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：LS808-BS
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 M NCHEN, GERMANY

IDENTIFICATION NUMBER CE 0123

(EC) CERTIFICATE(S): NO.G10828000026REV.01

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

START OF CE-MARKING: 2018-5-18

PLACE, DATE OF DECLARATION: ZHONGSHAN，2020-5-18

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:

Risk management	EN ISO 14971:2012
Labeling	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
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
Radio Equipment Directive 2014/53/EU	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