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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]	Veridian Healthcare, LLC	*Address*	1175 Lakeside Drive, Gurnee, Illinois 60031
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand[c]	SmartHeart	Model[d]	01-509

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]	LS808-B

Existing validated blood pressure measuring device.

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

Title: Validation of Transtek LS808-B for self/home measurement according to the European Society of Hypertension International Protocol revision 2010

Authors: Zhong Hua Liu

Publication: Blood Pressure Monitoring 2016 Dec; 21(6):352-55

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.

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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 January 11st,2018

Signature of Witness Havana Hu

Name Havana Hu

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

Comparison of the SmartHeart 01-509 with the TRANSTEK LS808-B

Devices – Item 9	SmartHeart 01-509	TRANSTEK LS808-B
Pictures		
Display Image		
Validation	*Upper arm device for self measurement of blood pressure*	*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* *130.9mm*73mm*29.4mm*	*Dimensions* *130.9mm*73mm*29.4mm*

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	Ports *Cuff port and DC power port* *Features* Cuff and AC adaptor connectors Model name printing Button printing SYS, DIA, Pul/min printing	*Ports* *Cuff port and DC power port* *Features* Cuff and AC adaptor connectors Model name printing Button printing SYS, DIA, Pul/min printing
Display – Item 11	*LCD*	*LCD*
Carrying/Mounting Facilities – Item 12	None	*None*
Software other than Algorithm – Item 13	Dual Users 250 sets memories/per user AHA indicator mmHg unit	Dual Users 60 sets memories/per user WHO indicator mmHg unit
Memory Capacity **Item 14**	250 sets memories/per user	60 sets memories/per user
Printing Facilities	N/A	N/A

Item 15		
Communication Facilities – Item 16	N/A	N/A
Power Supply **Item 17**	*1. lithium battery* *2. 6V DC Jack*	*1. lithium battery* *2. 6V DC Jack*
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:* *5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* *Method* *Oscillographic testing mode* *Ranges* *Rated cuff pressure:* *0mmHg~299mmHg(0kPa ~ 39.9kPa)* *Measurement pressure:* *SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)*	***Measurement*** *Accuracy* *Pressure:* *5°C-40°C within±3mmHg(0.4kPa)* *Pulse value:±5%* *Method* *Oscillographic testing mode* *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* *Sensors* *Piezo-resistive* *Measurements other than Blood Pressure* *Pluse rate* ***Buttons/Switches*** *Power* *User 1 / User 2 botton* *Measurement Records* *MEM button*	*DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)* *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* *User 1 / User 2 botton* *Measurement Records* *MEM button*

	Function	*Function*
	User 1 / User 2/ MEM/"lock" button	*User 1 / User 2/ MEM/"lock" button*
	Display/Symbols/Indicators	***Display/Symbols/Indicators***
	Preparation	*Preparation*
	Automatic Zero setting	*Automatic Zero setting*
	Measurement Procedure	*Measurement Procedure*
	Inflation symbol	*Inflation symbol*
	Pressure value indication	*Pressure value indication*
	Current time	*Current time*
	Measurement Records	*Measurement Records*
	Systolic blood pressure (SYS)	*Systolic blood pressure (SYS)*
	Diastolic blood pressure (DIA)	*Diastolic blood pressure (DIA)*
	Pulse rate	*Pulse rate*
	Measurement time	*Measurement time*
	Memory Query symbol	*Memory Query symbol*
	Power	*Power*
	Low power	*Low power*

	Features *Measuring during inflation* ***Algorithms*** *Equivalent device has the identical measurement algorithm as the validated device.*	*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 22cm-32cm or 22cm-42cm,polyester* *Measurement Records* *250 sets/per user,totel 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 22cm-42cm,polyester* *Measurement Records* *60 sets/per user,totel 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*	*Transmit symbol* *Function* *Measure blood pressure and heart rate* *Recall measurement records* *Delete measurement records* *Transmit measurement record to APP*

Comments		
Recommendation	**Recommended**	
Date	**19 January 2018**	