

Besmed Health Business Corp.  
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Arnhem, 2 April 2025

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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|---|---|--|--|
| 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 |
|---|---|--|--|
| MDI Spacer  | Ila   | MDI Spacer (Class I)   | 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 |
| 2025-04-02 | N/A                               | Addition of device MDI Spacer to Table 2               |