

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**,
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	Address	Zone A, No 105, Dongli Rd. Torch district, zhongshan, Guangdong, China. 528437	Development
Manufacturer ^b	Artsana S.P.A	Address	Via Saldarini Catelli, 122070, Grandate (C) Italy	
Brand ^c	PIC	Model ^d	HelpRAPID	

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	Address	Zone A, No 105, Dongli Rd. Torch district, zhongshan, Guangdong, China. 528437	Development
Manufacturer ^b	Guangdong Transtek Medical Electronics	Address	Zone A, No 105, Dongli Rd. Torch district, zhongshan, Guangdong, China. 528437	Development
Brand ^c	TRANSTEK	Model ^d	HelpRAPID	

Existing validated blood pressure measuring device.

which has previously passed the _____ protocol, the results of which were published as follows:

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 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.

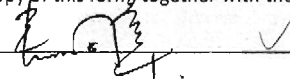
See Attached document

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  ✓

Company Stamp/Seal

Name Mike Mai



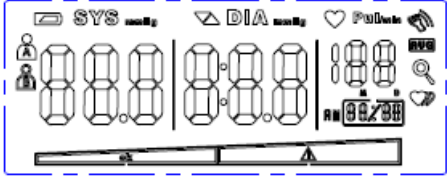
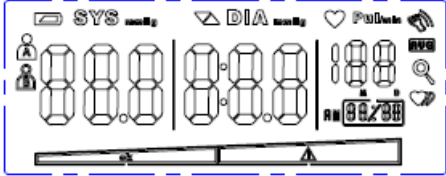
Date 2 Nov.2016

Signature of Witness Ariel Lv 2016.11.02

Name Ariel Lv

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


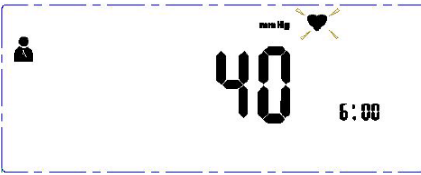

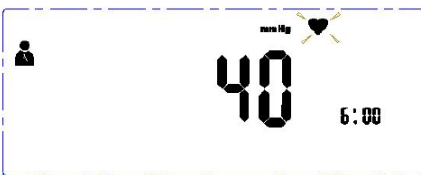
Comparison of the ARTSANA PIC HelpRAPID with the TRANSTEK ARTSANA HelpRAPID

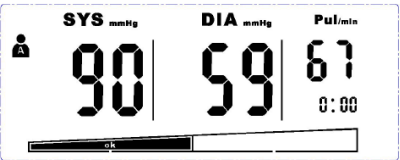
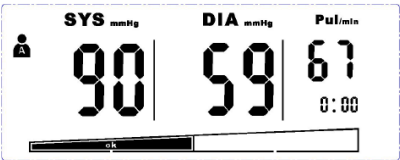
Devices – Item 9	<i>ARTSANA PIC HelpRAPID</i>	<i>TRANSTEK ARTSANA HelpRAPID</i>
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper Arm Blood Pressure Monitor	Upper Arm Blood Pressure Monitor
Casing – Item 10	<p><i>Dimensions</i></p> <p>22-42cm</p>	<p><i>Dimensions</i></p> <p>22-42cm</p>

	<p><i>Ports</i></p> <p><i>Cuff port and DC power port</i></p> <p><i>Features</i></p> <p><i>100*186*40mm;</i></p> <p><i>color and shape different;</i></p>	<p><i>Ports</i></p> <p><i>Cuff port and DC power port</i></p> <p><i>Features</i></p> <p><i>100*186*40mm;</i></p> <p><i>color and shape different;</i></p>
Display – Item 11	<p><i>Type</i></p> <p><i>One button and two touch buttons:START/STOP ,MEM and SET</i></p> <p><i>Measurement records:Maximum 100 records per each user(dual users)</i></p> <p><i>If the measurement results beyond the measuring range ,display shows OUT.</i></p> <p><i>mmHg unit</i></p> <p><i>ESH indicator</i></p> <p><i>Dual users</i></p>	<p><i>Type</i></p> <p><i>One button and two touch buttons:START/STOP ,MEM and SET</i></p> <p><i>Measurement records:Maximum 100 records per each user(dual users)</i></p> <p><i>If the measurement results beyond the measuring range ,display shows OUT.</i></p> <p><i>mmHg unit</i></p> <p><i>ESH indicator</i></p> <p><i>Dual users</i></p>
Carrying/Mounting Facilities – Item 12	<i>Blue-black bag</i>	<i>Blue-black bag</i>
Software other than Algorithm – Item 13	<p><i>Dual Users</i></p> <p><i>200 sets memories</i></p> <p><i>ESH indicator</i></p>	<p><i>Dual Users</i></p> <p><i>200 sets memories</i></p> <p><i>ESH indicator</i></p>

