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:	MQ6010
Product Description:	AirForce Mini Compressor Nebuliser
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.
Globalcare Medical Technology CO., LTD. is exclusively responsible for this EC Declaration of Conformity.

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 088855 0011 Rev.00
EC REP European Representative:	Donawa Lifescience Consulting Srl Piazza Albania, 10 00153 Rome Italy

Place, Date of Declaration:	Zhongshan, 2020-04-16
Signature:	Name: Lambert Zhao Position: General Manager

Product Category	**Aerosoltherapy nebulizers**
Product Family	**GCE831 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 60601-1-2:2014	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 60601-1-11:2015	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 13485:2016	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.
IEC 62133:2012	Secondary cells and batteries containing alkaline or other non-acid electrolytes -Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
IEC 62304:2006	Medical device software - Software life-cycle processes

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: **Laura Liang**	**Regulatory assistant**	April 16,2020	Laura Liang
APPROVED: **Janice Deng**	**Regulatory**	April 16,2020	Janice Deng