DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	**Shenzhen Urion Technology Co., Ltd.**
ADD:	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
MEDICAL DEVICE:	*DIGITAL BLOOD PRESSURE MONITORS*
MODLE:	U80AH,U80B,U80BH,U80C,U80CH,U81CH,U82CH,U83CH,U80E,U80EH, U80IH,U80J,U80K,U80KH,U80L,U80LH,U80N,U80NH,U807,U815,U80D, U81D,U81E,U82E,U83E,U85E,U86E,U87E,U80H,U81H,U82H,U83H,U85H, U80I,U81K,U80M,U81M,U81NH,U82NH,U80Q,U80QH,U81QU81QH,U80R, U81R,U81RH,U82RH,U80T,U80U,U81U,U82U U60AH,U60BH,U60CH,U60EH,U60GH,U60GH,U62GH,U60B,U60C,U60E, U60G.U60I.U62I.U63I
CLASSIFICATION - *ANNEX IX*:	*CLASS IIA, RULE10*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II EXCLUDING SECTION 4*

WE, THE MANUFACTURER, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES;
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
WE ARE EXCLUSIVELY RESPONSIBLE FOR THIS DOC.

NOTIFIED BODY:	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTRABE 65, 80339 MUNICH, GERMANY
IDENTIFICATION NUMBER	0123
(EC) CERTIFICATE(S):	G1 078672 0014 REV. 01
EC REP	
EUROPEAN REPRESENTATIVE: **ADD:**	**Shanghai International Holding Corp. GmbH (Europe)** Eiffestrasse 80, 20537 Hamburg, Germany
START OF CE-MARKING:	*DECEMBER 30, 2013*
PLACE, DATE OF DECLARATION:	*SHENZHEN, APRIL 15, 2021*
SIGNATURE:	Malik Zhu
	NAME: MALIK ZHU
	POSITION: (GENERAL MANAGER)

SHENZHEN URION TECHNOLOGY CO., LTD

No.	Standard reference	Title
1	EN 60601-1:2006/AC:2010	Medical electrical equipment –Part 1:General requirements for basic safety
2	IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
3	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
4	EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
5	EN ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
6	EN1041:2008	Information supplied by the manufacturer with medical devices
7	EN ISO 15223-1-2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
8	IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
9	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
10	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
11	EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
12	EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007); German version EN ISO 81060-1:2012
13	EN 1060-3: 1999+A2:2009	Non-invasive sphygmomanometers – Part 3: supplementary requirements for electro-mechanical blood pressure measuring systems
14	IEC 80601-2-30:2018	Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers
15	EN1060-4: 2004	Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
16	ISO 81060-2:2018	Non-invasive sphygmomanometers-Part 2:Clincal investigation of automated measurement type
17	EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)
18	EN ISO 780 2015	Packaging-Distribution packaging –Graphical symbols for handling and storage of packages
19	EN 60601-1-11:2015 IEC6060-1-11:2012+A1:2012	Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
20	EN IEC 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability