



**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:**

s995100-1

**PRODUCT DESCRIPTION:**

Adult mask

**CLASSIFICATION - ANNEX IX:**

CLASS I, RULE 1

**CONFORMITY ASSESSMENT ROUTE:**

ANNEX VII

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.

**NOTIFIED BODY:**

N/A

**IDENTIFICATION NUMBER**

N/A

**(EC) CERTIFICATE(S):**

N/A



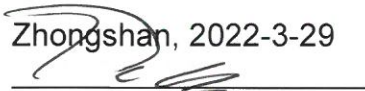
**EUROPEAN REPRESENTATIVE:**

Donawa Lifescience Consulting Srl  
Piazza Albania, 10  
00153 Rome  
Italy

**PLACE, DATE OF DECLARATION:**

Zhongshan, 2022-3-29

**SIGNATURE:**

  
NAME: Lambert Zhao  
POSITION: General Manager