

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



MANUFACTURER:
ADD:

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

MEDICAL DEVICE:
MODLE:

DIGITAL BLOOD PRESSURE MONITORS

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, U83Z,
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.

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:
SIGNATURE:

SHENZHEN, APRIL 27, 2021

Malik Zhu
NAME: MALIK ZHU

POSITION: (GENERAL MANAGER)