

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES



MANUFACTURER: NAME: GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD.
ADDRESS: ZONE A, NO.105, DONGLI ROAD, TORCH
DEVELOPMENT DISTRICT, ZHONGSHAN, GUANGDONG, CHINA

MEDICAL DEVICE: BLOOD PRESSURE MONITOR: H-BP100SBP-CE

CLASSIFICATION - ANNEX IX: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: MDD ANNEX II EXCLUDING (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 OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: SEE THE FOLLOWING STANDARDS ATTACHED

NOTIFIED BODY: TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER **CE 0123**

(EC) CERTIFICATE(S): NO.G1 082800 0026 REV.01



EUROPEAN REPRESENTATIVE: MDSS-MEDICAL DEVICE SAFETY SERVICE GMBH
SCHIFFGRABEN, 41,30175, HANNOVER, GERMANY

START OF CE-MARKING: 2019-10-30

PLACE, DATE OF DECLARATION: ZHONGSHAN, 2019-10-30

SIGNATURE: *Ken Zhai*

NAME: KEN ZHAI
POSITION: R&D DIRECTOR

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Standards applied:

Risk management	EN ISO 14971:2012
Labelling	EN ISO 15223-1:2016
User manual	EN 1041: 2008 +A1:2013
General requirements for safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 EN 60601-1-11:2015/ IEC 60601-1-11:2015 EN 60601-1-8:2006+A1:2012/IEC 60601-1-8:2006+A1:2012
Non-invasive sphygmomanometers General requirements	EN ISO 81060-1:2012 EN 1060-3:1997+A2:2009 IEC 80601-2-30: 2009+A1:2013
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 EN 62366-1:2015 + AC:2015/IEC 62366-1:2015 + COR1:2016
Software life-cycle	EN 62304:2006 + A1:2015/IEC 62304:2006+A1:2015
Biological evaluation	EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 10993-10:2010
Clinical Investigation	MEDDEV.2.7.1: 2016 ISO 81060-2:2013
Hazardous material control	RoHS Directive 2011/65/EU
RED	EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 300 328 V2.1.1 EN 62479: 2010