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

MANUFACTURER:	GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD. ADDRESS: ZONE A, NO.105, DONGLI ROAD, TORCH DEVELOPMENT DISTRICT, ZHONGSHAN, GUANGDONG, CHINA
MEDICAL DEVICE:	BLOOD PRESSURE MONITOR：TMB-2083-N
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, GEMANY

START OF CE-MARKING: 2021-03-31

PLACE, DATE OF DECLARATION: ZHONGSHAN，2021-03-31

SIGNATURE: Ken Zhai

NAME: KEN ZHAI
POSITION: R&D DIRECTOR

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Standards applied:

Risk management	EN ISO 14971:2019
Labelling	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/IEC 62304:2006+A1:2015
Biological evaluation	EN ISO 10993-1:2018 EN ISO 10993-5:2009 EN ISO 10993-10:2010
Clinical Investigation	MEDDEV.2.7.1: 2016 ISO 81060-2:2018
Hazardous material control	RoHS Directive 2015/863/EU
RED	Draft ETSI EN 301 489-1 V2.2.0 (2017-03) Draft ETSI EN 301 489-17 V3.2.0 (2017-03) EN 300 328 V2.1.1 (2016-11) EN 62479:2010