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]	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 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]	Pic Solution	Model[d]	helpRAPID

Existing validated blood pressure measuring device.

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

Zhonghua Liu, Xianyue Liu, Hengyi Zhou Validation of Artsana helpRAPID according to European Society of Hypertension International Protocol revision 2010 in adults [Internet]. Dublin: dabl Educational Trust; 2016 November 22.

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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland. Tel + 353 1 278 0247 Email info@dableducational.org
Fax + 353 1 278 3835 Web www.dableducational.org

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 helpRAPID Automatic Blood Pressure Monitor with Transtek Blood Pressure Monitor helpRAPID

Devices – Item 9	*Pic Solutions helpRAPID Automatic Blood Pressure Monitor*	*Transtek Blood Pressure Monitor helpRAPID*
Pictures		
Display Image		

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

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* 100mm×186mm×35mm *Ports* *Cuff port and DC power port* *Features* *Blood pressure measurement* *Heart rate* *ESH classification*	*Dimensions* 100mm×186mm×35mm *Ports* *Cuff port and DC power port* *Features* *Blood pressure measurement* *Heart rate* *ESH classification*
Display – Item 11	*LCD*	*LCD*
Carrying/Mounting Facilities – Item 12	With a storage bag	With a storage bag
Software other than Algorithm – Item 13	Two users 100 recorded measurements per each user	Two users 100 recorded measurements per each user

	ESH indicator Unit: mmHg	ESH indicator Unit: mmHg
Memory Capacity **Item 14**	100 recorded measurements per each user	100 recorded measurements per each user
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 or adapter 6V/ 1000mA.
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 Sept 2018)*	*Other Details on Validated device that are different to Equivalent device* N/A
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, Polyester	*Method* *Oscillographic method* *Ranges* *Rated cuff pressure:* *0mmHg~300mmHg(0kPa ~ 40kPa)* *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, Polyester

	Sensors Piezo-resistive *Measurement Records* 100 recorded measurements 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* 100 recorded measurements 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

	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 right corner of LCD *Power* Low battery *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* N/A *Features*	*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 ESH blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A	Measuring during inflation *Not described* ***Algorithms*** *Averages and Differences* Recall the average value of the last three measurements *Diagnostic* N/A, indicate ESH blood pressure classification *Functions* Measure blood pressure and heart rate *Communication* N/A
Comparable Criteria	*Appearance*	*Appearance*

	*100mm*186mm*35mm, color different* *Power* *Except 4*AAA battery, also can be supplied by authorized AC adapter* *Cuff size* *22-42cm*	*100mm*186mm*35mm, color different* *Power* *Except 4*AAA battery, also can be supplied by authorized AC adapter* *Cuff size* *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**	