

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 **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	Carematix Inc.	Address	209 W Jackson Blvd, Suite 401, Chicago, IL , 60606
Manufacturer ^b	Guangdong Transtek Medical Electronics Co.,Ltd	Address	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand ^c	Blipcare	Model ^d	BP 800

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 reversion 2010. 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 <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 ^e <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 ^e <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 checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A ^e <input 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
- 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, titles, or controls 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 October 14th, 2019

Signature of Witness Endless Chan

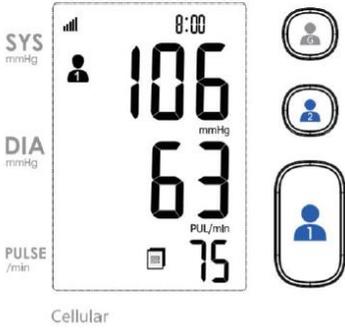
Name Endless Chan

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



Company Stamp/Seal

Comparison of Blipcare Blood Pressure Monitor BP800 with Transtek Blood Pressure Monitor TMB-1491

Devices – Item 9	<i>Blipcare Blood Pressure Monitor BP800</i>	<i>Transtek Blood Pressure Monitor TMB-1491</i>
Pictures	 <p>The image shows the Blipcare BP800 device, which is white with blue accents. It features a large LCD screen and three buttons on the right side. A grey and green arm cuff is attached to the device.</p>	 <p>The image shows the Transtek TMB-1491 device, which is white with a black arm cuff. It has a large LCD screen and several buttons, including a prominent blue 'START' button.</p>
Display Image	 <p>The display shows a digital readout of blood pressure. The top line shows 'SYS' and 'mmHg' with a value of '106'. The second line shows 'DIA' and 'mmHg' with a value of '63'. The third line shows 'PULSE' and '/min' with a value of '75'. There are also icons for signal strength, time (8:00), and user selection.</p>	 <p>The display shows a digital readout of blood pressure. The top line shows 'SYS' and 'mmHg' with a value of '100.0'. The second line shows 'DIA' and 'mmHg' with a value of '60.0'. The third line shows a heart icon and 'PUL/min' with a value of '188'. The bottom line shows a battery icon and 'M D Yr' with values '88 88 88'.</p>
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>118mm × 126mm × 72mm</p> <p><i>Ports</i></p> <p>Cuff port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p>	<p><i>Dimensions</i></p> <p>110mm × 110mm × 41mm</p> <p><i>Ports</i></p> <p>Cuff port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p> <p>WHO classification</p>
Display – Item 11	<p><i>Type</i></p> <p>LCD</p>	<p><i>Type</i></p> <p>LCD</p>
Carrying/Mounting Facilities – Item 12	<p>None</p>	<p>None</p>
Software other than Algorithm – Item 13	<p>two user</p> <p>Two users can record 170 measurements</p> <p>Unit: mmHg</p>	<p>One user</p> <p>60 recorded measurements</p> <p>WHO indicator</p> <p>Unit: mmHg or kPa</p>
Memory Capacity Item 14	<p><i>Number of stored measurements</i></p> <p>Two users can record 170 measurements</p>	<p><i>Number of stored measurements</i></p> <p>60 recorded measurements</p>

Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	4xAAA batteries	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>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, dacron</p> <p><i>Sensors</i></p> <p>Piezo-resistive</p> <p><i>Measurement Records</i></p> <p>Two users can record 170 measurements</p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Pulse rate</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>22-32cm 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>
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	<p>Buttons/Switches</p> <p><i>Power</i></p> <p>GUEST/USER 2/USER 1</p> <p><i>Measurement Records</i></p> <p>N/A</p> <p><i>Function</i></p> <p>GUEST/USER 2/USER 1</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>Automatic Zero setting</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> <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>Automatic Zero setting</p>
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	<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><i>Date and Time</i></p> <p>Time is displayed in upper right hand corner</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><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><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>
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	<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>N/A</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>Communication</i></p> <p>N/A</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>Communication</i></p> <p>N/A</p>
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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>
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Comments		<p><i>This equivalence relates to the blood pressure measurement characteristics of both devices. It is for home use only. Self-measurement.</i></p>
Recommendation	Recommended	
Date	October 2019	