	<i>mmHg unit</i>	<i>mmHg unit</i>
Memory Capacity Item 14	<i>Number of stored measurements</i> <i>Maximum 100 records per each user(dual users)</i>	<i>Number of stored measurements</i> <i>Maximum 100 records per each user(dual users)</i>
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	4 x AAA	4 x AAA
Other differences	<i>Other Details on Equivalent device that are different to Validated device</i> N/A	<i>Other Details on Equivalent device that are different to Validated device</i> N/A
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure: ± 3 mmHg</p> <p>Pulse value: $\pm 5\%$</p> <p><i>Method</i></p> <p><i>Oscillography</i></p> <p><i>Ranges</i></p> <p>Rated cuff pressure:0mmHg~300mmHg</p> <p>Measurement pressure:40mmHg~230mmHg</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure: ± 3 mmHg</p> <p>Pulse value: $\pm 5\%$</p> <p><i>Method</i></p> <p><i>Oscillography</i></p> <p><i>Ranges</i></p> <p>Rated cuff pressure:0mmHg~300mmHg</p> <p>Measurement pressure:40mmHg~230mmHg</p>

	<p><i>Pulse value:(40-199) beat/minute</i></p> <p><i>Inflation</i></p> <p><i>Automatic Inflation</i></p> <p><i>Zero pressure check before inflation</i></p> <p><i>Deflation</i></p> <p><i>Automatic Deflation</i></p> <p><i>Automatic safety release</i></p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p><i>22-42cm,Polyester</i></p> <p><i>Sensors</i></p> <p><i>Piezo-resistive</i></p> <p><i>Measurement Records</i></p> <p><i>Last 3 reading average</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Heart rate</i></p> <p><i>Buttons/Switches</i></p> <p><i>Power</i></p> <p><i>START/STOP</i></p> <p><i>Measurement Records</i></p> <p><i>200 sets memories</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>Zero pressure check before inflation</i></p> <p><i>Deflation</i></p> <p><i>Automatic Deflation</i></p> <p><i>Automatic safety release</i></p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p><i>22-42cm,Polyester</i></p> <p><i>Sensors</i></p> <p><i>Piezo-resistive</i></p> <p><i>Measurement Records</i></p> <p><i>Last 3 reading average</i></p> <p><i>Measurements other than Blood Pressure</i></p> <p><i>Heart rate</i></p> <p><i>Buttons/Switches</i></p> <p><i>Power</i></p> <p><i>START/STOP</i></p> <p><i>Measurement Records</i></p> <p><i>200 sets memories</i></p>
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	<p><i>Function</i></p> <p>START/STOP</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>Adjust to zero pressure</p>  <p><i>Measurement Procedure</i></p> <p>Display the cuff pressure, heart rate symbol and measurement time</p> 	<p><i>Function</i></p> <p>START/STOP</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>Adjust to zero pressure</p>  <p><i>Measurement Procedure</i></p> <p>Display the cuff pressure, heart rate symbol and measurement time</p> 
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	<p><i>Post Measurement</i></p> <p><i>Upper arm</i></p> <p><i>Measurement Records</i></p>  <p><i>Date and Time</i></p> <p><i>Display measurement time in the lower right corner of LCD</i></p> <p><i>Power</i></p> <p><i>Low battery</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>Communication</i></p> <p><i>N/A</i></p> <p><i>Features</i></p> <p><i>Measuring during inflation</i></p>	<p><i>Post Measurement</i></p> <p><i>Upper arm</i></p> <p><i>Measurement Records</i></p>  <p><i>Date and Time</i></p> <p><i>Display measurement time in the lower right corner of LCD</i></p> <p><i>Power</i></p> <p><i>Low battery</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>Communication</i></p> <p><i>N/A</i></p> <p><i>Features</i></p> <p><i>Measuring during inflation</i></p>
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	<p><i>Not described</i></p> <p><i>N/A</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p><i>Recall the average value of last measurement</i></p> <p><i>Diagnostic</i></p> <p><i>N/A</i></p> <p><i>Functions</i></p> <p><i>Measure blood pressure and heart rate</i></p> <p><i>Communication</i></p> <p><i>N/A</i></p> <p>Casing</p> <p><i>Display</i></p> <p><i>LCD</i></p> <p><i>Ports</i></p> <p><i>Cuff port and DC power port</i></p> <p><i>Power</i></p> <p><i>4 X AAA</i></p> <p><i>Features</i></p> <p><i>Touch buttons</i></p>	<p><i>Not described</i></p> <p><i>N/A</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p><i>Recall the average value of last measurement</i></p> <p><i>Diagnostic</i></p> <p><i>N/A</i></p> <p><i>Functions</i></p> <p><i>Measure blood pressure and heart rate</i></p> <p><i>Communication</i></p> <p><i>N/A</i></p> <p>Casing</p> <p><i>Display</i></p> <p><i>LCD</i></p> <p><i>Ports</i></p> <p><i>Cuff port and DC power port</i></p> <p><i>Power</i></p> <p><i>4 X AAA</i></p> <p><i>Features</i></p> <p><i>Touch buttons</i></p>
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<p>Comparable Criteria</p>	<p><i>Appearance:</i> <i>100*186*40mm;</i> <i>color and shape different;</i> <i>Cuffs sizes</i> <i>22-42cm, Polyester</i></p>	<p><i>Appearance:</i> <i>100*186*40mm;</i> <i>color and shape different;</i> <i>Cuffs sizes</i> <i>22-42cm, Polyester</i></p>

<p>Comments</p>	
<p>Recommendation</p>	<p>RECOMMENDED</p>
<p>Date</p>	<p>8 December 2016</p>