

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 **Mike Mai,** 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 Rd., Torch Development District, Zhongshan, Guangdong, China, 528437**

Manufacturer^b **Artsana S.P.A** Address **Via Saldarini Catelli, 122070, Grandate(C)), Italy**

Brand^c **Pic** Model^d **smartRAPID**

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 Rd., Torch Development District, Zhongshan, Guangdong, China, 528437**

Manufacturer^b **Guangdong Transtek Medical Electronics Co.,Ltd** Address **Zone A, No.105, Dongli Rd., Torch Development District, Zhongshan, Guangdong, China, 528437**

Brand^c **TRANSTEK** Model^d **TMB-988**

Existing validated blood pressure measuring device.

which has previously passed the **ESH 2002 Protocol** protocol, the results of which were published as follows:

Hui Yong Tian, Wen Jun Liu, Su Guang Li, Zhe Song, Wei Gong; Validation of the TRANSTEK TMB-988 wrist blood pressure monitor for home blood pressure monitoring according to the International Protocol. Blood Pressure Monitoring, 2010, 15:326-328

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 type="checkbox"/>	No <input checked="" 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
- 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 Mike Mai

Company Stamp/Seal

Name Mike Mai

Date Oct. 27th, 2015

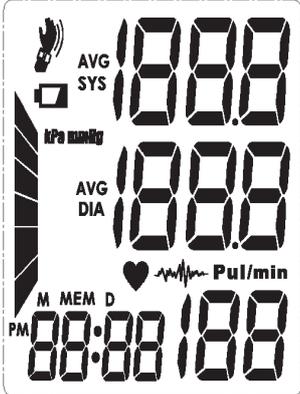
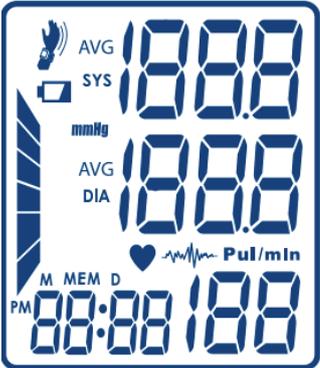
Signature of Witness Kevin Tan

Name Kevin Tan

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

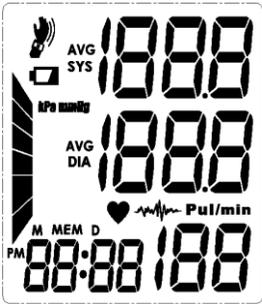
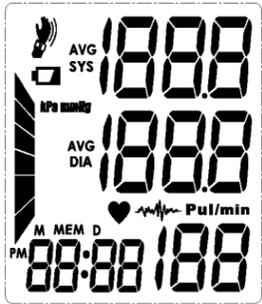


SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Existing Validated Device	Device applied for Validation
Model Name or Number	TMB-988	smartRAPID
Casing		
Display		
Carrying/ Mounting Facilities	NO	
Software other than Algorithm	<ul style="list-style-type: none"> • Single User • 60 sets memories • WHO indicator 	<ul style="list-style-type: none"> • Single User • 60 sets memories • WHO indicator

	<ul style="list-style-type: none"> • Low battery indicator 	<ul style="list-style-type: none"> • Low battery indicator
	<ul style="list-style-type: none"> • Day/Time setting 	<ul style="list-style-type: none"> • Day/Time setting
	<ul style="list-style-type: none"> • Blood pressure & heart rate measurement 	<ul style="list-style-type: none"> • Blood pressure & heart rate measurement
	<ul style="list-style-type: none"> • Kpa / mmHg unit 	<ul style="list-style-type: none"> • mmHg unit
	<ul style="list-style-type: none"> • Blood pressure data memorized with date/time 	<ul style="list-style-type: none"> • Blood pressure data memorized with date/time
	<ul style="list-style-type: none"> • Last 3 reading average 	<ul style="list-style-type: none"> • Last 3 reading average
	<ul style="list-style-type: none"> • Error message indication 	<ul style="list-style-type: none"> • Error message indication
	<ul style="list-style-type: none"> • Auto shut off when no operation for 1 min 	<ul style="list-style-type: none"> • Auto shut off when no operation for 1 min
Memory Capacity/ Number of stored measurements	60 sets(single user)	60 sets(single user)
Power Supply	2 x AAA	2x AAA

Comparison of the PIC smartRAPID Automatic Blood Pressure Monitor with the Transtek TMB-988

