



**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

**Product Category:** Aerosoltherapy Nebulizers

**Product Code:** GCE836

**Product Description:** GC IH58

**Classification - Annex IX:** Class IIa, Rule 11

**Conformity Assessment Route:** ANNEX V

We, the manufacturer, herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, the amendments by Council Directive 2007/47/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:** TÜV SÜD Product service GmbH  
Ridlerstr 65, D-80339 München, Germany

**Identification Number** 0123

**(EC) Certificate(s):** G2 088855 0009



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

**Place, Date of Declaration:** Zhongshan, 2019-03-04

**Signature:**   
Name: Lambert Zhao  
Position: General Manager