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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.p.A	*Address*	Via saldarina Catelli 10-22-70-Casnate con Bernate (CO)-Italy
Brand[c]	PiC	Model[d]	liteRAPID WRIST REF 02022534000000

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-988

Existing validated blood pressure measuring device.

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

Title: Validation of the Transtek TMB-988 wrist blood pressure monitor for home blood pressure monitoring according to the International Protocol.

Authors: Tian HY,Liu WJ,Li SG,Song Z,Gong W.

Publication: Blood Press Monit 2010;15(6):326-8 doi:10.1097/MBP.0b013e32833f56fb

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.

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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 Kevin Tan

Company Stamp/Seal

Name Kevin Tan

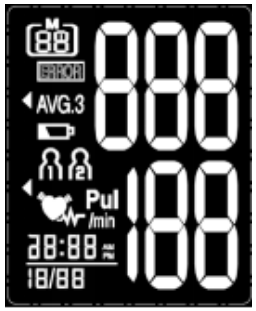
Date August 17,2020

Signature of Witness Lian Zhou

Name Lian Zhou

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

Comparison of the PiC liteRAPID WRIST with the TRANSTEK TMB-988

Devices – Item 9	PiC liteRAPID WRIST – REF 02022534000000	TRANSTEK TMB-988
Pictures		
Display Image		
Validation	*wrist device for self measurement of blood pressure*	*ESH 2002*
Category	*wrist device for self measurement of blood pressure*	*wrist device for self measurement of blood pressure*
Casing – Item 10	*Dimensions* *79mm*60mm*19.7mm* *Ports* *Cuff port* *Features* Cuff PiC printing Button printing	*Dimensions* *73mm*67.5mm*22.5mm* *Ports* *Cuff port* *Features* Cuff Transtek printing Button printing
Display – Item 11	*LCD*	*LCD*
Carrying/Mounting Facilities – Item 12	*Bag*	*None*

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	Dimensions *160mm*140mm* *Features* *Blue*	
Software other than Algorithm – Item 13	*Dual Users* *60 sets memories/per user* *2 grade indicator* *mmHg unit*	*Dual Users* *60 sets memories/per user* *2 grade indicator* *mmHg unit*
Memory Capacity Item 14	*60 sets memories/per user*	*60 sets memories/per user*
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	*2 dry cells 1.5V AAA*	*2 dry cells 1.5V AAA*
Other differences	*Other Details on Equivalent device that are different to Validated device* *N/A*	*Other Details on Validated device that are different to Equivalent device* *N/A*
Same Criteria	***Measurement*** *Accuracy* *Pressure:within±3mmHg(0.4kPa)* *Pulse value:±5% Max* *Method* *Oscillographic testing mode* *Ranges* *Rated cuff pressure:* *Pressure:0mmHg~299mmHg* *Pulse value: (40-199)beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Sensors* *Piezo-resistive* *Measurements other than Blood Pressure*	***Measurement*** *Accuracy* *Pressure:5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* *Method* *Oscillographic testing mode* *Ranges* *Rated cuff pressure:* *0kpa – 39.9kpa (0mmHg~299mmHg)* *pulse value: (40-199) beat/minute* *Inflation* *Automatic inflation* *Deflation* *Automatic deflation* *Sensors* *Piezo-resistive* *Measurements other than Blood Pressure*

	Pluse rate ***Buttons/Switches*** *power button* *Memory button* ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation symbol* *Pressure value indication* *Current time* *Measurement Records* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time* *Memory Query symbol* *Power* *Low power* *Features* *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*	*Pluse rate* ***Buttons/Switches*** *Power button* *Memory button* *Set button* ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation symbol* *Pressure value indication* *Current time* *Measurement Records* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time* *Memory Query symbol* *Power* *Low power* *Features* *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*
Comparable Criteria	***Measurement*** *Cuffs (Please state sizes and materials used)* *About 13.5cm-19.5cm, polyester* *Measurement Records* *60 sets/per user,total two users* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time*	***Measurement*** *Cuffs (Please state sizes and materials used)* *About 13.5cm-21.5cm,polyester* *Measurement Records* *60 sets/per user,total two users* ***Display/Symbols/Indicators*** *Post Measurement* *Systolic blood pressure (SYS)* *Diastolic blood pressure (DIA)* *Pulse rate* *Measurement time*

	Function *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records*	*Function* *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records*

Comments		
Recommendation	**Recommended**	
Date	**June 2021**	