



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

Single registration number (SRN): CN-MF-000033595

Product Category: Z12030205 - NON INVASIVE BLOOD PRESSURE
MONITORS

Product Type: GCE627

Product Code: 106.23

Product Description: Blood Pressure Measuring Equipment

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

Address: Ridlerstraße 65
80339 Munich, Germany

Identification Number: 0123

(EC) Certificate(s): G10 088855 0016 Rev. 00



European Representative:

Donawa Lifescience
Piazza Albania, 10
00153 Rome
Italy

Place, Date of Declaration: Zhongshan, 2025-8-28

Signature:

Name: Lambert Zhao
Position: General Manager

Product Category	Blood pressure measuring equipment
Product Family	GCE627 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

STATE	FUNCTION	DATE	SIGNATURE
ISSUED: Yoyo Zhang	Regulatory specialist	August 28, 2025	<i>Yoyo Zhang</i>
APPROVED: Janice Deng	Regulatory and compliance Officer	August 28, 2025	<i>Janice Deng</i>