

EC Declaration of Conformity

F-REG-002 Rev.00 20200110

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:

GCE803

Product Code:

MQ5890EU

Product Description:

AirForce One Euro-Version

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

EC REP

European Representative:

Donawa Lifescience Piazza Albania, 10

00153 Rome

Italy

Place, Date of Declaration:

Zhongshan, 2024-5-27

Signature:

Name:Lambert Zhao

Position: General Manager