BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan. 24888
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File no.: DOC-3704-04-02
Date: 2024-08-12

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):	Casus Europe B.V
Authorized Representative Address	Lange Viestraat 2b, Utrecht, 3511 BK, The Netherlands.
SRN (Single Registration Number) of Authorized Representative:	NL-AR-000037688
Basic UDI-DI:	4716770CT01600XX
Name of the Device Group (s):	BREATHING CIRCUIT
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R020199
Conformity assessment route:	Conformity assessment based on a Quality Management System, and technical documentation (Annex II of MDD 93/42/EEC-M5 2007/47/EC)
Intended use:	Besmed Breathing Circuit is intended to administer medical gases to a patient during anesthesia or using a ventilator. It provides both an inhalation and exhalation route and includes a connector, adaptor and Y-pieces.
Classification:	CLASS IIa, **Rule 2:** Besmed Breathing Circuit is a non-invasive device that is designed for those patients who needs respiratory ventilation or used in anesthesia.
Notified Body Name:	DEKRA Certification B.V.
Notified Body Address:	Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands
Notified Body Identification number:	NB 0344
Harmonized standards or CS are applied:	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 24971:2020, EN ISO 20417:2021, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 18562-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 15223-1:2021, ISTA 2A, ASTM F1980-21, ASTM F88/F88M-23, ASTM F1140/F1140M-13(2020), EN ISO 5356:2015, EN ISO 5367:2023, EN ISO 9360-1: 2009, and EN ISO 80601-2-74:2021.
CE certificate no.	6092261CE01

Besmed Health Business Corp. CONFIDENTIAL

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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.

Place and date (yyyy.mm.dd) of issue: Taipei, 2024.08.12

Signature:

Sarah Lu
Vice President
For and on behalf of Besmed

Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Besmed Health Business Corp. CONFIDENTIAL

Attachment to declaration of conformity [Breathing Circuit]

BREATHING CIRCUIT

Medline Reference number	Besmed Reference number	Description
1077B	CT-13171	Aerosol Tee Connector (22M, 22M, 22M/15F)
1659B	CT-13181	Disposable MDI T Connector
1651B	CT-13113	T Piece (22M/15F, 22F, 22M/15F)
1642B	CT-14451	Straight Connector W/ 6mm L Connector Port (22M, 22F)

Revision log

Rev No.	Doc. No.	Reason for Change	Approval / Date
1	DOC-3704-04-01	Establishment of first version	Sarah Lu / 2021.05.21
2	DOC-3704-04-02	Revised to update the co-branding	Sarah Lu / 2024.08.12