# 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, 528437 ZHONGSHAN,GUANGDONG, CHINA

MEDICAL DEVICE: BLOOD PRESSURE MONITOR：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 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

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

START OF CE-MARKING: 2018-5-18

PLACE, DATE OF DECLARATION: ZHONGSHAN，2021-12-23

SIGNATURE: Kevin Tan

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 +A1:2013 |
| **General requirements for safety** | EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012<br>EN 60601-1-11:2015/ IEC 60601-1-11:2015 |
| **Non-invasive sphygmomanometers General requirements** | EN ISO 81060-1:2012<br>EN 1060-3:1997+A2:2009<br>IEC 80601-2-30: 2018 |
| **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<br>IEC 62366:2007+AMD1:2014 |
| **Software life-cycle** | EN 62304:2006 + A1:2015/IEC 62304:2006+A1:2015 |
| **Biological evaluation** | EN ISO 10993-1:2009<br>EN ISO 10993-5:2009<br>EN ISO 10993-10:2010 |
| **Clinical Investigation** | MEDDEV.2.7.1: 2016<br>ISO 81060-2:2013 |
| **Hazardous material control** | Parliament and Council Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment(RoHS) with its Amendment Directive (EU) 2015/863 |
| | REACH (EC) No 1907/2006 |
| **Radio Equipment Directive 2014/53/EU** | EN 301 489-1 V2.2.3<br>EN 301 489-17 V3.2.4<br>EN 61000-3-2:2014<br>EN 61000-3-3:2013<br>EN 300 328 V2.2.2<br>EN 62479:2010<br>EN 50663:2017 |