

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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 **PIKDARE S.r.l** Address **Via Saldarini Catelli 10,22070 - Casnate con Bernate (CO)-Italy**

Brand^c **Pic** Model^d **clearRAPID**

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 ^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 checked="" type="checkbox"/>	No <input 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 October 11th, 2018




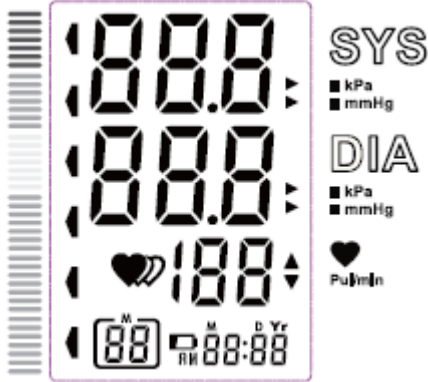
Signature of Witness Elly He

Name Elly He

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



Comparison of Pic Solutions clearRAPID Automatic Blood Pressure Monitor with Transtek Blood Pressure Monitor TMB-1491

<p>Devices – Item 9</p>	<p><i>Pic Solutions clearRAPID Automatic Blood Pressure Monitor</i></p>	<p><i>Transtek Blood Pressure Monitor TMB-1491</i></p>
<p>Pictures</p>		
<p>Display Image</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>100mm×186mm×35mm</p> <p><i>Ports</i></p> <p><i>Cuff port and DC power port</i></p> <p><i>Features</i></p> <p><i>Blood pressure measurement</i></p> <p><i>Heart rate</i></p> <p><i>ESH 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	<i>LCD</i>	<i>LCD</i>
Carrying/Mounting Facilities – Item 12	<i>With a storage bag</i>	<i>None</i>
Software other than Algorithm – Item 13	<p><i>Two users</i></p> <p><i>100 recorded measurements per each user</i></p>	<p><i>One user</i></p> <p><i>60 recorded measurements</i></p>

	<p>ESH indicator</p> <p>Unit: mmHg</p>	<p>WHO indicator</p> <p>Unit: mmHg or kPa</p>
<p>Memory Capacity</p> <p>Item 14</p>	<p>100 recorded measurements per each user</p>	<p>60 recorded measurements</p>
<p>Printing Facilities</p> <p>Item 15</p>	<p>N/A</p>	<p>N/A</p>
<p>Communication Facilities – Item 16</p>	<p>N/A</p>	<p>N/A</p>
<p>Power Supply</p> <p>Item 17</p>	<p>4xAAA batteries, 6V DC or adapter 6V/ 1000mA.</p>	<p>4xAAA batteries, 6V DC</p>
<p>Other differences</p>	<p><i>Other Details on Equivalent device that are different to Validated device</i></p> <p><i>New MCU in order to fulfill the new ESD requirements (last production with old MCU in Oct 2018)</i></p>	<p><i>Other Details on Validated device that are different to Equivalent device</i></p> <p>N/A</p>
<p>Same Criteria</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>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><i>22-42cm, nylon</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><i>22-32cm and 22-42cm, nylon</i></p>
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	<p><i>Sensors</i></p> <p>Piezo-resistive</p> <p><i>Measurement Records</i></p> <p>100 measurement records per each user</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse rate</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>START/STOP key</p> <p><i>Measurement Records</i></p> <p>Memory key</p> <p><i>Function</i></p> <p>Setting Key</p> <p>Memory Key</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>Pulse rate</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>
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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><i>Display/Symbols/Indicators</i></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>Post Measurement</i></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><i>Display/Symbols/Indicators</i></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>Post Measurement</i></p>
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	<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> <p>Delete measurement records</p> <p><i>Communication</i></p> <p>N/A</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> <p>Delete measurement records</p> <p><i>Communication</i></p> <p>N/A</p>
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	<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 ESH 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><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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<p>Comparable Criteria</p>	<p><i>Appearance</i></p> <p><i>100mm*186mm*35mm, color different</i></p> <p><i>Power</i></p> <p><i>Except 4*AAA battery, also can be supplied by authorized AC adapter</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>

<p>Comments</p>	<p>This equivalence relates to the blood pressure measurement characteristics of both devices. It is for home use only. Self-measurement.</p>
<p>Recommendation</p>	<p>Recommended</p>
<p>Date</p>	<p>12th February 2019</p>