EU Declaration of Conformity

Manufacturer:	SHENZHEN FINICARE CO., LTD. 201 and 301 of Building A22, Building A22 and A23, No.4 Industr ial Park, Tantou Community, Songgang Street, Bao'an District, Shenzhen 518105,PEOPLE'S REPUBLIC OF CHINA
SRN:	CN-MF-000024364
European Representative:	RIOMAVIX S.L. Calle de Almansa 55, 1D, Madrid, 28039 Spain
SRN:	ES-AR-000001202
Product Name:	Wrist Electronic Blood Pressure Monitor
Model:	FC-BP200, FC-BP201, FC-BP210, FC-BP211, FC-BP220, FC-BP221.
EMDN Code:	Z1203020302
Basic UDI-DI:	697152282WEBP1LL

Intended purpose of device: The Wrist Blood Pressure Monitor is intended used to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Wrist.
Classification (MDR, Annex VIII): Class IIa, Rule 10.
Conformity Assessment Route: Annex IX Chapter I & III of Regulation (EU) 2017/745.

We herewith declare that the above-mentioned products meet the provisions of the MDR (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.
SHENZHEN FINICARE CO., LTD. is exclusively responsible for the declaration of conformity.
General applicable regulations, directives:
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.
Applied standards, common specification, guidance:
EN ISO 13485:2016/A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015/A1:2021, IEC 80601-2-30:2018, ISO 81060-2:2018/+A1:2020, IEC 60601-1-11:2015+A1:2020, IEC 62304:2006+A1:2015, EN 62366-1-2015, EN 60601-1-6:2010+A1:2015, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, ETSI EN 300 328 V2.2.2(2019-07), EN 62479:2010, EN 50663:2017, ETSI EN 301 489-1 V2.2.3(2019-11), ETSI EN 301 489-17 V3.2.4(2020-09), ASTM D4169-22, MEDDEV. 2.7.1 Rev.4.
Battery Directive 2006/66/EC, Battery Regulation (EU) 2023/1542，
Battery standard IEC/EN 60086-1:2021,IEC/EN 60086-2:2021,IEC/EN 60086-5:2021;

Notified Body:	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
NB Identification number:	0123
(EC) Certificate(s):	No. G10 004665 0011 Rev. 01
Expire date of the Certificate:	2028-10-16
Start of CE Marking:	2025-12-29

Signature:	Chao Li
Name:	Chao Li
Position:	General Manager
Place/date	Shenzhen City, 2025-12-30