EU Declaration of Conformity

Manufacturer:	Shenzhen Yuezhongxing Technology Co., Ltd. No.2, Zhenye Road, Liulian Community, Pingshan Avenue, Pingshan District, Shenzhen,518015,CHINA
SRN:	CN-MF-000024102
EU Representative:	Kingsmead Service B.V. Zonnehof 36,2632 BE,Nootdorp,Netherland SRN: NL-AR-000002066 Contact Person: Kun Yan Tel/Fax: +31(0)646571005 E-mail:office@kingsmead-service.com
Product Name:	Arm Blood Pressure Monitor
Models:	111,B1681,B1682,B1683
Basic UDI-DI:	697120916111FV,697120916B168139,697120916B16823B,697120916B16833D
MDR code	MDA203

Classification (According to the Annex VIII of MDR): Class IIa, Rule 10

Conformity assessment procedure: Annex IX of MDR

We herewith declare in our own responsibility that the above products mentioned meet the transposition into national law, the provisions of the following EU regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

Regulation:

Regulation (EU) 2017/745 on medical devices

Standards:

EN ISO 14971:2019,EN ISO 13485:2016,EN 60601-1:2006+A1:2013,EN IEC 80601-2-30:2019, ISO 81060-2:2018, EN 60601-1-11:2015, EN 60601-1-2:2015, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-23:2021, EN ISO 15223-1:2021 EN 62304:2006+A1:2015, EN 62366:2008+A1:2015, EN 60601-1-6:2010+A1:2015

The EU declaration of conformity is issued under the sole responsibility of manufacturer.

Notified body:	**SGS Fimko Oy** Takomotie 8 00380 Helsinki Finland
Notified body number:	0598
Conformity assessment procedure:	Annex IX
Certificate number:	F123/1008001
Issued date:	24 Aug 2023
Signature:	Xiongjun Wu
Name:	Xiongjun Wu
Funtion of person signed:	PRRC
On behalf of:	Shenzhen Yuezhongxing Technology Co., Ltd.
Place:	Shenzhen, China
Date of issue:	March 09, 2023