head Hardness - Laryngeal Airway Mask (Sterile) - Disposable Laryngoscope Set - Water Trap - Nasal Cannula - Hi-Oxygen Mask - Oxygen Mask - Oxygen Tubing - Aerosol Mask - Tracheotomy Mask- Face Tent - Artificial Nose - Venturi Mask - Breathing Circuit	IIa

	- Silicone T Tube (Sterile) - Silicone Penrose Tube (Sterile) - Bacterial Filter - Humidification Chamber - Continous Positive Airway Pressure (CPAP) Mask - Incentive Spirometer - Bag Valve Mask(BVM) - HME Filter (Sterile) - Expiratory Filter Heater and Accessories - Gas Sampling Line - Expiratory Muscle Trainer - Nasal Washer - Peak Flow Meter - Compressor Nebulizer	

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Legal Manufacture Besmed Health Business Corp.	No. 5, Lane 116, Wu-Kong 2nd Road., Wu-Ku District, New Taipei City 24888, Taiwan
Factory Ningbo Besmed Medical Equipment Corp.	No. 51, Mogan Shan Rd., Beilun, Ningbo, 315800, China

EU Representative

Name	Address
Mdi Europa GmbH	Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany

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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