Devices	<i>PIC smartRAPID Automatic Blood Pressure Monitor</i>	<i>Transtek TMB-988</i>
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		<i>Analysis</i> Irregular heartbeat

		<p><i>Appearance</i> color and shape different</p> <p><i>Button</i> Touch buttons</p>
<p>Device 2 Criteria</p>	<p><i>Analysis</i> The average of last three measurements Irregular heartbeat</p> <p><i>Appearance</i> color and shape different</p> <p><i>Button</i> Mechanical buttons</p>	
<p>Same Criteria</p>	<p>Measurement</p> <p><i>Accuracy</i> Pressure: 5°C-40°C within±0.4kPa(3mmHg) pulse value:±5%</p> <p><i>Method</i> : Oscillographic</p> <p><i>Ranges</i> Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: 40mmHg-230mmHg pulse value: (40-199) beat/minute</p> <p><i>Inflation</i> Automatic Inflation Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic Deflation Automatic safety release</p>	<p>Measurement</p> <p><i>Accuracy</i> Pressure: 5°C-40°C within±0.4kPa(3mmHg) pulse value:±5%</p> <p><i>Method</i>: Oscillographic</p> <p><i>Ranges</i> Rated cuff pressure: 0mmHg~300mmHg Measurement pressure: 40mmHg-230mmHg pulse value: (40-199) beat/minute</p> <p><i>Inflation</i> Automatic Inflation Zero pressure check before inflation</p> <p><i>Deflation</i> Automatic Deflation Automatic safety release</p> <p><i>Cuffs(Please state sizes and materials used)</i></p>

	<p><i>Cuffs (Please state sizes and materials used)</i> 13.5-21.5cm, Polyester</p> <p><i>Sensors</i> Piezo-resistive</p> <p><i>Measurement Records</i> 60 (single user)</p> <p><i>Measurements other than Blood Pressure</i> Heart rate</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/stop</p> <p><i>Function</i> SET button MEM button</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Adjust to zero pressure</p>	<p>13.5-21.5, Polyester</p> <p><i>Sensors</i> Piezo-resistive</p> <p><i>Measurement Records</i> 60 (single user)</p> <p><i>Measurements other than Blood Pressure</i> Heart rate</p> <p>Buttons/Switches</p> <p><i>Power</i> Start/stop</p> <p><i>Function</i> SET button MEM button</p> <p><i>Analysis</i> N/A</p> <p><i>Event Marking</i> N/A</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i> Adjust to zero pressure</p>
--	--	---



Measurement Procedure

Display the cuff pressure, heart rate symbol and measurement time



Post Measurement

Wrist

Date and Time

Display measurement time in the lower left corner of LCD

Power

Low battery

Function

- Measure blood pressure and heart rate
- Recall measurement records
- Delete measurement records



Measurement Procedure

Display the cuff pressure, heart rate symbol and measurement time



Post Measurement

Wrist

Date and Time

Display measurement time in the lower left corner of LCD

Power

Low battery

Function

- Measure blood pressure and heart rate
- Recall measurement records
- Delete measurement records

	<p><i>Communication</i> N/A</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms <i>Averages and Differences</i> Recall the average value of the last measurement</p> <p><i>Diagnostic</i> N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p>Casing <i>Display</i> LCD</p> <p><i>Ports</i> No</p> <p><i>Power</i> 2*AAA battery</p> <p><i>Features</i> 73mm*67.5mm*22.5mm, ABS, trapezoid</p>	<p><i>Communication</i> N/A</p> <p><i>Features</i> Measuring during inflation</p> <p>Algorithms <i>Averages and Differences</i> Recall the average value of the last measurement</p> <p><i>Diagnostic</i> N/A, indicate WHO blood pressure classification</p> <p><i>Functions</i> Measure blood pressure and heart rate</p> <p><i>Communication</i> N/A</p> <p>Casing <i>Display</i> LCD</p> <p><i>Ports</i> No</p> <p><i>Power</i> 2*AAA battery</p> <p><i>Features</i> 73mm*67.5mm*22.5mm, ABS, trapezoid</p>
<p>Comparable Criteria</p>	<p><i>Appearance</i> color different</p> <p><i>Button</i> Mechanical buttons</p>	<p><i>Appearance</i> color different</p> <p><i>Button</i> Touch buttons</p>

Comments		<i>Home Use Only, Self-measurement</i>
Recommendation	Recommended	
Date	18 November 2015	