

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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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.p.A** Address **Via saldarina Catelli 10-22-70-Casinate con Bernate (CO)-Italy**
 Brand^c **PiC** Model^d **MaxiRAPID REF02022535000000**

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 **2010** protocol, the results of which were published as follows:

Title: Validation of the Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension international Protocol.

Authors: Hui Yong Tian,Si Jian Zeng,Xiao Yan Zhong,Wei Gong and Wen Jun Liu.

Publication: Blood Press Monit 2010;15(6):326-8 doi:10.1097/MBP.0b013e32833f56fb

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 August 17, 2020

Signature of Witness Jie Zhu

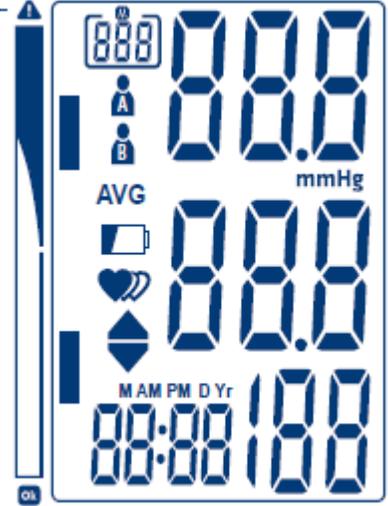
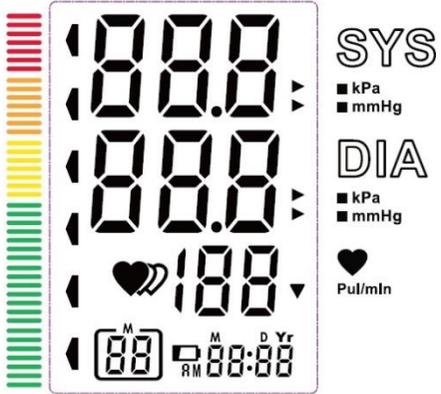


Name Jie.Zhu

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

Comparison of the PiC MaxiRAPID with the TRANSTEK TMB-1491

Devices – Item 9	PiC MaxiRAPID REF 02022535000000	TRANSTEK TMB-1491
<p>Pictures</p>		

<p>Display Image</p>	 <p>The image shows a blue LCD display on a white background. It features several rows of digital numbers and icons. At the top, there are three large digits '000' with a small 'M' icon above them. Below this are two rows of '00.0' with 'A' and 'B' icons to the left. The text 'AVG' and 'mmHg' are visible. Further down, there are two more '00.0' digits with a heart icon and a pulse icon. At the bottom, there are two rows of '00:00' and '100' with 'M AM PM D Yr' and 'RM' indicators.</p>	 <p>The image shows a white LCD display with a colorful vertical bar on the left. It displays '000' and '00.0' with 'kPa' and 'mmHg' options. It also shows '100' with a heart icon and 'Pul/min'. At the bottom, it shows '00' and '00:00' with 'M', 'D', 'Yr', and 'RM' indicators. The text 'SYS' and 'DIA' are visible on the right side.</p>
<p>Validation</p>	<p>Arm device for self measurement of blood pressure</p>	<p>ESH 2002</p>
<p>Category</p>	<p>Arm device for self measurement of blood pressure</p>	<p>wrist device for self measurement of blood pressure</p>
<p>Casing – Item 10</p>	<p><i>Dimensions</i> 123.5mm*140mm*58.5mm</p> <p><i>Ports</i> Cuff port</p> <p><i>Features</i> Cuff PiC printing Button printing</p>	<p><i>Dimensions</i> 110mm*110mm*40mm</p> <p><i>Ports</i> Cuff port</p> <p><i>Features</i> Cuff Transtek printing Button printing</p>
<p>Display – Item 11</p>	<p>LCD</p>	<p>LCD</p>
<p>Carrying/Mounting Facilities – Item 12</p>	<p>None</p>	<p>None</p>
<p>Software other than Algorithm – Item 13</p>	<p><i>Dual Users</i> 100sets memories/per user 2 grade indicator mmHg unit</p>	<p><i>Dual Users</i> 60 sets memories/per user 2 grade indicator mmHg unit</p>

Memory Capacity Item 14	<i>60 sets memories/per user</i>	<i>60 sets memories/per user</i>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	<i>4 dry cells 1.5V AAA</i>	<i>4 dry cells 1.5V AAA</i>
Other differences	<i>Other Details on Equivalent device that are different to Validated device N/A</i>	<i>Other Details on Validated device that are different to Equivalent device N/A</i>
Same Criteria	<p>Measurement <i>Accuracy Pressure:within±3mmHg(0.4kPa) Pulse value:±5% Max</i></p> <p>Method <i>Oscillographic testing mode</i></p> <p>Ranges <i>Rated cuff pressure: Pressure:0mmHg~300mmHg Pulse value: (40-199)beat/minute</i></p> <p>Inflation <i>Automatic inflation</i></p> <p>Deflation <i>Automatic deflation</i></p> <p>Sensors <i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure Pluse rate</i></p> <p>Buttons/Switches <i>power button Memory button Set button</i></p> <p>Display/Symbols/Indicators</p>	<p>Measurement <i>Accuracy Pressure:5°C-40°C within±3mmHg(0.4kPa) Pulse value:±5%</i></p> <p>Method <i>Oscillographic testing mode</i></p> <p>Ranges <i>Rated cuff pressure: 0kpa – 40kpa (0mmHg~300mmHg) pulse value: (40-199) beat/minute</i></p> <p>Inflation <i>Automatic inflation</i></p> <p>Deflation <i>Automatic deflation</i></p> <p>Sensors <i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure Pluse rate</i></p> <p>Buttons/Switches <i>Power button Memory button Set button</i></p>

	<p><i>Preparation</i> Automatic Zero setting</p> <p><i>Measurement Procedure</i> Inflation symbol Pressure value indication Current time</p> <p><i>Measurement Records</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Measurement time Memory Query symbol</p> <p><i>Power</i> Low power</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms Equivalent device has the identical measurement algorithm as the validated device.</p>	<p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Automatic Zero setting</p> <p><i>Measurement Procedure</i> Inflation symbol Pressure value indication Current time</p> <p><i>Measurement Records</i> Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Measurement time Memory Query symbol</p> <p><i>Power</i> Low power</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms Equivalent device has the identical measurement algorithm as the validated device.</p>
<p>Comparable Criteria</p>	<p>Measurement Cuffs (Please state sizes and materials used) About 22-42cm polyester</p> <p><i>Measurement Records</i> 100sets/per user,total two users</p> <p>Display/Symbols/Indicators Post Measurement Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Measurement time</p> <p><i>Function</i> Measure blood pressure and heart rate Recall measurement records1</p>	<p>Measurement Cuffs (Please state sizes and materials used) About 22cm-32cm or 22-42cm,polyester</p> <p><i>Measurement Records</i> 60 sets/per user,total two users</p> <p>Display/Symbols/Indicators Post Measurement Systolic blood pressure (SYS) Diastolic blood pressure (DIA) Pulse rate Measurement time</p> <p><i>Function</i> Measure blood pressure and heart rate Recall measurement records</p>

	<i>Delete measurement records</i>	<i>Delete measurement records</i>
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Comments		
Recommendation	Recommended	
Date	June 2021	