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Declaration of Equivalence Form

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 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[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.r.I *Address* Via Saldarini Catelli 10,22070 - Casnate con Bernate (CO)-Italy

Brand[c] Pic Model[d] CARDIOmaxi

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-1491

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Tian H., Zeng S., Zhong X., Gong W. and Liu W. Validation of Transtek blood pressure monitor TMB-1491 for self-measurement according to the European Society of Hypertension International Protocol reversion 2010. 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 ☐	No ☒	N/A[e] ☐
	2	Algorithm for Auscultatory Measurements	Yes ☐	No ☐	N/A[f] ☒
	3	Artefact/Error Detection	Yes ☐	No ☒	
	4	Microphone(s)	Yes ☐	No ☐	N/A[f] ☒
	5	Pressure Transducer	Yes ☐	No ☒	
	6	Cuffs or Bladders	Yes ☐	No ☒	
	7	Inflation Mechanism	Yes ☐	No ☒	
	8	Deflation Mechanism	Yes ☐	No ☒	
Part II	9	Model Name or Number	Yes ☒	No ☐	
	10	Casing	Yes ☒	No ☐	
	11	Display	Yes ☒	No ☐	
	12	Carrying/Mounting Facilities	Yes ☒	No ☐	
	13	Software other than Algorithm	Yes ☒	No ☐	
	14	Memory Capacity/Number of stored measurements	Yes ☒	No ☐	
	15	Printing Facilities	Yes ☐	No ☐	N/A[g] ☒
	16	Communication Facilities	Yes ☐	No ☐	N/A[g] ☒
	17	Power Supply	Yes ☒	No ☐	
	18	Other Facilities	Yes ☐	No ☐	N/A[g] ☒

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.

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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.

Declaration of Equivalence Form

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 Kevin Tan

Company Stamp/Seal

Name Kevin Tan

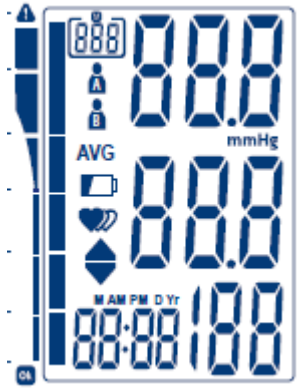
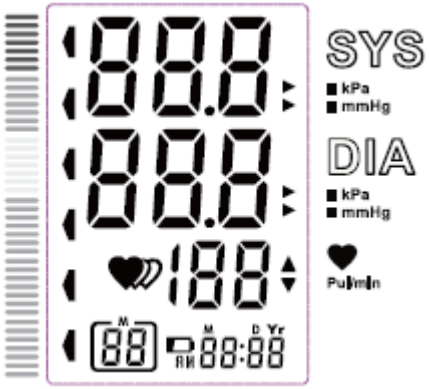
Date October 11th, 2018

Signature of Witness Elly He

Name Elly He

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

Comparison of Pic Solutions CARDIOmaxi Automatic Blood Pressure Monitor with Transtek Blood Pressure Monitor TMB-1491

Devices – Item 9	*Pic Solutions CARDIOmaxi Automatic Blood Pressure Monitor*	*Transtek Blood Pressure Monitor TMB-1491*
Pictures		
Display Image		

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Validation		ESH 2010
Category	*Upper arm device for self measurement of blood pressure*	*Upper arm device for self measurement of blood pressure*
Casing – Item 10	*Dimensions* 123.5mm×140mm×58.5mm *Ports* *Cuff port and DC power port* *Features* *Blood pressure measurement* *Heart rate* *WHO classification*	*Dimensions* 110mm×110mm×41mm *Ports* *Cuff port* *Features* *Blood pressure measurement* *Heart rate* *WHO classification*
Display – Item 11	*LCD*	*LCD*
Carrying/Mounting Facilities – Item 12	With a storage bag	*None*
Software other than Algorithm – Item 13	Two users 100 recorded measurements per each user	One user 60 recorded measurements

	ESH indicator Unit: mmHg	WHO indicator Unit: mmHg or kPa
Memory Capacity **Item 14**	100 recorded measurements per each user	60 recorded measurements
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply **Item 17**	4×AAA batteries, 6V DC or adapter 6V/ 1000mA.	4×AAA batteries, 6V DC
Other differences	*Other Details on Equivalent device that are different to Validated device* *New MCU in order to fulfill the new ESD requirements (last production with old MCU in Oct 2018)*	*Other Details on Validated device that are different to Equivalent device* -
Same Criteria	***Measurement*** *Accuracy* *Pressure:* *5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%*	***Measurement*** *Accuracy* *Pressure:* *5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%*

	Method *Oscillographic method* *Ranges* *Rated cuff pressure:* *0mmHg~299mmHg(0kPa ~ 39.9kPa)* *Measurement pressure:* *SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)* *DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)* *Pulse value: (40-199)beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Cuffs (Please state sizes and materials used)* 22-42cm, nylon	*Method* *Oscillographic method* *Ranges* *Rated cuff pressure:* *0mmHg~299mmHg(0kPa ~ 39.9kPa)* *Measurement pressure:* *SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)* *DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)* *Pulse value: (40-199)beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Cuffs(Please state sizes and materials used)* 22-32cm and 22-42cm, nylon

	Sensors Piezo-resistive *Measurement Records* 100 measurement records per each user *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power* START/STOP key *Measurement Records* Memory key *Function* Setting Key Memory Key	*Sensors* Piezo-resistive *Measurement Records* 60 measurement records *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power* START/STOP button *Measurement Records* MEM button *Function* MEM button SET button

	Analysis N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation symbol* *Pressure value indication* *Current time* *Post Measurement* Upper arm	*Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation symbol* *Pressure value indication* *Current time* *Post Measurement* Upper arm

	Measurement Records *Systolic pressure (SYS)* *Diastolic pressure (DIA)* *Pulse rate* *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 *Communication* N/A	*Measurement Records* *Systolic pressure (SYS)* *Diastolic pressure (DIA)* *Pulse rate* *Date and Time* Display measurement time in the lower right corner of LCD *Power* Low battery *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* N/A

	Features Measuring during inflation *Not described* ***Algorithms*** *Averages and Differences* Recall the average value of the last three measurements *Diagnostic* N/A, indicate WHO blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A	*Features* Measuring during inflation *Not described* ***Algorithms*** *Averages and Differences* Recall the average value of the last three measurements *Diagnostic* N/A, indicate WHO blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A

Comparable Criteria	*Appearance* *123.5mm*140mm*58.5mm, color different* *Power* *Except 4*AAA battery, also can be supplied by authorized AC adapter* *Cuff size* *22-42cm*	*Appearance* *110mm*110mm*41mm, color different* *Power* *Only supplied by 4*AAA battery* *Cuff size* *22-32cm and 22-42cm*

Comments		This equivalence relates to the blood pressure measurement characteristics of both devices. It is for home use only. Self-measurement.
Recommendation	***Recommended***	
Date	12th February 2019	