globalcare 中山市全康医疗科技有限公司	EC Declaration of Conformity	F-REG-002 Rev.00 20200110

MANUFACTURER:	Globalcare Medical Technology CO., LTD. 7th Building, 39 Middle Industrial Main Road,EuropeanIndustrial Zone, Xiaolan Town, 528415 Zhongshan City,Guangdong Province, PEOPLE'S REPUBLIC OF CHINA
Single registration number (SRN):	CN-MF-000033595
Product Category:	Z12030205-NON INVASIVE BLOOD PRESSURE MONITORS
Product Type:	GCE609
Product Description:	Veroval Compact+ BPU 26
Basic UDI-DI:	697022925GCE6XXEB
Classification - Annex VIII:	Class IIa, Rule 10
Conformity Assessment Route:	ANNEX IX Chapters I and III

We, the manufacturer, herewith declare that the stated medical device meets the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/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:

Name:	TÜV SÜD Product Service GmbH Certification Body
Address:	Ridlerstraße 65 80339 Munich, Germany
Identification Number	0123
(EC) Certificate(s):	G10 088855 0016 Rev. 00

EC REP

European Representative:	Donawa Lifescience Piazza Albania, 10 00153 Rome Italy
Single registration number (SRN):	IT-AR-000007785

Place, Date of Declaration:	Zhongshan, 2024-7-8
Signature:	Name:Lambert Zhao Position: General Manager

Product Category	Blood pressure measuring equipment
Product Family	GCE609 product family

Reference	Title
Regulation(EU) 2017/745	Medical Device Regulation
IEC60601-1:2005/A2:2020 EN 60601-1:2006/A2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+AMD1:2020 EN 60601-1-2:2015+A1:2021	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/A2:2021	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability.
IEC 60601-1-11:2015/A1 :2020 EN 60601-1-11:2015/A1 :2021	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.
ISO 14971:2019 EN ISO14971:2019/A11:2021	Medical devices - Application of risk management to medical devices.
IEC 80601-2-30: 2018 EN 80601-2-30 :2019	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 20417:2021	Medical devices — Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements.
ISO 10993-1 :2018 EN ISO 10993-1: 2020	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.
ISO 13485:2016 EN ISO 13485:2016/A11:2021	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/A1:2020	Medical devices - Application of usability engineering to medical devices.

2014/53/EU	The Radio Equipment Directive, RED
ISTA-2A	ISTA 2 Series Partial Simulation Performance Test Procedure:Packaged-Products 1 50 lb (68 kg) or Less

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: **Yoyo Zhang**	**Regulatory specilist**	July 8, 2024	Yoyo Zhang
APPROVED: **Cherry Feng**	**Regulatory and compliance manager**	July 8, 2024	Cherry Feng