



**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:**

MQ5890EU

**PRODUCT DESCRIPTION:**

AirForce One EU Compressor Nebulizer

**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.

**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, 2017-02-23

**SIGNATURE:**

  
NAME: Roberto Stefanelli  
POSITION: General Manager

Product Category	Aerosoltherapy nebulizers
Product Family	GCE803 product family

Reference	TITLE
MDD 93/42/EEC	Medical Device Directive.
EN 60601-1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
EN 60601-1-11:2010	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
EN 13544-1:2007+A1:2009	Respiratory therapy equipment - Part 1: Nebulizing systems and their components.
EN ISO 15223-1:2012	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
EN 1041:2008	Information supplied by the manufacturer of medical devices.
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
EN ISO 10993-10:2010	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization.
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes.
DIR 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment.
DIR 2012/19/EU	Waste electrical and electronic equipment.
EN 62366:2008	Medical devices - Application of usability engineering to medical devices.

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: Janice Deng	Regulatory	Feb 23, 2017	Janice Deng 2017-02-23
APPROVED: Cherry Feng	Quality Manager	Feb 23, 2017	Cherry Feng 2017.02.23



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PEOPLE'S REPUBLIC OF CHINA

**PRODUCT CATEGORY:**

AEROSOLTHERAPY NEBULIZERS

**PRODUCT CODE:**

MQ5900UK

**PRODUCT DESCRIPTION:**

AirForce One UK Compressor Nebulizer

**CLASSIFICATION - ANNEX IX:**

CLASS IIA, RULE 11

**CONFORMITY ASSESSMENT ROUTE:**

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

G2 16 07 88855 005

**EC REP**

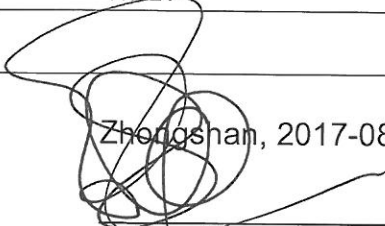
**EUROPEAN REPRESENTATIVE:**

DONAWA LIFESCIENCE CONSULTING SRL  
PIAZZA ALBANIA, 10  
00153 ROME  
ITALY

**PLACE, DATE OF DECLARATION:**

Zhongshan, 2017-08-30

**SIGNATURE:**

  
NAME: Roberto Stefanelli  
POSITION: General Manager



Product Category	<b>Aerosoltherapy nebulizers</b>
Product Family	<b>GCE803 product family</b>

Reference	TITLE
MDD 93/42/EEC	Medical Device Directive.
IEC 60601-1:2005+A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2007 and AC2010	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
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STATE	FUNCTION	DATE	SIGNATURE
ISSUED: <b>Candy Chen</b>	<b>Regulatory</b>	Jan 29,2016	<i>Candy Chen</i>
APPROVED: <b>Cherry Feng</b>	<b>Quality Manager</b>	Jan 29,2016	<i>Cherry Feng</i>