

**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 MONITORS: BPA-9301-GB

**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 ATTACHED**

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

**IDENTIFICATION NUMBER**

**CE 0123**

**(EC) CERTIFICATE(S):** NO.G1 16 11 82800 026



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

**START OF CE-MARKING:** 2018-10-25

**PLACE, DATE OF DECLARATION:** ZHONGSHAN, 2018-10-25

**SIGNATURE:**

NAME: *Kevin Tan*  
POSITION: R&D DIRECTOR

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

**Standards applied:**

<b>Risk management</b>	EN ISO 14971:2012
<b>Labeling</b>	EN ISO 15223-1:2016
<b>User manual</b>	EN 1041: 2008 +A1:2013
<b>General requirements for safety</b>	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 EN 60601-1-11:2015/ IEC 60601-1-11:2015
<b>Non-invasive sphygmomanometers General requirements</b>	EN ISO 81060-1:2012 EN 1060-3:1997+A2:2009 IEC 80601-2-30: 2009+A1:2013
<b>Electromagnetic compatibility</b>	EN 60601-1-2:2015/ IEC 60601-1-2:2014
<b>Usability</b>	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
<b>Software life-cycle</b>	EN 62304:2006 + A1:2015/IEC 62304:2006+A1:2015
<b>Biological evaluation</b>	EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 10993-10:2010
<b>Clinical Investigation</b>	MEDDEV.2.7.1: 2016 ISO 81060-2:2013
<b>Hazardous material control</b>	RoHS Directive 2011/65/EU
<b>Radio Equipment Directive 2014/53/EU</b>	Draft ETSI EN 301 489-1 V2.2.0:2017 Draft ETSI EN 301 489-17 V3.2.0:2017 EN 300 328 V2.1.1:2016 EN 62479:2010