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Declaration of Equivalence Form

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 ,
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-1117-S

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-988

Existing validated blood pressure measuring device.

which has previously passed the ESH2002 protocol, the results of which were published as follows:

Title: Validation of the Transtek TMB-988 wrist blood pressure monitor for home blood pressure monitoring according to the International Protocol.

Author: Tian HY, Liu WJ, Li SG, Song Z, Gong W.

Publication: *Blood Press Monit* 2010;**15**(6):326-8 doi: 10.1097/MBP.0b013e32833f56fb
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 ☒	
	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.

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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	☒
An image of the validated device	☒
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

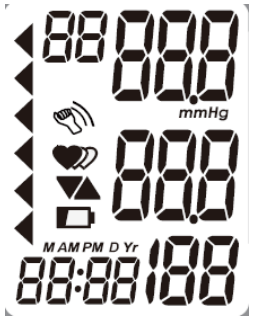
Signature of Witness Caroline Liu

Name Caroline.liu

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

528437 Zhongshan, Guangdong, China

Comparison of the Alvita/Kinetik Wellbeing TMB-1117-S with the Guangdong Transtek Medical TMB-988

Devices – Item 9	Alvita/Kinetik Wellbeing TMB-1117-S	Guangdong Transtek Medical TMB-988
Pictures		
Display Image		
Validation		ESH 2010
Category	*wrist device for self measurement of blood pressure*	*wrist device for self measurement of blood pressure*
Casing – Item 10	*Dimensions* *62mm*75mm*31mm*	*Dimensions* *73mm*67.5mm*22.5mm*

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	Ports *Cuff port* *Features* Alvita 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 LCD V.A32㎜*44mm	*Type* LCD LCD V.A.35mm×41mm
Carrying/Mounting Facilities – Item 12	None	None
Software other than Algorithm – Item 13	One User 60 sets memories/per user 2 grade indicator mmHg unit	Dual Users 60 sets memories/per user 2 grade indicator mmHg unit
Memory Capacity **Item 14**	60 sets memories/one user	60 sets memories/two user
Printing Facilities Item 15	N/A	*N/A*
Communication Facilities – Item 16	N/A	N/A

Power Supply **Item 17**	2 dry cells 1.5V AAA	2 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* 5°C-40°C within±3mmHg Pulse value:±5% *Method* *Oscillographic testing mode* *Ranges* *Rated cuff pressure:* *Pressure: 0mmHg~299mmHg* *Pulse value: (40-199)beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Cuffs (Please state sizes and materials used)* 13.5CM-21.5CM,*polyester*	***Measurement*** *Accuracy* 5°C-40°C within±3mmHg(0.4kPa) Pulse value:±5% *Method* *Oscillographic testing mode* *Ranges* *Rated cuff pressure:* *Pressure: 0kpa – 39.9kpa (0mmHg~299mmHg)* *Pulse value: (40-199) beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Cuffs(Please state sizes and materials used)* 13.5CM-21.5CM *polyester*

	Sensors *Piezo-resistive* *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power button – 'ON SYMBOL' button* *Memory button – MEM button* *Set button – SET 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* *Measurement time* *Memory Query symbol* *Power*	*Sensors* *Piezo-resistive* *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power button – START/STOP button* *Memory button – MEM button* *Set button – SET 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* *Measurement time* *Memory Query symbol* *Power*

	Low power *Features* *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*	*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 13.5cm-21.5cm, polyester* *Measurement Records* *60 sets/per user,total one user* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate*	***Measurement*** *Cuffs (Please state sizes and materials used)* *About 13.5cm-21.5cm,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*
Comments		
Recommendation	**RECOMMENDED**	
Date	**May 2022**	