DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I Kevin Tan, a Director of Guangdong Transtek Medical Electronics Co.,Ltd Co.,Ltd ,

Name of a Company Director | Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker[a]	GuangdongTranstek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand[c]	Kinetik Wellbeing	Model[d]	TMB-2080

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker[a]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand[c]	TRANSTEK	Model[d]	TMB-1491

Existing validated blood pressure measuring device.

which has previously passed the 2010 protocol, the results of which were published as follows:

Title: Validation of Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol

Authors: Tian H., Zeng S., Zhong X., Gong W. and Liu W.

Publication: Blood Press Monit. 2015 May

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1–18.

Part I	1	Algorithm for Oscillometric Measurements	Yes ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	

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	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☐	No ☒	
	13	Software other than Algorithm	Yes ☒	No ☐	
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐	
	15	Printing Facilities	Yes ☐	No ☐	N/A[g] ☒
	16	Communication Facilities	Yes ☐	No ☐	N/A[g] ☒
	17	Power Supply	Yes ☒	No ☐	
	18	Other Facilities	Yes ☐	No ☐	N/A[g] ☒

An explanation of each item ticked "Yes" must be included in *Section B* or on a separate sheet.

Notes:
a Provide the name and address of the actual maker of the device.
b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

See attached document

SECTION C Please check that the following are included with the application

A manual for the validated device	☒
A manual for the device for which equivalence is being sought	☒
Completed DET9 Form	☒
An image of the device for which equivalence is being sought	☒
An image of the screen layout of validated device*	☒
An image of the screen layout of the device for which equivalence is being sought*	☒

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director Kevin Tan

Company Stamp/Seal

Name Kevin Tan

Date October 14 , 2021

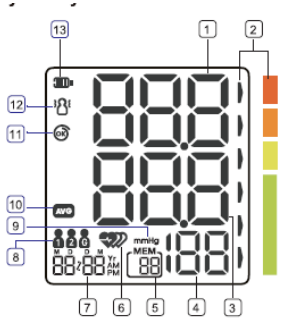
Signature of Witness

Name Jie.Zhu

Address Zone A, No.105 ,Dongli Road, Torch Development District,

528437,Zhongshan,Guangdong,China

Comparison of the Kinetik Wellbeing TMB-2080 with the TRANSTEK TMB-1491

Devices – Item 9	Kinetik Wellbeing TMB-2080	TRANSTEK TMB-1491
Pictures		
Display Image		
Validation	/	ESH 2010
Category	*Upper Arm device for self measurement of blood pressure*	*Upper Arm device for self measurement of blood pressure*
Casing – Item 10	***Dimensions*** 100x129x45mm	***Dimensions*** *110mm*110mm*40mm*

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	Ports *Cuff port* ***Features*** Kinetik Wellbeing printing Blood pressure measurement WHO Classification Pulse rate Button printing	***Ports*** *Cuff port* ***Features*** Transtek printing Blood pressure measurement WHO Classification Pulse rate Button printing
Display – Item 11	*Type* LCD	*Type* *LCD*
Carrying/Mounting Facilities – Item 12	None	None
Software other than Algorithm – Item 13	*Dual Users* *90 sets memory/per user (2 users total) + guest mode* *WHO Indicator* *mmHg unit*	*One User* *60 sets memories/per user* *WHO Indicator* *mmHg unit or kPa*
Memory Capacity **Item 14**	*90 sets memories/per user (2 users total) + guest mode*	*60 sets memories/per user*
Printing Facilities Item 15	N/A	*N/A*
Communication Facilities – Item 16	N/A	N/A

Power Supply **Item 17**	*4 dry cells 1.5V AAA, 6V DC* *5V/1Apower adapter*	*4 dry cells 1.5V AAA, 6V DC*
Other differences	*Other Details on Equivalent device that are different to Validated device* *N/A*	*Other Details on Validated device that are different to Equivalent device* N/A
Same Criteria	***Measurement*** ***Accuracy*** *Pressure:5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* ***Method*** *Oscillographic testing mode* ***Ranges*** *Rated cuff pressure:* *0 mmHg~299 mmHg* *Measurement pressure:* *SYS: 60 mmHg ~ 230 mmHg* *DIA: 40 mmHg ~ 130 mmHg* *Pulse value: (40-199) beat/minute* ***Inflation*** *Automatic inflation* ***Deflation*** *Automatic deflation*	***Measurement*** ***Accuracy*** *Pressure:5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* ***Method*** *Oscillographic testing mode* ***Ranges*** *Rated cuff pressure:* *0kpa - 40kpa (0mmHg~300mmHg)* *Measurement pressure:* *SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)* *DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)* *Pulse value: (40-199)beat/minute* ***Inflation*** *Automatic inflation* ***Deflation*** *Automatic deflation*

	Cuffs (Please state sizes and materials used) 22CM-42CM, Nylon ***Sensors*** *Piezo-resistive* ***Measurement Records*** *2 users x 90 readings each (plus guest mode)* ***Measurements other than blood pressure*** *Pulse rate* ***Buttons/Switches*** *Power button – ON SYMBOL* *Memory button - MEM* *User button – USER 1 & USER 2 SYMBOL* *Analysis – N/A* *Event Marking – N/A* *Communication – N/A* ***Display/Symbols/Indicators*** ***Preparation*** *Automatic Zero setting* ***Measurement Procedure*** *Inflation symbol* *Pressure value indication*	***Cuffs(Please state sizes and materials used)*** *22cm-32cm or 22-42cm, nylon* ***Sensors*** *Piezo-resistive* ***Measurement Records*** *60 measurement records* ***Measurements other than blood pressure*** *Pulse rate* ***Buttons/Switches*** *Power button – START/STOP button* *Memory button – M button* *Set button – S button* *Analysis – N/A* *Event Marking – N/A* *Communication – N/A* ***Display/Symbols/Indicators*** ***Preparation*** *Automatic Zero setting* ***Measurement Procedure*** *Inflation symbol* *Pressure value indication*

	Current time ***Post measurement*** *Upper Arm* ***Measurement Records*** *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time* *Memory Query symbol* ***Date and Time*** *Time is displayed in the lower left corner of LCD* ***Power*** *Low power* ***Function*** *Measuring blood pressure and heart rare* *Recall measurement records* *Delete measurement records* ***Communication*** *N/A* ***Features*** *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*	*Current time* ***Post measurement*** *Upper Arm* ***Measurement Records*** *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time* *Memory Query symbol* ***Date and Time*** *Time is displayed lower right corner of LCD* ***Power*** *Low power* ***Function*** *Measuring blood pressure and heart rate* *Recall measurement records* *Delete measurement records* ***Communication*** *N/A* ***Features*** *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*

Comparable Criteria	***Measurement*** *Cuffs (Please state sizes and materials used)* *About 22cm-42cm, Nylon* *Measurement Records* *90 sets/per user, total two users (plus guest measurement)* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate*	***Measurement*** *Cuffs (Please state sizes and materials used)* *About 22cm-32cm or 22-42cm, nylon* *Measurement Records* *60 sets/per user,total two users* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate*

Comments		
Recommendation	**Recommended**	
Date	**January 2022**	