DNV·GL

# EC CERTIFICATE

## Full Quality Assurance System

| Certificate No.: | Project No.: | Valid Until: |
|---|---|---|
| 10000349226-PA-NA-TWN | PRJC-77155-2008-PRC-TWN | 27 May 2024 |

This is to certify that the quality system of:

## Da Chung Medical Co., Ltd

No. 600, Sec. 1, Dong Shan Rd., Dong Shan Township, Yilan County, 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.

Digitally signed by Jighili Tatiana
Date: 2024.12.23 14:50:09 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Place and date:
**Høvik, 06 March 2020**

NORWEGIAN ACCREDITATION
**PROD 021**

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

**Palani Damodharan**

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

Certificate No.:
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27 May 2024

**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 | Initial Certification | 06-03-2020 |

Products covered by this Certificate:

| Product Description | Product Name | Class |
|---|---|---|
| Respiratory Care Devices | - Oxygen Mask Kit and Accessories<br>- Bubble Humidifier<br>- Nebulizer Mask Kit and Accessories<br>- Heated-Wire Circuit Kit and Accessories<br>- CPAP Mask Kit and Accessories<br>- NIV Mask Kit and Accessories | IIa |

The complete list of devices is filed with the Notified Body

**Sites covered by this certificate**

| Site Name | Address |
|---|---|
| Da Chung Medical Co., Ltd<br>- Dong Shan | No. 600, Sec. 1, Dong Shan Rd.,<br>Dong Shan Township, Yilan county, Taiwan |
| Da Chung Medical Co., Ltd<br>- Lung Te | No. 44, Te-Xing 6th Rd., Lung-Te Industrial Park,<br>Dong Shan Township, Yilan county, Taiwan |

**EU Representative**

| Name | Address |
|---|---|
| Obelis s.a. | Bd. Général Wahis, 53, 1030 Brussels<br>Belgium |

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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

# APPENDIX TO EC CERTIFICATE

Certificate no.:
10000349226-PA-NA-TWN Rev.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
**Da Chung Medical Co., Ltd.**

originally issued in compliance with:
**the Council Directive 93/42/EEC on Medical Devices, as amended**

There are no changes to the certification to MDD, the basis for the certification nor the activities performed to maintain the certification.
The Accreditation with Norwegian Accreditation will cease from 01 Jan. 2022 and the accreditation mark has no validity.

| Appendix History - | | |
|---|---|---|
| **Revision** | **Description** | **Issued Date** |
| 0 | Admin change: removal of Norwegian accreditation | 16 December 2021 |

Place and date:
**Høvik, 16 December 2021**

For the issuing office:
**DNV Product Assurance AS - Notified Body 2460**
**Veritasveien 3, 1363 Høvik, Norway**

**Eren Pehlivan**
Senior Engineer