globalcare 中山市全康医疗科技有限公司	EC Declaration of Conformity	F-REG-002 Rev.01 20260403

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:	Blood Pressure Measuring Equipment 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.

Intended purpose: see attached intended purpose
Standards applied: see attached list

Notified body:	
Name:	TÜV SÜD Product Service GmbH
Address:	Ridlerstraße 65 80339 Munich, Germany
Identification Number	0123
(EC) Certificate(s):	G15 088855 0021Rev.01

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

Place, Date of Declaration:	Zhongshan, 2026-11-4
Signature:	Name:Lambert Zhao Position: General Manager

globalcare 中山市全康医疗科技有限公司	EC Declaration of Conformity attachment Intended Purpose	Page 1 / 1

Product Category	Blood pressure measuring equipment
Product Family	**GCE609 product family**

Intended Purpose:
The automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm.

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: **Yoyo Zhang**	**Regulatory specilist**	November 4, 2026	Yoyo Zhang
APPROVED: **Janice Deng**	**Regulatory and compliance Officer**	November 4, 2026	Janice Deng

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 81060-2:2018+A1:2020	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.
ISO 10993-10 :2021 EN ISO 10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for skin sensitization.
ISO 10993-23 :2021 EN ISO 10993-23: 2021	Biological evaluation of medical devices – Part 23: Tests for irritation
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.
ISTA-2A	ISTA 2 Series Partial Simulation Performance Test Procedure:Packaged-Products 1 50 lb (68 kg) or Less

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APPROVED: **Janice Deng**	**Regulatory and compliance Officer**	November 4, 2026	Janice Deng