



EC Declaration of Conformity

Manufacturers Name: Besmed Health Business Corp.

Manufacturers Address: No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888

SRN (Single Registration Number) of Manufacturer: [TW-MF-000007246]

Authorized Representative Name (if applicable): Mdi Europa GmbH

Authorized Representative Address: Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany

SRN (Single Registration Number) of Authorized Representative: [DE-AR-000006218]

Basic UDI-DI: 4716770LS78490

Name of the Device Group (s): Disposable Laryngoscope Set

Product (MDN) code: 1201

Conformity assessment route: Conformity assessment based on a Quality Management System, and technical documentation (Annex IX of MDD 93/42/EEC-M5 2007/47/EC)

Intended use: Laryngoscope set is used to examine and visualize a patient's upper airway and aid placement of a tracheal tube.

Classification: CLASS IIa, rule 5; Besmed Laryngoscope set is a device that is intended to be used to examine and visualize a patient's upper airway and aid placement of a tracheal tube

Notified Body Name: DEKRA Certification B.V.

Notified Body Address: Meander 105J / P.O. Box 5185
6825 MJ ARNHEM / 6802 ED ARNHEM
Netherlands

Notified Body Identification number: NB 0344

harmonized standards or CS are applied: EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 13485:2016/AC: 2018, IEC 62366-1:2015/AMD1:2020, ISO 10993-1:2018, 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. 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.

Signature:

Sarah Lu

FUNCTION: Vice President

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

New Taipei City, 2021.06.24

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Attachment to declaration of conformity [Disposable Laryngoscope Set]

Disposable Laryngoscope Set

| Device | Reference number | Description |
|-----------------------------|------------------|---|
| Disposable Laryngoscope Set | LS-78120 | DISPOSABLE FIBER OPTIC MACINTOSH BLADE SMALL ADULT #2 |
| | LS-78130 | DISPOSABLE FIBER OPTIC MACINTOSH BLADE ADULT #3 |
| | LS-78140 | DISPOSABLE FIBER OPTIC MACINTOSH BLADE LARGE ADULT #4 |
| | LS-78200 | DISPOSABLE FIBER OPTIC MILLER BLADE SMALL INFANT #0 |
| | LS-78210 | DISPOSABLE FIBER OPTIC MILLER BLADE CHILD #1 |
| | LS-78220 | DISPOSABLE FIBER OPTIC MILLER BLADE CHILD #2 |
| | LS-78390 | OPTIC HANDLE W/O BATTERY |
| | LS-78490 | LARYNGOSCOPE FIBER OPTIC SET INCLUDES ONE MIDDLE SIZE HANDLE, 6 BLADES AND STORAGE CASE |

Besmed Health Business Corp. RA CONFIDENTIAL 20210113