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:	Blood Pressure Measuring Equipment
Product Code:	GCE602
Product Description:	Blood Pressure Monitor
Classification - Annex IX:	Class IIa, Rule 10
Conformity Assessment Route:	ANNEX V.3

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 Ridlerstraße 65 80339 Munich, Germany
Identification Number	0123
(EC) Certificate(s):	G2 088855 0011
EC REP European Representative:	Donawa Lifescience Consulting Srl Piazza Albania,10 00153 Rome Italy

Place, Date of Declaration:	Zhongshan, 2021-03-01
Signature:	Name: Lambert Zhao Position: General Manager

Product Category	Blood pressure measuring equipment
Product Family	GCE602 product family

Reference	Title
MDD 93/42/EEC as amended by 2007/47/EEC	Medical Device Directive
IEC 60601-1:2005+A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 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+A1 :2015	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
IEC 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 ISO 81060-1:2012	Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type
IEC 80601-2-30: 2009 +AMD1:2013	Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2:2013	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices.
EN ISO 10993-1:2009/AC:2010	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 10993-10:2013	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 (RoHS)	Restriction of the use of certain hazardous substances in electrical and electronic equipment.
Reg. 1907/2006/EU (REACH)	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency

Dir. 2012/19/EU	Waste electrical and electronic equipment
IEC 62304:2006/A1: 2015	Medical device software - Software life-cycle processes
EN 62366-1:2015/AC:2016-09	Medical devices - Application of usability engineering to medical devices.

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: **Yoyo Zhang**	**Regulatory Specialist**	March 1st,2021	Yoyo Zhang
APPROVED: **Janice Deng**	**Regulatory and compliance Officer**	March 1st,2021	Janice Deng