

EC Declaration of Conformity

F-QA-037 Rev.01 20160107

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:

GCE834

Product Description:

GC IH60

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

EC REP

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