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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 078672 0022 Rev. 00

Manufacturer:

Shenzhen Urion Technology Co., Ltd.
Floor 4-6th of Building D
Jiale Science & Technology Industrial Zone
No.3, ChuangWei Road
Heshuikou Community, MaTian Street
GuangMing New District
518106 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000018740

Authorized Representative:

Wellkang Ltd
Enterprise Hub, NW Business Complex, 1 Beraghmore Road,
Derry, BT48 8SE, UNITED KINGDOM - NORTHERN IRELAND

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 078672 0022 Rev. 00

Report No.: GZ2217903

Valid from: 2024-03-01
Valid until: 2029-02-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-01

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 078672 0022 Rev. 00

Classification:	Class IIa
Device Group:	V03010102 - DIGITAL THERMOMETERS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Z12030205 - NON–INVASIVE BLOOD PRESSURE GAUGES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2024-03-01	GZ2217903	Initial issuance

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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	IIa
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
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.	
Applied standards	See the Annex
Notified body	TÜV SÜD Product Service GmbH Westendstraße 19980686 München, Germany Phone: +49 (89) 50084261 Fax: +49 (89) 50084230 http://tuvsud.com/ps
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	Changming Zhu Name: Changming Zhu Title: General Manager		