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, U80D, U81D, U80E, U80EH, U81E, U82E, U83E, U85E, U86E, U87E, U80H, U81H, U82H, U83H, U85H, U80I, U80IH, U80J, U80K, U80KH, U81K, U80L, U80LH, U80M, U81M, U80N, U80NH, U81NH, U82NH, U80Q, U80QH, U81Q, U81QH, U80R, U81R, U81RH, U82RH, U80T, U80U, U81U, U82U, U80Y, U807, U815, U83Z,U80Y U60AH, U60BH, U60B, U60CH, U60C, U60EH, U60E,U60G, U60GH, U61GH,U62GH,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.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

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:	**Shanghai International Holding Corp. GmbH (Europe)**
ADD:	Eiffestrasse 80, 20537 Hamburg, Germany

START OF CE-MARKING: *DECEMBER 30, 2013*

PLACE, DATE OF DECLARATION: *SHENZHEN, DECEMBER 1, 2021*

SIGNATURE:

SHENZHEN URION TECHNOLOGY CO., LTD. 深圳市优瑞恩科技有限公司

NAME: *MALIK ZHU*

POSITION: *(GENERAL MANAGER)*

Malik Zhu

No.	Standard reference	Title
1	EN 60601-1:2006/A12:2014	Medical electrical equipment – Part 1:General requirements for basic safety and essential Performance
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	EN ISO 10993-2:2006	Biological evaluation of medical devices - Part 5, 10 and 2
4	ENISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
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	ENISO 15223-1-2016	Medical devices — Symbols tobe used with medical device labels, labelling and informationto be suppliedPart 1: General requirements(ISO 15223-1:2016,Corrected version 2016-12-15)
8	EN 62366:2008	Medical devices - 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	EN62304:2006/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 1060-3：1997+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	ISO81060-2	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 60601-1-6:2010	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 60601-1-6:2010