



MANUFACTURER:

Globalcare Medical Technology CO., LTD.
7th Building, 39 Middle Industrial Main Road, European Industrial Zone,
Xiaolan Town, 528415 Zhongshan City, Guangdong Province,
PEOPLE'S REPUBLIC OF CHINA

Single registration number (SRN): CN-MF-000033595

Product Category: Z12159002 - AEROSOL GENERATORS
Product Type: GCE841
Product Code: P957010-X
Product Description: NEB PRO

Basic UDI-DI: 697022925GCE8XXEM

Classification - Annex VIII: Class IIa, Rule 20

Conformity Assessment Route: ANNEX IX Chapters I and III

We, the manufacturer, herewith declare that the stated medical device meets the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

All supporting documentation is retained at the premises of the manufacturer.
Globalcare Medical Technology CO., LTD. is exclusively responsible for this EC Declaration of Conformity.

Standards Applied: See attached list

Notified Body
Name: TÜV SÜD Product Service GmbH

Address: Ridlerstraße 65
80339 Munich, Germany

Identification Number 0123

(EC) Certificate(s): G10 088855 0016 Rev. 00



European Representative: Donawa Lifescience
Piazza Albania, 10
00153 Rome
Italy

Place, Date of Declaration: Zhongshan, 2024-11-28

Signature:
Name: Lambert Zhao
Position: General Manager

Product Category	Aerosoltherapy nebulizers
Product Family	GCE841 product family

Reference	TITLE
Regulation(EU) 2017/745	Medical Device Regulation
IEC 60601-1: 2005+A1:2012+A2:2020 EN 60601-1: 2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2020 EN 60601-1-2:2015/A1:2021	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6 :2010/A2:2021	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
IEC 60601-1-11: 2015+AMD1:2020 EN 60601-1-11:2015/A1:2021	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
ISO 14971:2019	Medical devices - Application of risk management to medical devices.
EN ISO 27427:2019	Anaesthetic and respiratory equipment - Nebulizing systems and components
EN ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
ISO 10993-1:2018 EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes.
DIR 2011/65/EU (RoHS)	Restriction of the use of certain hazardous substances in electrical and electronic equipment.
DIR 2012/19/EU	Waste electrical and electronic equipment.
EN 62366-1: 2015/A1:2020	Medical devices - Application of usability engineering to medical devices.
ISO 18562-1:2017 EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications —Part 1:Evaluation and testing within a risk management process
ISO 18562-2:2017 EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications —Part 2:Tests for emissions of particulate matter
ISO 18562-3:2017 EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare applications —Part 3:Tests for emissions of volatile organic compounds (VOCs)
ISO 18562-4:2017	Biocompatibility evaluation of

EN ISO 18562-4:2020	breathing gas pathways in healthcare applications —Part 4:Tests for leachables in condensate
ISTA-2A	ISTA 2 Series Partial Simulation Performance Test Procedure:Packaged-Products 1 50 lb (68 kg) or Less
ISO 17664-1:2021 EN ISO 17664-1: 2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices —Part 1:Critical and semi-critical medical devices

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: Yoyo Zhang	Regulatory specialist	Nov 28, 2024	<i>Yoyo Zhang</i>
APPROVED: Cherry Feng	Regulatory and compliance Manager	Nov 28, 2024	<i>Cherry Feng 24.11.28</i>