Section 7.1 EU Declaration of Conformity

Document No.	:	TD-BPM-YE610D-07-001
Version	:	V1.1
Issuing date	:	2024.03.05
Prepared by	:	Yaqing Zhu
Reviewed by	:	Rui Li
Approved by	:	He Wei

Revision History

No.	Version	Revision Date	Revised Content	Reviser
1	V1.0	2023.09.22	Initial version.	Yaqing Zhu
2	V1.1	2024.03.05	Add identification of the certificate.	Yaqing Zhu

EU Declaration of Conformity

1. Manufacturer

Name	:	JIANGSU YUYUE MEDICAL EQUIPMENT&SUPPLY CO., LTD.
Trade Name	:	NA
Trade Mark	:	yuwell
SRN	:	CN-MF-000012834
Address	:	NO.1 Baisheng Road Development Zone, Danyang, Jiangsu 212300 CHINA

2. Authorised Representative

Name	:	Metrax GmbH
Address	:	Rheinwaldstr. 22, D-78628 Rottweil, Germany
SRN	:	DE-AR-000005481

3. Basic UDI-DI

Basic UDI-DI	:	693325792246J6

4. Device Information

Product Category	:	Electronic Blood Pressure Monitor
Trade Name	:	Electronic Blood Pressure Monitor
Model	:	YE610D and YE660D
Photograph	:	 YE610D  YE660D
Basic UDI-DI	:	693325792246J6
EMDN Code	:	Z1203020501
Intended Purpose	:	This product is intended to measure the blood pressure and pulse rate of adult whom more than 12 years old at household or medical center (not suitable for neonate, pregnancy or pre-eclampsia).

5. Risk Classification

Risk Classification	:	IIa according to rule 10 from Annex VIII of MDR (EU) 2017/745

6. Reference to CS

There is no any applicable CS.

7. Manufacturer Statement

We declare the EU declaration of conformity is issued under the sole responsibility of the manufacturer, and the device covered by the present declaration is in conformity with MDR (EU) 2017/745.

8. Notified Body

Name	:	TÜV SÜD Product Service GmbH, Ridlerstr.65, 80339MÜnchen, Germany
Identification Number	:	0123

9. Conformity Assessment Procedure

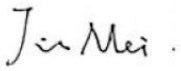
Based on Annex IX, Chapter I & III of MDR (EU) 2017/745

10. Identification of the Certificate

(EC)Certificate(s)	:	G10 109546 0009 REV. 00

Place of Issue: Dan Yang, Jiangsu, P.R.CHINA

Date of Issue: 2023-03-05

Signature: 

Name: Jie Mei

Position: Person Responsible for Regulatory Compliance

List of EU harmonized and international standards

No.	Ref. No.	Edition No./Date	Title
1	2017/745	2020.04.24	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
2	2011/65	2017.06.08	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
3	2017/2102	2017.11.15	DIRECTIVE (EU) 2017/2102 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 November 2017 amending Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
4	MEDDEV 2.7/1	Rev 4 /2016.06	A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC