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：2000

CLASSIFICATION - *ANNEX IX*: CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE: MDD ANNEX II

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 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

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

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

START OF CE-MARKING: 2018-5-14

PLACE, DATE OF DECLARATION: ZHONGSHAN，2018-5-14

SIGNATURE: *NAME:* Kevin Tan

POSITION:R&D DIRECTOR

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Standards applied:

Risk management	EN ISO 14971:2012
Labeling	EN ISO 15223-1:2016
User manual	EN 1041: 2008
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
Non-invasive sphygmomanometers General requirements	EN ISO 81060-1:2012 EN 1060-3:1997+A2:2009 IEC 80601-2-30:2013
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/ IEC 62366-1:2015
Software life-cycle	EN 62304:2006+AC: 2008
Biological evaluation	EN ISO 10993-1:2009 EN ISO 10993-5:2009 EN ISO 10993-10:2010
Clinical Investigation	MEDDEV.2.7.1: 2016 EN 1060-4: 2004