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:	*U80BH, U80B, U80CH, U80C ,U80EH, U80E, U80L,U807, U815, U80K, U80KH, U80LH, U80J, U80N,U80NH, U80IH, U81CH, U82CH, U83CH, U80D,U81D, U81E, U82E, U83E, U85E, U86E, U87E,U80H, U81H, U82H, U83H, U85H, U80I, U81K,U80M, U81M, U81NH, U82NH, U80Q, U80QH,U81Q, U81QH, U80R, U81R, U81RH, U82RH,U80T, U80U, U81U, U82U,U82V,U60BH, U60CH, U60EH, U60GH, 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 RIDLERSTR 65, D-80339 MÜNCHEN, 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:	*FEBRUARY 28, 2012*
PLACE, DATE OF DECLARATION:	*SHENZHEN, SEPTEMBER 21, 2022*
SIGNATURE:	Malik Zhu
	NAME: MALIK ZHU
	POSITION: (GENERAL MANAGER)