



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: GCE825
Product code: Microlife NEB 200
Product Description: Aerosoltherapy Nebulizer

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.

Intended purpose: see attached intended purpose
Standards applied: see attached list

Notified body:

Name: TÜV SÜD Product Service GmbH
Certification Body
Address: Ridlerstraße 65
80339 Munich, Germany
Identification Number 0123

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

EC REP

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

Single registration number (SRN): IT-AR-000007785

Place, Date of Declaration: Zhongshan, 2026-09-04

Signature:

Name: Lambert Zhao
Position: General Manager

