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-3704-06
Date: 2026-07-23

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:	4716770NB31141XX
Name of the Device Group (s):	JET NEBULIZER SET
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R03010304
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 Jet nebulizer set is a device intended to aerosolize prescribed medicine for inhalation by a patient at home, hospital, or institutional environments. It is available for adult and pediatric patients.
Classification:	CLASS IIa, **Rule 2**: Besmed Jet nebulizer set is a non-invasive device that is used to aerosolize liquids into aerosol-form gases that are delivered directly to the patient for breathing.
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 15223-1:2021, ISTA 2A-2011, ASTM F1980-21, ASTM F88/F88M-21, EN ISO 5356:2015, and EN ISO 27427:2023.
CE certificate no.	6092261CE01

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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, 2026.07.23

Signature:

.....
Sarah Lu
Vice President
For and on behalf of Besmed

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Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [Jet Nebulizer Set]

JET NEBULIZER SET

Medline Reference number	Besmed Reference number	Description
HCS88010	NB-31800	Disposabe Nebulizer,OD:22mm,10cc
HCS89310	NB-31811	Nebulizer Kit, Mask,7FT Tube,Adult
HCS89410	NB-31821	Nebulizer Kit, Mask,7FT Tube,Child

Revision log

Rev No.	Doc. No.	Reason for Change	Approval / Date
1	DOC-3704-01	Establishment of first version	Sarah Lu / 2021.05.21
2	DOC-3704-02	Revised to update the co-branding	Sarah Lu / 2024.06.12
3	DOC-3704-03	Added new item	Sarah Lu / 2024.08.08
4	DOC-3704-04	Revised to update the required model	Sarah Lu / 2026.05.27
5	DOC-3704-05	Revised to update the required model	Sarah Lu / 2026.06.26
6	DOC-3704-06	Revised to correct Medline Referecne Number	Sarah Lu / 2026.07.23