globalcare 中山市全康医疗科技有限公司	EC Declaration of Conformity	F-QA-037 Rev.01 20160107

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

globalcare 中山市全康医疗科技有限公司	EC Declaration of Conformity	F-QA-037 Rev.01 20160107

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:	MQ5900UK
PRODUCT DESCRIPTION:	AirForce One UK 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, 2017-08-30
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.
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.
IEC 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.
UNI CEI EN ISO 14971:2012	Medical devices - Application of risk management to medical devices.
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EN ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.
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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: **Candy Chen**	**Regulatory**	Jan 29,2016	Candy Chen
APPROVED: **Cherry Feng**	**Quality Manager**	Jan 29,2016	Cherry Feng