

## **EC** Declaration of Conformity

F-QA-037 Rev.01 20160107



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:

MQ6010

PRODUCT DESCRIPTION:

AirForce Mini

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 11

CONFORMITY ASSESSMENT ROUTE:

ANNEX V

WE, <u>THE MANUFACTURER</u>, 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.

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 16 07 88855 005

EC REP

**EUROPEAN REPRESENTATIVE:** 

DONAWA LIFESCIENCE CONSULTING SRL

PIAZZA ALBANIA, 10

**00153 ROME** 

ITALY

PLACE, DATE OF DECLARATION:

Zhongshan, 2018-06-15

SIGNATURE:

NAME: Lambert Zhao

POSITION: General Manager