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]	Kinetik Wellbeing	Model[d]	TMB-1970

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-986

Existing validated blood pressure measuring device.

which has previously passed the 2002 protocol, the results of which were published as follows:

Title: Validation of the Transtek blood pressure monitor TMB-986 for self-measurement according to the European Society of Hypertension international Protocol.

Authors: Wen Jun Liua, Su Gang Lia, Zhe Songa and Wei Gongb

Publication: Blood Press Monit 2010;15(5):278-80 doi: 10.1097/MBP.0b013e32833e43ca
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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Tel + 353 1 278 0247 Email info@dableducational.org
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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

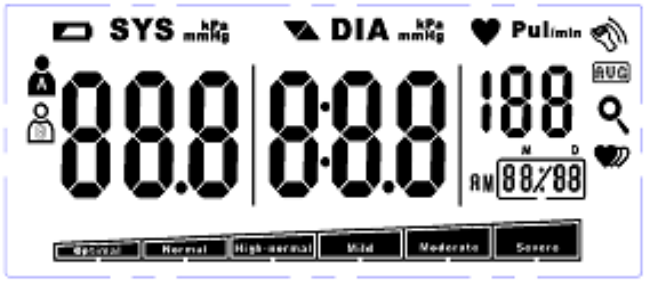
Date 9 September 2021

Signature of Witness Jie Zhu

Name Jie.Zhu

Address Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China

Comparison of the Kinetic Wellbeing TMB-1970 with the TRANSTEK TMB-986

Devices – Item 9	Kinetic Wellbeing TMB-1970	TRANSTEK TMB-986
Pictures		
Display Image		
Validation	*Arm device for self measurement of blood pressure*	ESH 2002
Category	*Arm device for self measurement of blood pressure*	*Arm device for self measurement of blood pressure*
Casing – Item 10	*Dimensions* *102mm*107mm*40mm* *Ports* *Cuff port* *Features* Kinetik Wellbeingprinting Button printing	*Dimensions* *182mm*100mm*40mm* *Ports* *Cuff port* *Features* Transtek printing Button printing
Display – Item 11	*Type* LCD	*Type* *LCD*

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Carrying/Mounting Facilities – Item 12	None *Dimensions* *52mm*58mm*	None
Software other than Algorithm – Item 13	*One User* *90 sets memories/per user* *1 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*	*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*	*4dry cells 1.5V AAA & 6V/1Apower adapter*
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:within±3mmHg Pulse value:±5% Max *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)* 22CM-42CM,nylon *Sensors* *Piezo-resistive*	***Measurement*** *Accuracy* *Pressure:5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* *Method* *Oscillographic testing mode* *Ranges* *Rated cuff 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)* 22CM-42CM *polyester* *Sensors* *Piezo-resistive*

	Measurement Records *Measurements other than Blood Pressure* *Pluse rate* ***Buttons/Switches*** *power button* *Memory button* ***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.*	*Measurement Records* *Measurements other than Blood Pressure* *Pluse rate* ***Buttons/Switches*** *Power button* *Memory button* *Set button* ***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.*
Comparable Criteria	***Measurement*** *Cuffs (Please state sizes and materials used)* *About* 22CM-42CM,nylon *Measurement Records* *90 sets/per user,total one user* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)*	***Measurement*** *Cuffs (Please state sizes and materials used)* *About* 22CM-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*	*Diastolic blood pressure (DIA)* *Pulse rate*

Comments		
Recommendation	**Recommended**	
Date	**November 2021**	