EC CERTIFICATE

Number: 6092261CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:

Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road,
Wu-Ku District, New Taipei City
Taiwan

For the product category(ies)

Respiratory Care Products

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them:

0344

Documents, that form the basis of this certificate:

Certification Notice 6092261CN, initially dated 25 December 2020
Addendum, initially dated 25 December 2020

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 26 May 2024
Issued for the first time: 25 December 2020
Reissued: 22 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-product-safety.com Company registration 09085396

ADDENDUM

Belonging to certificate: 6092261CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Respiratory Care Products

Issued to:

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

This certificate covers the following product(s):

- Bubble Humidifier
- Jet Nebulizer Set
- Peep Valve
- Guedel Airway (sterile)
- Silicone Mask
- Disposable Cushion Mask
- Silicone Breathing Bag
- Silicone Drainage Tube & Reservoir (sterile)
- Silicone Stomach Tubing (sterile)
- Laryngeal Airway Mask (sterile)
- Disposable Laryngoscope Set
- Nasal Cannula
- Hi-Oxygen Mask
- Oxygen Mask
- Oxygen Tubing
- Aerosol Mask
- Tracheotomy Mask

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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Certification Manager

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CE MARKING OF CONFORMITY
MEDICAL DEVICES

Respiratory Care Products

Issued to:

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

This certificate covers the following product(s):

- Venturi Mask
- Breathing Circuit
- Silicone Penrose Tube (sterile)
- Bacterial Filter
- Humidification Chamber
- CPAP Mask
- Incentive Spirometer
- HME Filter (sterile)
- Gas Sampling Line
- Peak Flow Meter

Initial date: 25 December 2020
Revision date: 22 May 2021

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

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