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

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| 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, U807, U815, U80RH,U81V,U82V, 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.*

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| NOTIFIED BODY: | TÜV SÜD PRODUCT SERVICE GMBH<br>RIDLERSTRABE 65, 80339 MUNICH, GERMANY |
| *IDENTIFICATION NUMBER* | 0123 |
| (EC) CERTIFICATE(S): | G1 078672 0014 REV. 01 |

**EC REP**

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| EUROPEAN REPRESENTATIVE:<br>**ADD:** | **Shanghai International Holding Corp. GmbH (Europe)**<br>Eiffestrasse 80, 20537 Hamburg, Germany |
| START OF CE-MARKING: | *DECEMBER 30, 2013* |
| PLACE, DATE OF DECLARATION: | *SHENZHEN, AUGUST 24, 2022* |
| SIGNATURE: | Malik Zhu<br>*NAME: MALIK ZHU*<br>*POSITION: (GENERAL MANAGER)* |