



**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: Blood Pressure Measuring Equipment  
Product Type: GCE613  
Product Code: SBM49  
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  
Certification Body  
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, 2023-5-24

**Signature:**

Name: Lambert Zhao  
Position: General Manager