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 ElectronicsCo.,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]	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]	Alvita/Kinetik Wellbeing	Model[d]	TMB-2083-N

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 ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	

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Fax + 353 1 278 3835 Web www.dableducational.org

	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.

Declaration of Equivalence Form

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.

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 8 April ,2022

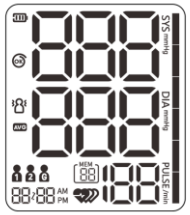
Signature of Witness Caroline Liu

Name Caroline.liu

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

528437 Zhongshan,Guangdong,China

Comparison of the Alvita/Kinetik Wellbeing TMB-2083-N with the Guangdong Transtek Medical TMB-1491

Devices – Item 9	Alvita/Kinetik Wellbeing TMB-2083-N	Guangdong Transtek Medical TMB-1491
Pictures		
Display Image		
Validation	*Arm device for self measurement of blood pressure*	ESH 2010
Category	*Arm device for self measurement of blood pressure*	*Arm device for self measurement of blood pressure*
Casing – Item 10	*Dimensions* 100x130x44mm *Ports*	*Dimensions* *110mm*110mm*40mm* *Ports*

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	Piezo-resistive *Measurements other than Blood Pressure* ***Buttons/Switches*** *Power button – ON SYMBOL* *Memory button – NOTEBOOK SYMBOL* *User button – USER 1 & USER 2 SYMBOL* *Triple mode - Switch* *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* *Measurement Records* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate*	*Piezo-resistive* *Measurements other than Blood Pressure* *Pulse rate* ***uttons/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* *Measurement Records* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate*

	Cuff port *Features* Alvita printing Blood pressure measurement WHO classification Pulse rate Button printing	*Cuff port* *Features* Transtek printing Blood pressure measurement WHO classification Pulse rate Button printing
Display – Item 11	*Type* LCD LCD V.A 71㎜*82mm	*Type* *LCD* LCD V.A.60×40.5mm
Carrying/Mounting Facilities – Item 12	None	None
Software other than Algorithm – Item 13	*Dual Users* *90 sets memories/per user (+ guest)* *2 grade indicator* *mmHg unit*	*Dual Users* *60 sets memories/per user* *2 grade indicator* *mmHg unit*
Memory Capacity Item 14	*90 sets memories/per user (+ guest)*	*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	*4dry cells 1.5V AAA, 6V* *5V 1A power adapter*	*4 dry cells 1.5V AAA*

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* *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* *Cuffs (Please state sizes and materials used)* 22CM-42CM,Nylon *Sensors*	***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)* *About 22cm-32cm or 32-42cm,polyester* *Sensors*

	Measurement time *Memory Query symbol* *Power* *Low power* *Features* *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*	*Measurement time* *Memory Query symbol* *Power* *Low power* *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* ***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 32-42cm, polyester* *Measurement Records* *60 sets/per user,total two users* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time*

	Function *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records*	*Function* *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records*

Comments		
Recommendation	**Recommended**	
Date	**May 2022**	