DEKRA

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
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E-mail medical.nl@dekra.com

Besmed Health Business Corp.
CONFIDENTIAL

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Besmed Health Business Corp.
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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

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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
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

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Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Besmed Health Business Corp.
Manufacturer address and contact details	No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
Single Registration Number (SRN) (if available)	TW-MF-000007246

Authorised Representative name (if applicable)	Emergo Europe B.V.
Authorised Representative address and contact details	Lange Viestraat 2b, Utrecht, 3511 BK, The Netherlands.
Single Registration Number (SRN) (if available)	NL-AR-000037688

Notified body name (if applicable)	DEKRA Certification B.V., TUV Rheinland LGA Products GmbH □ See attached schedule
Notified body number (if applicable)	NB 0344, NB 0197 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	6092261CE01, DD 601421990001 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26/05/2024 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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End date of extended validity/transition period	31/12/2028 ☐ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or an aspect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

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☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☑ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

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Signed for and on behalf of the manufacturer:

Full Company Name: Besmed Health Business Corp.

Location & Date: No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 248 2023/12/27

Signature,

Print Name: Ms. Sarah Lu,

Title: Vice President

Contact Details (at least email): sarah.lu@besmed.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date extended validity / transition period**	**Substitute Device(s)** (if applicable)
Bubble humidifier	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Jet Nebulizer Set	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Peep Valve	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Guedel Airway (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Silicone Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Disposable Cushion Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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Silicone Breathing Bag	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Silicone Drainage Tube & Reservoir (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Silicone Stomach Tubing (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Laryngeal Airway Mask (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Disposable Laryngoscope Set	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Nasal Cannula	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Hi-Oxygen Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Oxygen Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Oxygen Tubing	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Aerosol Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Tracheotomy Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Venturi Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V.	NB Name: DEKRA Certification B.V.	31/12/2028	NA

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			NB Number: 0344	NB Number: 0344		
Breathing Circuit	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Silicone Penrose Tube (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Bacterial Filter	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Humidification Chamber	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
CPAP Mask	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Incentive Spirometer	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
HME Filter (sterile)	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Gas Sampling Line	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Peak Flow Meter	Certificate No: 6092261CE01	26/05/2024	NB Name: DEKRA Certification B.V. NB Number: 0344	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA
Manual Resuscitator Sets	Certificate No: DD 50142199001	26/05/2024	NB Name: TUV Rheinland LGA Products GmbH NB Number: 0197	NB Name: DEKRA Certification B.V. NB Number: 0344	31/12/2028	NA

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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 references 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

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Besmed Health Business Corp. CONFIDENTIAL

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

Besmed Health Business Corp.
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DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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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):

- 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

Besmed Health Business Corp.
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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

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