

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 **Vic Li**, 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 Saldarini Catelli 10
22070 Casnate con Bernate (CO) – Italy**

Brand^c **PiC** Model^d **OneRAPID REF 02010394000000,
02010394000100, 02010394000200, 02010394000300**

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-2296-BT**

Existing validated blood pressure measuring device.

which has previously passed the **ISO 81060-2.2018+Amd.1:2020** protocol, the results of which were published as follows:

Title: Validation of the TMB-2296-BT blood pressure monitor in adults according to the ISO 81060-2:2018+Amd.1:2020.

Authors: Bin Peng,Jia Hu,Xinda Wang,Zijian Xie,Xiaoqin Du,Chaoya Li and Jiahui Liang.

Publication: <http://www.dableducational.org/Publications/Validation of the Transtek TMB-2296-BT for Home BPM>.

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 type="checkbox"/>	No <input checked="" 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
- 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 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 Vic Li

Company Stamp/Seal

Name Vic Li

Date Oct 10, 2023

 Nicole Hu





Signature of Witness _____

Name Nicole Hu

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



Comparison of the PiC OneRAPID with the TRANSTEK TMB-2296-BT

<p>Devices – Item 9</p>	<p>PiC OneRAPID REF 02010394000000, 02010394000100, 02010394000200,02010394000300</p>	<p>TRANSTEK TMB-2296-BT</p>
<p>Pictures</p>	 <p>(The 4 ref no. are only different on packaging printing artworks.)</p>	
<p>Display Image</p>		
<p>Validation</p>	<p>Arm device for self-measurement of blood pressure</p>	<p>ISO 81060-2:2018 + Amd.1:2020</p>
<p>Category</p>	<p>Arm device for self-measurement of blood pressure</p>	<p>Arm device for self-measurement of blood pressure</p>
<p>Casing – Item 10</p>	<p>Dimensions 123 mm×44 mm×22 mm</p> <p>Ports Cuff port</p>	<p>Dimensions 123 mm×44 mm×22 mm</p> <p>Ports Cuff port</p>

	<p><i>Features</i> Cuff-blue color OneRAPID printing Small Buttons shape Button printing</p>	<p><i>Features</i> Cuff-grey color Transtek printing Small Buttons shape Button printing</p>
Display – Item 11	<i>LEDs</i>	<i>LEDs</i>
Carrying/Mounting Facilities – Item 12	<i>None</i>	<i>None</i>
Software other than Algorithm – Item 13	<p><i>Dual Users</i> <i>200sets memories/per user</i> 2 grade indicator mmHg unit</p>	<p><i>Dual Users</i> <i>199 sets memories/per user</i> 2 grade indicator mmHg unit</p>
Memory Capacity Item 14	<i>200 sets memories/per user</i>	<i>199 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	3,6V -1000mAh Li-ion battery	3,6V -1000mAh Li-ion battery
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
Same Criteria	<p>Measurement <i>Accuracy</i> Pressure:5°C-40°C within±3mmHg Pulse value: ±5%</p> <p><i>Method</i> Oscillographic testing mode</p> <p><i>Measurement Range:</i> SYS: 60mmHg~230mmHg DIA: 40mmHg~130mmHg pulse value: (40-199) beat/minute</p> <p><i>Inflation</i> Automatic inflation Deflation Automatic deflation</p>	<p>Measurement <i>Accuracy</i> Pressure:5°C-40°C within±3mmHg Pulse value:±5%</p> <p><i>Method</i> Oscillographic testing mode</p> <p><i>Measurement Range:</i> SYS: 60mmHg~230mmHg DIA: 40mmHg~130mmHg pulse value: (40-199) beat/minute</p> <p><i>Inflation</i> Automatic inflation Deflation Automatic deflation</p>

	<p><i>Sensors</i> <i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure</i> <i>Pulse rate</i></p> <p>Buttons/Switches <i>Start-Stop button</i> <i>User button (Up button)</i> <i>Memory button (Down button)</i></p> <p>Display/Symbols/Indicators <i>Preparation</i> <i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i> <i>Cuff tightness detection symbol</i> <i>Pressure value indication</i> <i>Bluetooth transmission symbol</i></p> <p><i>Measurement Records</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i> <i>Memory Query symbol</i> <i>User symbol</i></p> <p><i>Power</i> <i>Low power indication</i></p> <p><i>Features</i> <i>Measuring during inflation</i></p> <p>Algorithms <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>	<p><i>Sensors</i> <i>Piezo-resistive</i></p> <p><i>Measurements other than Blood Pressure</i> <i>Pulse rate</i></p> <p>Buttons/Switches <i>Start-Stop button (User button)</i> <i>Voice Mute button (Up button)</i> <i>Memory button (Down button)</i></p> <p>Display/Symbols/Indicators <i>Preparation</i> <i>Automatic Zero setting</i></p> <p><i>Measurement Procedure</i> <i>Cuff tightness detection symbol</i> <i>Pressure value indication</i> <i>Bluetooth transmission symbol</i></p> <p><i>Measurement Records</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i> <i>Pulse rate</i> <i>Memory Query symbol</i> <i>User symbol</i></p> <p><i>Power</i> <i>Low power indication</i></p> <p><i>Features</i> <i>Measuring during inflation</i></p> <p>Algorithms <i>Equivalent device has the identical measurement algorithm as the validated device.</i></p>
<p>Comparable Criteria</p>	<p>Measurement <i>Cuffs (Please state sizes and materials used)</i> <i>About 22-42cm polyester</i></p> <p><i>Measurement Records</i> <i>200 sets/per user, total two users</i></p> <p>Display/Symbols/Indicators <i>Post Measurement</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i></p>	<p>Measurement <i>Cuffs (Please state sizes and materials used)</i> <i>About 22cm-32cm or 22-42cm, polyester</i></p> <p><i>Measurement Records</i> <i>199 sets/per user, total two users</i></p> <p>Display/Symbols/Indicators <i>Post Measurement</i> <i>Systolic blood pressure (SYS)</i> <i>Diastolic blood pressure (DIA)</i></p>

	<p><i>Pulse rate</i></p> <p><i>Function</i></p> <p><i>Measure blood pressure and heart rate</i></p> <p><i>Recall measurement records</i></p> <p><i>Delete measurement records</i></p> <p><i>Bluetooth transmission</i></p>	<p><i>Pulse rate</i></p> <p><i>Function</i></p> <p><i>Measure blood pressure and heart rate</i></p> <p><i>Recall measurement records</i></p> <p><i>Delete measurement records</i></p> <p><i>Bluetooth transmission</i></p> <p><i>Voice broadcast</i></p>
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Office Use Only

Comments	
Recommendation	Recommended
Date	February 2024