EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
9909-2017-CE-RGC-NA-PS Rev. 1.0	**PRJC-268377-2010-PRC-TWN**	**13 November 2022**

This is to certify that the quality system of:

VADI Medical Technology Co., Ltd. Yangmei
No. 198, Lane 298, Huandong Rd., Zhongshan Village, Yangmei Dist., Taoyuan City 32665, Taiwan

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

Emergency Medical Care Devices

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, 26 January 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Villy Rønneberg

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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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	Original Certificate	2017-11-13
1.0	Changed company name and address	2018-01-26

Products covered by this Certificate:

Product Description	Product Name	Class
Emergency Medical Care Devices		
(A) Manual Resuscitator Set	A01. Silicone resuscitators / Ventilation set A02. Disposable manual resuscitators / Ventilation A03. Pocket Size Resuscitator A04. Tracheal Mask A05. Air-cushion masks A06. Silicon masks A07. Jaw spreader (Teeth Screw Driver) A08. Air way A09. Guedel Code Air Way A10. Compact Storage Case A11. Wall Mount Holder For Manual Resuscitator A12. Hose Retaining Clip A13. Oxygen masks-medium concentration A14. Oxygen Nipple Connector Green Color A15. Oxygen Tube Connector A16. Test Lung	IIa
(B) Nebulizer	B01. Nebulizer kits B02. Disposable Mouth piece B03. Disposable Large Volume Nebulizer Bottle	IIa

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(C) Breathing Circuit	C01. Disposable Ventilator Circuit Tube C02. Reusable Ventilator Circuit Tube C03. Water Trap C04. Disposable Pressure Cap C05. Straight Connector C06. Anesthesia Circuit C07. Swivel Flex Tube	IIa
(D) HME / Bacterial Filters	D01. Bacteria HME/ Filter	IIa
(E) Expiratory Bacteria Filter Heater	E01. Bacteria Filter Heater	IIa
(F) Respiratory Humidifier	F01. Respiratory Humidifier F02. Humidifier Chamber F03. Disposable Humidifier Bottle	IIb IIa IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Vadi Medical Technology Co., Ltd. **Yangmei**	No. 198, Lane. 298, Huandong Rd.,Yangmei Dist., Taoyuan City 32665, Taiwan

EU Representative

Name	Address
Obelis S.A.	Bd 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