

# EU DECLARATION OF CONFORMITY

TO REGULATION (EU) 2017/745 OF THE EUROPEAN  
PARLIAMENT AND OF THE COUNCIL

Manufacturer	Shenzhen Urion Technology Co.,Ltd. Address: Floor 4-6th of Building D, Jiale Science&Technology Industrial Zone, No.3. ChuanaWei Road ,Heshuikou Community,MaTian Street GuangMing New District, 518106 ShenZhen, PEOPLE'S REPUBLIC OF CHINA Trademark: N/A SRN: CN-MF-000018740
Authorised Representative	WellKang Ltd Address: Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland. SRN: XI-AR-000001836
Device information	Product name: Upper Arm Electronic Blood Pressure Monitor Trade name: Upper Arm Electronic Blood Pressure Monitor Model: U80R,U80CH ,U82CH ,U83CH ,U80EH EMDN code: Z12030205 Basic UDI-DI: 69538259UBP8K
Intended Purpose	This automatic blood pressure monitor intends to measure the systolic pressure, diastolic pressure and pulse rate through upper arm. It expected to be used at home or in the hospital,intended for people over 12 years old.
Risk Class	Ila
Classification rule	Rule 10 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity assessment route	Chapter I and III of Annex IX of the Regulation (EU) 2017/745
<p>We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.</p>	
Applied standards	See the Annex
Notified body	TÜV SÜD Product Service GmbH Westendstraße 19980686 München, Germany Phone: +49 (89) 50084261 Fax: +49 (89) 50084230 <a href="http://tuvsud.com/ps">http://tuvsud.com/ps</a>
Identification number	0123

EC Certificate(s)	G10 078672 0022 Rev. 00	Valid until	2029-02-28
Start of CE marking	2024-03-01		
Place, date of Issue	Shenzhen, Guangdong, Mar.1, 2024		
Signature	 Name: Changming Zhu Title: General Manager		