

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-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 home blood pressure monitoring according to the International Protocol](#)

Authors: [Liu WJ, Lia SG, Songa Z, Gongb W.](#)

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>

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
- 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 2 April, 2022





Signature of Witness Caroline Liu



Name Caroline.liu

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

Comparison of the Alvita/Kinetik Wellbeing TMB-1970 with the Guangdong Transtek Medical TMB-986

Devices – Item 9	Alvita/Kinetik Wellbeing TMB-1970	Guangdong Transtek Medical TMB-986
Pictures		
Display Image		
Validation	<p>Arm device for self measurement of blood pressure</p>	<p>ESH 2002</p>
Category	<p>Arm device for self measurement of blood pressure</p>	<p>Arm device for self measurement of blood pressure</p>
Casing – Item 10	<p>Dimensions 102mm*107mm*40mm</p> <p>Ports</p> <p>Cuff port</p>	<p>Dimensions 182mm*100mm*39mm</p> <p>Ports</p> <p>Cuff port</p>

	<i>Features</i> Alvita printing Button printing	<i>Features</i> Transtek printing Button printing
Display – Item 11	<i>Type</i> LCD LCD V.A.52*58mm	<i>Type</i> LCD LCD V.A.128*50mm
Carrying/Mounting Facilities – Item 12	None	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, 6V	4dry cells 1.5V AAA, 6V & 6V/1A power adapter
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> N/A	<i>Other Details on Validated device that are different to Equivalent device</i> N/A

<p>Same Criteria</p>	<p>Measurement</p> <p>Pressure:</p> <p>5°C-40°C within ±3mmHg</p> <p>pulse value:±5%</p> <p>Method</p> <p><i>Oscillographic testing mode</i></p> <p>Ranges</p> <p><i>Rated cuff pressure:</i></p> <p><i>Pressure: 0mmHg~299mmHg</i></p> <p><i>Pulse value: (40-199)beat/minute</i></p> <p><i>Measurement pressure:</i></p> <p><i>SYS: 60mmHg~230mmHG</i></p> <p><i>DIA: 40mmHg~130mmHg</i></p> <p>Inflation</p> <p><i>Automatic inflation</i></p> <p>Deflation</p> <p><i>Automatic deflation</i></p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>22CM-42CM,nylon</p> <p>Sensors</p> <p><i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Pulse rate</i></p>	<p>Measurement</p> <p>Pressure:</p> <p>5°C-40°C within ±0.4kpa(3mmHg)</p> <p>pulse value:±5%</p> <p>Method</p> <p><i>Oscillographic testing mode</i></p> <p>Ranges</p> <p><i>Rated cuff pressure:</i></p> <p><i>Pressure: 0kpa – 40.0kpa (0mmHg~300mmHg)</i></p> <p><i>pulse value: (40-199) beat/minute</i></p> <p><i>Measurement pressure: 5.33kPa-30.67kPa (40mmHg-230mmHg)</i></p> <p>Inflation</p> <p><i>Automatic inflation</i></p> <p>Deflation</p> <p><i>Automatic deflation</i></p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <p>22CM-42CM,22-32CM polyester</p> <p>Sensors</p> <p><i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Pulse rate</i></p>
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	<p>Buttons/Switches</p> <p><i>Power button: START/STOP</i></p> <p><i>Memory button: MEM</i></p> <p><i>Set button: SET</i></p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p><i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i></p> <p><i>Inflation symbol</i></p> <p><i>Pressure value indication</i></p> <p><i>Current time</i></p> <p><i>Measurement Records</i></p> <p><i>Systolic blood pressure (SYS)</i></p> <p><i>Diastolic blood pressure (DIA)</i></p> <p><i>Pulse rate</i></p> <p><i>Measurement time</i></p> <p><i>Memory Query symbol</i></p> <p><i>Power</i></p> <p><i>Low power</i></p> <p><i>Features</i></p> <p><i>Measuring during inflation</i></p> <p>Algorithms</p> <p><i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>	<p>Buttons/Switches</p> <p><i>Power button: START/STOP</i></p> <p><i>Memory button: MEM</i></p> <p><i>Set button: SET</i></p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <p><i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i></p> <p><i>Inflation symbol</i></p> <p><i>Pressure value indication</i></p> <p><i>Current time</i></p> <p><i>Measurement Records</i></p> <p><i>Systolic blood pressure (SYS)</i></p> <p><i>Diastolic blood pressure (DIA)</i></p> <p><i>Pulse rate</i></p> <p><i>Measurement time</i></p> <p><i>Memory Query symbol</i></p> <p><i>Power</i></p> <p><i>Low power</i></p> <p><i>Features</i></p> <p><i>Measuring during inflation</i></p> <p>Algorithms</p> <p><i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>
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<p>Comparable Criteria</p>	<p>Measurement</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>About 22CM-42CM,nylon</p> <p><i>Measurement Records</i></p> <p>90 sets/per user,total one user</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p><i>Systolic blood pressure (SYS)</i></p> <p><i>Diastolic blood pressure (DIA)</i></p> <p><i>Pulse rate</i></p>	<p>Measurement</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>About 22CM-42CM,22-32CM polyester</p> <p><i>Measurement Records</i></p> <p>60 sets/per user,total two users</p> <p>Display/Symbols/Indicators</p> <p><i>Post Measurement</i></p> <p><i>Systolic blood pressure (SYS)</i></p> <p><i>Diastolic blood pressure (DIA)</i></p> <p><i>Pulse rate</i></p>
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<p>Comments</p>	
<p>Recommendation</p>	<p>Recommended</p>
<p>Date</p>	<p>May 2022</p>