

# EC Declaration of Conformity

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|-----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Manufacturers Name:</b>                                            | Besmed Health Business Corp.                                                                                                                                                                                                                                                                                      |
| <b>Manufacturers Address:</b>                                         | No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888                                                                                                                                                                                                                                  |
| <b>SRN (Single Registration Number) of Manufacturer:</b>              | [TW-MF-000007246]                                                                                                                                                                                                                                                                                                 |
| <b>Authorized Representative Name (if applicable):</b>                | Mdi Europa GmbH                                                                                                                                                                                                                                                                                                   |
| <b>Authorized Representative Address:</b>                             | Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany                                                                                                                                                                                                                                                        |
| <b>SRN (Single Registration Number) of Authorized Representative:</b> | [DE-AR-000006218]                                                                                                                                                                                                                                                                                                 |
| <b>Basic UDI-DI:</b>                                                  | 4716770OT08300MQ                                                                                                                                                                                                                                                                                                  |
| <b>Name of the Device Group (s):</b>                                  | BUBBLE HUMIDIFIER                                                                                                                                                                                                                                                                                                 |
| <b>Product (MDN) code:</b>                                            | 1201                                                                                                                                                                                                                                                                                                              |
| <b>European Medical Device Nomenclature (EMDN):</b>                   | R060202                                                                                                                                                                                                                                                                                                           |
| <b>Conformity assessment route:</b>                                   | Conformity assessment based on a Quality Management System, and technical documentation (Annex II excluding (4) of MDD 93/42/EEC-M5 2007/47/EC)                                                                                                                                                                   |
| <b>Intended use:</b>                                                  | Besmed bubble humidifier is a device that is intended to add moisture to the breathing gases for administration to a patient. It can be used with different kinds of oxygen sources such as: oxygen concentrators, liquid tank or wall outlets in home, physician's office or hospital/institutional environment. |
| <b>Classification:</b>                                                | CLASS IIa, rule 2                                                                                                                                                                                                                                                                                                 |
| <b>Notified Body Name:</b>                                            | DEKRA Certification B.V.                                                                                                                                                                                                                                                                                          |
| <b>Notified Body Address:</b>                                         | Meander 1051 / P.O. Box 5185<br>6825 MJ ARNHEM / 6802 ED ARNHEM<br>Netherlands                                                                                                                                                                                                                                    |
| <b>Notified Body Identification number:</b>                           | NB 0344                                                                                                                                                                                                                                                                                                           |
| <b>harmonized standards or CS are applied:</b>                        | EN ISO 20417:2021, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 13485:2016/AC: 2018, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013                                                                                                                                 |

**CE certificate no.** [6092261CE01]

This declaration of conformity is issued under the sole responsibility of Besmed Health Business Corp. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDD 93/42/EEC-M5 2007/47/EC for medical devices. There are no significant changes in the design or intended purpose in the meaning of Article 120(3) MDR. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V.

All supporting documentation is retained at the premises of the manufacturer.

## EC Declaration of Conformity

Signature:

*Sarah Lu*

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NAME: Sarah Lu  
FUNCTION: Vice President

Place and date (yyyy.mm.dd) of issue:

New Taipei City, 2021.11.22

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Besmed Health Business Corp. RA CONFIDENTIAL 20210113

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Attachment to declaration of conformity [BUBBLE HUMIDIFIER]

## BUBBLE HUMIDIFIER

| Device            | Reference number                  | Description                                  |
|-------------------|-----------------------------------|----------------------------------------------|
| Bubble Humidifier | HB-72462<br>(FIAB Ref# OS/17-6)   | BUBBLE HUMIDIFIER 400cc (6 psi), DISPOSABLE. |
|                   | HB-72465<br>(FIAB Ref# OS/17-6LN) | BUBBLE HUMIDIFIER 400cc (6 psi), DISPOSABLE. |

Besmed Health Business Corp. RA CONFIDENTIAL 20210113