

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,
Co.,Ltd,

Name of a Company Director

a Director of Guangdong Transtek Medical Electronics

Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker ^a	Inventum Huishoudelijke Apparaten B.V.	Address	Meander 861 6825 MH Arnhem The Netherlands
Manufacturer ^b	Guangdong Transtek Medical Electronics Co.,Ltd	Address	Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, 528437, China
Brand ^c	INVENTUM	Model ^d	BDA432

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, Guangdong, 528437, China
Manufacturer ^b	Guangdong Transtek Medical Electronics Co.,Ltd	Address	Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, 528437, China
Brand ^c	TRANSTEK	Model ^d	TMB-1491

Existing validated blood pressure measuring device.

which has previously passed the ESH 2010 Protocol protocol, the results of which were published as follows:

Title: Validation of Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol revision 2010.

Authors: Tian H., Zeng S., Zhong X., Gong W. and Liu W.

Publication: 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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" 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.

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 June 23, 2016

Signature of Witness Kevin Tan

Name Kevin Tan

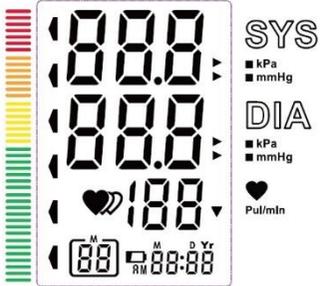
Address Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, 528437, China



SECTION B of Declaration of Blood Pressure Measuring Device Equivalence

	Device applied for Validation	Existing Validated Device
Model Name or Number	BDA432	TMB-1491
Carrying/ Mounting Facilities		

Comparison of the Inventum BDA432 with the Transtek TMB-1491

Devices – Item 9	Inventum BDA432	Transtek TMB-1491
<p>Pictures</p>	<p>Image height: Picture 3.2 cm</p> 	<p>Image height: Picture 3.2 cm</p> 
<p>Display Image</p>	<p>Image height: Picture 4 cm</p> 	<p>Image height: Picture 4 cm</p> 
<p>Validation</p>	<p>-</p>	<p>ESH 2010</p>
<p>Category</p>	<p>Upper Arm Devices for Self-measurement of Blood Pressure</p>	<p>Upper Arm Devices for Self-measurement of Blood Pressure</p>
<p>Casing – Item 10</p>	<p>Dimensions 110 x 110 x 47 mm</p> <p>Ports: Air outlet for cuff</p> <p>Features: 60 memory places, 22-32 cm cuff, Irregular heartbeat detection, WHO indicator</p>	<p>Dimensions 110 x 110 x 47 mm</p> <p>Ports: Air outlet for cuff</p> <p>Features: 60 memory places, 22-32 cm cuff, Irregular heartbeat detection, WHO indicator</p>
<p>Display – Item 11</p>	<p>Type: LCD display No differences</p>	<p>Type: LCD display No differences</p>

<p>Carrying/Mounting Facilities – Item 12</p>	<p>Storage bag</p> 	<p>Zipper bag</p> 
<p>Software other than Algorithm – Item 13</p>	<p>Same software (V1.0)</p>	<p>Same software (V1.0)</p>
<p>Memory Capacity Item 14</p>	<p><i>Number of stored measurements: 60</i></p>	<p><i>Number of stored measurements: 60</i></p>
<p>Printing Facilities 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 Item 17</p>	<p>4 x AAA</p>	<p>4 x AAA</p>
<p>Other differences</p>	<p><i>Other Details on Equivalent device that are different to Validated device:</i></p> <ul style="list-style-type: none"> - <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i> 	<p><i>Other Details on Validated device that are different to Equivalent device</i></p> <ul style="list-style-type: none"> - <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i>
<p>Same Criteria</p>	<p>Measurement <i>Accuracy</i> No differences</p> <p><i>Method</i> No differences</p> <p><i>Ranges</i> No differences</p> <p><i>Inflation</i></p>	<p>Measurement <i>Accuracy</i> No differences</p> <p><i>Method</i> No differences</p> <p><i>Ranges</i> No differences</p> <p><i>Inflation</i></p>

	<p>No differences</p> <p><i>Deflation</i> No differences</p> <p><i>Cuffs (Please state sizes and materials used)</i> No differences</p> <p><i>Sensors</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Measurements other than Blood Pressure</i> No differences</p> <p>Buttons/Switches <i>Power</i></p>  <p>The color/font is different</p> <p><i>Measurement Records</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Analysis</i> No differences</p> <p><i>Event Marking</i> No differences</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p>	<p>No differences</p> <p><i>Deflation</i> No differences</p> <p><i>Cuffs (Please state sizes and materials used)</i> No differences</p> <p><i>Sensors</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Measurements other than Blood Pressure</i> No differences</p> <p>Buttons/Switches <i>Power</i></p>  <p>The color/font is different</p> <p><i>Measurement Records</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Analysis</i> No differences</p> <p><i>Event Marking</i> No differences</p> <p><i>Communication</i> N/A</p> <p>Display/Symbols/Indicators</p>
--	---	---

	<p><i>Preparation</i> No differences</p> <p><i>Measurement Procedure</i> No differences</p> <p><i>Post Measurement</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Date and Time</i> No differences</p> <p><i>Power</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Communication</i> No differences</p> <p><i>Features</i> No differences</p> <p><i>Not described</i> None</p> <p>Algorithms <i>Averages and Differences</i> No differences</p> <p><i>Diagnostic</i> No differences</p> <p><i>Functions</i> No differences</p> <p><i>Communication</i></p>	<p><i>Preparation</i> No differences</p> <p><i>Measurement Procedure</i> No differences</p> <p><i>Post Measurement</i> No differences</p> <p><i>Measurement Records</i> No differences</p> <p><i>Date and Time</i> No differences</p> <p><i>Power</i> No differences</p> <p><i>Function</i> No differences</p> <p><i>Communication</i> No differences</p> <p><i>Features</i> No differences</p> <p><i>Not described</i> None</p> <p>Algorithms <i>Averages and Differences</i> No differences</p> <p><i>Diagnostic</i> No differences</p> <p><i>Functions</i> No differences</p> <p><i>Communication</i></p>
--	---	---

	No differences	No differences
Comparable Criteria	- Everything except of: <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i>	- Everything except of: <i>Control panel colour, text colour + knobs colour, rating label, giftbox design, User manual</i>

Comments		none
Recommendation	Recommended	
Date	29th July 2016	