



中華民國文件證明書 **DOCUMENT AUTHENTICATION**

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This public document

2. 簽署人  
has been signed by 蔡宜樺  
Tsai, Yi-Hua

3. 簽署人職務  
acting in the capacity of 民間公證人  
Notary public

4. 用印人／單位  
bears the seal/stamp of 臺北地方法院  
Taipei District Court

茲證明  
Certified

5. 地點  
at 臺北  
Taipei

6. 日期  
the June 05, 2019

7. 由  
by 外交部  
Ministry of Foreign Affairs

8. 案號  
Number 108200019432-002

9. 章戳  
Seal/stamp: 10. 簽署  
Signature:  
Liu, Shih-Chieh  
Secretary, Bureau of Consular Affairs  
For The Minister of Foreign Affairs

*Shih Chieh Liu*

11. 附註：  
remarks:

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G098167





VĂN PHÒNG KINH TẾ - VĂN HÓA VIỆT NAM TẠI ĐÀI BẮC  
VIETNAM ECONOMIC AND CULTURAL OFFICE IN TAIPEI  
CHỨNG NHẬN/HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia:  
*Country* VIỆT NAM  
Vietnam  
Giấy tờ, tài liệu này  
*This public document*
2. do Ông (Bà):  
*has been signed by* Liu, Shih Chieh ký
3. với chức danh:  
*acting in the capacity of* Bí thư, Cục Lãnh sự  
Secretary, Bureau of Consular Affairs
4. và con dấu của:  
*bears the seal/stamp of* Bộ Ngoại giao  
The Ministry of Foreign Affairs  
được chứng nhận/hợp pháp hoá lãnh sự  
*Certified*
5. tại: Đài Bắc  
*at Taipei*
6. ngày: 12/06/2019
7. Cơ quan cấp: Văn phòng Kinh tế - Văn hoá Việt Nam tại Đài Bắc  
*by the Vietnam Economic and Cultural Office in Taipei*
8. Số: 2182/2019  
Nº

TL. Chủ nhiệm Văn phòng / *For the Head of Office*  
Trợ lý Chủ nhiệm / *Assistant Head*

Nguyễn Đức Biên



Great Group Medical Co., Ltd.  
No. 168, Xingong 2<sup>nd</sup> Rd., Tianzhong Township,  
Changhua County 52046, Taiwan

DNV GL BUSINESS ASSURANCE CO., LTD.

29F., No. 293, Sec. 2, Wenhua Rd.,  
Banqiao Dist., New Taipei City, Taiwan,  
R.O.C.

Att. To Whom It May Concern

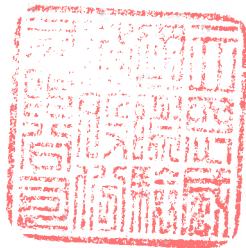
Your ref.:	Our ref.:	Date:	Tel: +886 2 8253 7800
	DNV GL Business Assurance	2018-06-05	Fax: +886 2 8353 7666
	Co., Ltd.HSIEH180605-01		<a href="http://www.dnvba.com.tw">http://www.dnvba.com.tw</a>
			NO 945 748 931 MVA

## Confirmation Letter

This is to confirm that the following certificate is originally issued by DNV GL Norway:

- Company Name:  
Great Group Medical Co., Ltd.
- Site Address:  
No. 168, Xingong 2nd Rd., Tianzhong Township, Changhua County 52046, Taiwan
- Certificate Standard:  
CE/MDD
- Certificate No.:  
9786-2017-CE-RGC-NA-PS
- Product Description:  
Respiratory Care Products
- Product Name: Non-sterile and Sterile HME (Heat and Moisture Exchangers), Non-sterile and Sterile Respiratory Bacteria Filters, Non-sterile Spirometer Filters, Non-sterile and Sterile Breathing Circuits, Connectors & Water Traps, Non-sterile Auto Feed Respiratory Humidifier Chambers, Respiratory Humidifier, Infant Bubble CPAP System with Air/O2 blender, safety valve kit

Yours faithfully



Kim  
Nikolaus



DNV GL Business Assurance Co., Ltd.

President: Kim Nikolaus

DNV GL Headquarters, Veritasveien 1, P.O.Box 300, 1322 Høvik, Norway. Tel: +47 67 57 99 00. [www.dnvgl.com](http://www.dnvgl.com)

2019 per-yuan-ming-jen-Hua-tzu

案號：北院民認樺字 280724 號日期： JUN 04 2019

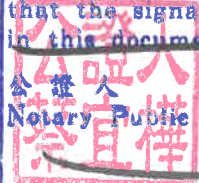
Case No.: 280724 Date: JUN 04 2019

本文件 立恩威國際驗證股份有限公司 之簽名或蓋章，在臺灣  
臺北地方法院所屬民間公證人天正聯合事務所認證。

公證人：蔡宜樺

Attested at The Tian Zheng Notary Public Office,  
Taiwan Taipei District Court, Republic of China,

that the signature(s)/seal(s) of DNV GL Business Assurance Co., Ltd  
in this document is/are authentic



Tsai, Yi H.

事務所地址：台北市信義區基隆路1段163號6樓之3  
(02)2764-6000/emma@taipeinotary.org



# EC Certificate Full Quality Assurance System

CERTIFIED TRUE COPY

Certificate No.:  
9786-2017-CE-RGC-NA-PS

Project No.:  
PRJC-14323-2007-PRC-RGC

Valid until:  
06 September 2021

This is to certify that the quality system of:

**Great Group Medical Co., Ltd.**

**No. 168, Xingong 2<sup>nd</sup> Rd., Tianzhong Township, Changhua County, 52046, 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**

and found to comply.

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



Place and date:  
**Høvik, 27 March 2017**

For:  
**DNV GL NEMKO PRESAFE AS**



*Tone Kolpus*

**Tone Kolpus**  
Certification Manager

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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.



# EC Certificate

## Full Quality Assurance System

Certificate No.:  
9786-2017-CE-RGC-NA-PS

Project No.:  
PRJC-14323-2007-PRC-RGC

Valid until:  
06 September 2021

### 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
	Replace the certificate 94407-2011-CE-RGC-NA 2.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued after scope extension (bold font) certification	27.03.2017

### Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Care Products	- Non-sterile and Sterile HME (Heat and Moisture Exchangers) - Non-sterile and Sterile Respiratory Bacteria Filters - Non-sterile Spirometer Filters - Non-sterile and Sterile Breathing Circuits, Connectors & Water Traps - Non-sterile Auto Feed Respiratory Humidifier Chambers	IIa
	- <b>Respiratory Humidifier</b> - <b>Infant Bubble CPAP System with Air/O2 blender, safety valve kit</b>	IIb

The complete list of devices is filed with the Notified Body

### Sites covered by this certificate

Site Name	Address
Great Group Medical Co., Ltd.	No. 168, Xingong 2 <sup>nd</sup> . Rd., Tianzhong Township, Changhua County, 52046, Taiwan R.O.C.

### EU Representative

Name	Address
Wellkang Ltd.	Suite B, 29 Harley Street, London W1G 9QR, England, United Kingdom





# EC Certificate

## Full Quality Assurance System

Certificate No.:  
9786-2017-CE-RGC-NA-PS

Project No.:  
PRJC-14323-2007-PRC-RGC

Valid until:  
06 September 2021

### 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

10/11/21