

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

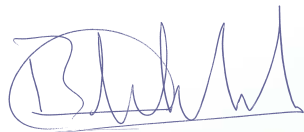
Documents, that form the basis of this certificate:

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

1/2

CE MARKING OF CONFORMITY MEDICAL DEVICES

Respiratory Care Products

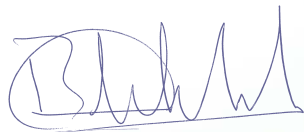
Issued to:

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.

A blue ink signature of B.T.M. Holtus, consisting of stylized, overlapping loops and lines.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, featuring a large, flowing 'J' and 'V'.

J.A. van Vugt
Certification Manager

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ADDENDUM

Belonging to certificate: 6092261CE01

2/2

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

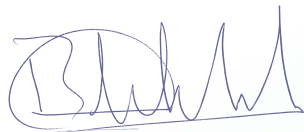
This certificate covers the following product(s):

- 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.

A blue ink signature of B.T.M. Holtus, consisting of stylized initials and a surname.

B.T.M. Holtus
Managing Director

A blue ink signature of J.A. van Vugt, consisting of stylized initials and a surname.

J.A. van Vugt
Certification Manager

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

Your ref.
Our ref. MED/23-7409383
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 14 May 2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (dated 30 April 2020) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Besmed Health Business Corp.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District
New Taipei City 24888
Taiwan
SRN Number: TW-MF-000007246

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2

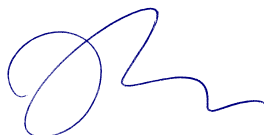
identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Xiaoli Ren
Project Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Bubble Humidifier	Class IIa	N/A	Certificate #6092261CE01; NB0344
Jet Nebulizer Set	Class IIa	N/A	Certificate #6092261CE01; NB0344
Peep Valve	Class IIa	N/A	Certificate #6092261CE01; NB0344
Guedel Airway (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Silicone Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Disposable Cushion Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Silicone Breathing Bag	Class IIa	N/A	Certificate #6092261CE01; NB0344
Silicone Drainage Tube & Reservoir (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Silicone Stomach Tubing (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Laryngeal Airway Mask (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Disposable Laryngoscope Set	Class IIa	N/A	Certificate #6092261CE01; NB0344
Nasal Cannula	Class IIa	N/A	Certificate #6092261CE01; NB0344
Hi-Oxygen Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Oxygen Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Oxygen Tubing	Class IIa	N/A	Certificate #6092261CE01; NB0344

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aerosol Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Tracheotomy Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Venturi Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Breathing Circuit	Class IIa	N/A	Certificate #6092261CE01; NB0344
Silicone Penrose Tube (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Bacterial Filter	Class IIa	N/A	Certificate #6092261CE01; NB0344
Humidification Chamber	Class IIa	N/A	Certificate #6092261CE01; NB0344
CPAP Mask	Class IIa	N/A	Certificate #6092261CE01; NB0344
Incentive Spirometer	Class Im	N/A	Certificate #6092261CE01; NB0344
HME Filter (sterile)	Class IIa	N/A	Certificate #6092261CE01; NB0344
Gas Sampling Line	Class IIa	N/A	Certificate #6092261CE01; NB0344
Peak Flow Meter	Class Im	N/A	Certificate #6092261CE01; NB0344
Manual Resuscitator Sets	Class IIa	N/A	Certificate #DD 60142199 0001; NB0197

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023-11-28	6092261CN04.1	Initial issue
2024-05-14	6092261CN07	Addition of device Manual Resuscitator Sets to Table 1