

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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SECTION A - Please complete all items.

I **Ken Zhai**, 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 **Kinetik Medical Devices Limited** Address **Unit 3, Perrywood Business Park, Honeycrook Lane, Salfords, Surrey RH15DZ**

Manufacturer^b **Harvard Medical Devices Ltd. HK** Address **1002, Railway Plaza, TST, HK**

Brand^c **Kinetik Wellbeing** Model^d **WBP1**

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 **ESH2010** protocol, the results of which were published as follows:

Tian H., Zeng S., Zhong X., Gong W. and Liu W. Validation of Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol revision 2010. Blood Pressure Monitor. 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 <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 ^e <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^e <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^e <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 Ken Zhai _____

Name Ken Zhai

Date August 21st 2019,



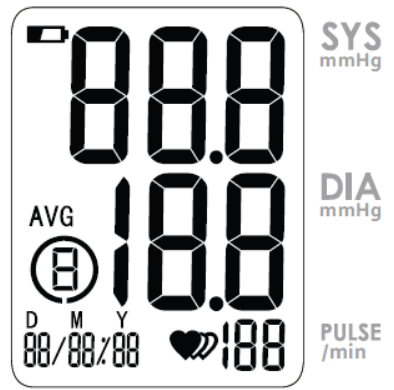
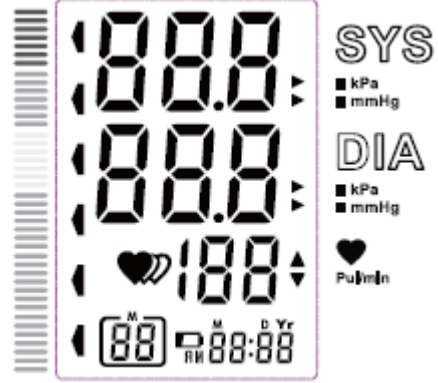


Signature of Witness Elly He _____

Name Elly He

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

Comparison of Kinetik Blood Pressure Monitor WBP1 Wellbeing with Transtek Blood Pressure Monitor TMB-1491

Devices – Item 9	<i>Kinetik Blood Pressure Monitor WBP1 Wellbeing</i>	<i>Transtek Blood Pressure Monitor TMB-1491</i>
Pictures		
Display Image		

Validation	/	ESH 2010
Category	<i>Upper arm device for self measurement of blood pressure</i>	<i>Upper arm device for self measurement of blood pressure</i>
Casing – Item 10	<p><i>Dimensions</i></p> <p><i>Approx.120.2mm×108.2mm×68.5mm</i></p> <p><i>Ports</i></p> <p><i>Cuff port</i></p> <p><i>Features</i></p> <p><i>Blood pressure measurement</i></p> <p><i>Heart rate</i></p> <p><i>WHO classification</i></p>	<p><i>Dimensions</i></p> <p>110mm×110mm×41mm</p> <p><i>Ports</i></p> <p><i>Cuff port</i></p> <p><i>Features</i></p> <p><i>Blood pressure measurement</i></p> <p><i>Heart rate</i></p> <p><i>WHO classification</i></p>
Display – Item 11	<p><i>Type</i></p> <p><i>LCD</i></p>	<p><i>Type</i></p> <p><i>LCD</i></p>
Carrying/Mounting Facilities – Item 12	<i>None</i>	<i>None</i>
Software other than Algorithm – Item 13	<p><i>One user</i></p> <p><i>90 recorded measurements</i></p> <p><i>WHO indicator</i></p> <p><i>Unit: mmHg</i></p>	<p><i>One user</i></p> <p><i>60 recorded measurements</i></p> <p><i>WHO indicator</i></p> <p><i>Unit: mmHg or kPa</i></p>
Memory Capacity Item 14	<p><i>Number of stored measurements</i></p> <p><i>90 recorded measurements</i></p>	<p><i>Number of stored measurements</i></p> <p><i>60 recorded measurements</i></p>

Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	4xAAA batteries, 6V DC	4xAAA batteries, 6V DC
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> <i>New MCU in order to fulfill the new ESD requirements</i>	<i>Other Details on Validated device that are different to Equivalent device</i> -
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p><i>Pressure:</i></p> <p><i>5°C-40°C within±3mmHg(0.4kPa)</i></p> <p><i>Pulse value:±5%</i></p> <p><i>Method</i></p> <p><i>Oscillographic method</i></p> <p><i>Ranges</i></p> <p><i>Rated cuff pressure:</i></p> <p><i>0mmHg~299mmHg(0kPa ~ 39.9kPa)</i></p> <p><i>Measurement pressure:</i></p> <p><i>SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)</i></p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p><i>Pressure:</i></p> <p><i>5°C-40°C within±3mmHg(0.4kPa)</i></p> <p><i>Pulse value:±5%</i></p> <p><i>Method</i></p> <p><i>Oscillographic method</i></p> <p><i>Ranges</i></p> <p><i>Rated cuff pressure:</i></p> <p><i>0mmHg~299mmHg(0kPa ~ 39.9kPa)</i></p> <p><i>Measurement pressure:</i></p> <p><i>SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)</i></p>

	<p><i>DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)</i></p> <p><i>Pulse value: (40-199)beat/minute</i></p> <p><i>Inflation</i></p> <p><i>Automatic inflation</i></p> <p><i>Deflation</i></p> <p><i>Automatic deflation</i></p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>22-42cm, nylon</p> <p><i>Sensors</i></p> <p>Piezo-resistive</p> <p><i>Measurement Records</i></p> <p>90 measurement records</p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Pulse rate</i></p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>START/STOP button</p> <p><i>Measurement Records</i></p> <p>M button</p> <p><i>Function</i></p> <p>M button</p>	<p><i>DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)</i></p> <p><i>Pulse value: (40-199)beat/minute</i></p> <p><i>Inflation</i></p> <p><i>Automatic inflation</i></p> <p><i>Deflation</i></p> <p><i>Automatic deflation</i></p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <p>22-32cm and 22-42cm, nylon</p> <p><i>Sensors</i></p> <p>Piezo-resistive</p> <p><i>Measurement Records</i></p> <p>60 measurement records</p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Pulse rate</i></p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>START/STOP button</p> <p><i>Measurement Records</i></p> <p>MEM button</p> <p><i>Function</i></p> <p>MEM button</p>
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	<p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</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</i></p> <p><i>Pressure value indication</i></p> <p><i>Current time</i></p> <p><i>Post Measurement</i></p> <p>Upper arm</p> <p><i>Measurement Records</i></p> <p><i>Systolic pressure (SYS)</i></p> <p><i>Diastolic pressure (DIA)</i></p> <p><i>Pulse rate</i></p>	<p>SET button</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</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</i></p> <p><i>Pressure value indication</i></p> <p><i>Current time</i></p> <p><i>Post Measurement</i></p> <p>Upper arm</p> <p><i>Measurement Records</i></p> <p><i>Systolic pressure (SYS)</i></p> <p><i>Diastolic pressure (DIA)</i></p> <p><i>Pulse rate</i></p>
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	<p><i>Date and Time</i></p> <p>Display measurement time in the lower left corner of LCD</p> <p><i>Power</i></p> <p>Low battery</p> <p><i>Function</i></p> <p>Measure blood pressure and heart rate</p> <p>Recall measurement records</p> <p>Delete measurement records</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>Measuring during inflation</p> <p><i>Not described</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Recall the average value of the last three measurements</p> <p><i>Diagnostic</i></p> <p>N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i></p> <p>Measure blood pressure and heart rate</p>	<p><i>Date and Time</i></p> <p>Display measurement time in the lower right corner of LCD</p> <p><i>Power</i></p> <p>Low battery</p> <p><i>Function</i></p> <p>Measure blood pressure and heart rate</p> <p>Recall measurement records</p> <p>Delete measurement records</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>Measuring during inflation</p> <p><i>Not described</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Recall the average value of the last three measurements</p> <p><i>Diagnostic</i></p> <p>N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i></p> <p>Measure blood pressure and heart rate</p>
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	<p><i>Communication</i></p> <p>N/A</p>	<p><i>Communication</i></p> <p>N/A</p>
Comparable Criteria	<p><i>Appearance</i></p> <p><i>Approx.120.2mm×108.2mm×68.5mm, color different</i></p> <p><i>Power</i></p> <p><i>Only supplied by 4*AAA battery</i></p> <p><i>Cuff size</i></p> <p><i>22-42cm</i></p>	<p><i>Appearance</i></p> <p><i>110mm*110mm*41mm, color different</i></p> <p><i>Power</i></p> <p><i>Only supplied by 4*AAA battery</i></p> <p><i>Cuff size</i></p> <p><i>22-32cm and 22-42cm</i></p>

Comments		This equivalence relates to the blood pressure measurement characteristics of both devices. It is for home use only. Self-measurement.
Recommendation	Recommended	
Date	September 2019	