

**DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE**

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

**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<sup>a</sup> **Guangdong Transtek Medical Electronics Co., Ltd** Address **Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China**

Manufacturer<sup>b</sup> **Guangdong Transtek Medical Electronics Co., Ltd** Address **Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China**

Brand<sup>c</sup> **Alvita/Kinetik Wellbeing** Model<sup>d</sup> **TMB-1491-S**

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<sup>a</sup> **Guangdong Transtek Medical Electronics Co., Ltd** Address **Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China**

Manufacturer<sup>b</sup> **Guangdong Transtek Medical Electronics Co., Ltd** Address **Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China**

Brand<sup>c</sup> **TRANSTEK** Model<sup>d</sup> **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 Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol

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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <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 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 <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <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 <sup>g</sup> <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.

**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](mailto:info@dableducational.org).

Signature of Director Kevin Tan Company Stamp/Seal

Name Kevin Tan

Date April 2nd, 2022

Signature of Witness \_\_\_\_\_

Name Caroline.liu

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