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 PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: BLOOD PRESSURE MONITORS：BC87

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 082800 0026 REV. 01

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

START OF CE-MARKING: 2021-7-1

PLACE, DATE OF DECLARATION: ZHONGSHAN，2021-12-21

SIGNATURE: Ken Zhai *NAME: KEN ZHAI*

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 EN 60601-1-11:2015/ IEC 60601-1-11:2015
Non-invasive sphygmomanometers General requirements	EN ISO 81060-1:2012 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 EN 62366-1:2015 + AC:2015/IEC 62366-1:2015 + COR1:2016
Software life-cycle	EN 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 (EU)2015/863