



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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PRODUCT CATEGORY:

AEROSOLTHERAPY NEBULIZERS

PRODUCT CODE:

MQ5900UK

PRODUCT DESCRIPTION:

AirForce One UK Compressor Nebulizer

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 11

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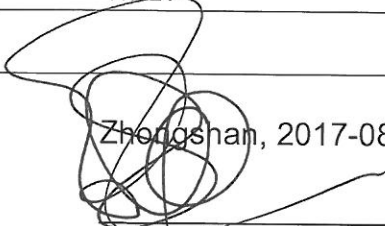
EUROPEAN REPRESENTATIVE:

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

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Product Family	GCE803 product family

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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
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STATE	FUNCTION	DATE	SIGNATURE
ISSUED: Candy Chen	Regulatory	Jan 29,2016	<i>Candy Chen</i>
APPROVED: Cherry Feng	Quality Manager	Jan 29,2016	<i>Cherry Feng</i>