EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60142199 0001

Report No.: 50248503 002

Manufacturer:

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

Products: Manual Resuscitator Sets

(see attachment for additional site included)

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2020-01-10

Date: 2020-01-10

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60142199 0001
Report No.: 50248503 002

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

Site included:

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

Besmed Health Business Corp.
No. 2, Lane 106, Wu-Kong 3rd Road, Wu-Ku District,
New Taipei City 24889, Taiwan

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Certifizierungsstelle

Fuxiu Sheng

Date: 2020-01-10

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

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