BESMED HEALTH BUSINESS CORP.
No. 5, Lane 116, Wu-Kong 2nd Rd, Wu-Ku District,
New Taipei City, Taiwan, 24888
☎ : +886-2-2290-3959 🖷 : +886-2-2299-9076
✉ : info@besmed.com 🌐 : www.besmed.com

File no.: DOC-3704-03
Date: 2024-08-08

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, 2024.08.08

Signature:

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

.....
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
HCS745	NB-31180	Nebulizer with Valved Tee, Star Lumen Tubing and Standard Connector
HCS755	NB-31643	Filtered Nebulizer System with 2.1m Star Lumen Tubing and Standard Connector
HCS880	NB-31100	Nebulizer with Jar, Jet and Cap only
HCS883	NB-31141	Nebulizer with Mouthpiece, Tee, Reservoir Tubing, Star Lumen Tubing and Standard Connector
HCS890	NB-31200	Nebulizer with Jar, Jet and 22mm Cap only
HCS891	NB-31283	Nebulizer with Tee, Star Lumen Tubing and Standard Connector
HCS892	NB-31288	Nebulizer with Mouthpiece, Tee, Star Lumen Tubing and Standard Connector
HCS893	NB-31211	Nebulizer with Adult Aerosol Mask, Star Lumen Tubing and Standard Connector
HCS894	NB-31221	Nebulizer with Pediatric Aerosol Mask, Star Lumen Tubing and Standard Connector
HCS895	NB-31242	Nebulizer with Mouthpiece, Tee, Reservoir Tubing, Star Lumen Tubing and Universal Connector
HCS898	NB-31212	Nebulizer with Adult Aerosol Mask, Star Lumen Tubing and Universal Connector
HCS993	NB-31284	Nebulizer with Adult Tracheostomy Aerosol Mask, Star Lumen Tubing and Standard Connector

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EC Declaration of Conformity

HCS994	NB-31285	Nebulizer with Pediatric Tracheostomy Aerosol Mask, Star Lumen Tubing and Standard Connector
1770B	HB-72400	Disposable Large Volume Nebulizer Bottle 500cc

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

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