dabl®Educational Trust — 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 Bill Huang, (Name of a Company Director) a Director of AViTA Corporation, (Company name)

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker[a]	Kaz Europe Sàrl	*Address*	Place Chauderon 18, 1003 Lausanne, Switzerland
Manufacturer[b]	AViTA Corporation	*Address*	9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.
Brand[c]	Braun	Model[d]	BPW4500

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]	AViTA Corporation	*Address*	9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.
Manufacturer[b]	AViTA Corporation	*Address*	9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.
Brand[c]	AViTA (Wellex)	Model[d]	BPM17

Existing validated blood pressure measuring device.

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

Kang YY, Chen Q, Liu CY, Li Y, Wang JG. Validation of the AVITA BPM17 wrist blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol revision 2010.

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.
- 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.

Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland.
Form DET7 130102

(dabl®Educational Trust Limited is a not-for-profit organisation)
Tel + 353 1 278 0247 Email info@dableducational.org
Fax + 353 1 278 3835 Web www.dableducational.org

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.

(6) Cuff

New device has the same cuff size and same bladder but different colors and different materials on outside of cuff (white "faux leather" - PVC)

(9) Model Name or Number

Braun BPW4500 (Marketing name iCheck 7), including regional (language) versions BPW4500WE and BPW4500CEME

(10) Casing

New model has a different housing design and different buttons configuration (only one button with touch-sensing)

(11) Display

New Device has a graphic (dot matrix) display based on OLED technology

(13) SW other than algorithm

New device has simplified user Interface SW without averages, memory display or date/time setting. Visuals on display are also different due to graphic dot-matrix display

(14) Memory capacity/Number of stored measurements

New device has 100 readings which are only available for download thru Bluetooth connection with smartphone

(16) Communication Facilities

New device has Bluetooth Low Energy (BT Smart) communication facitily for download of stored readings and automatic date/time settings when connected to smartphone (dedicated APP required).

(18) Other Facilities

New device prompts user for correct wrist position vs heart (wrist angle) to start measurement

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 _____ Company Stamp/Seal

Name Bill Huang AVITA CORPORATION

Authorized Signature

Date 15-March-2018

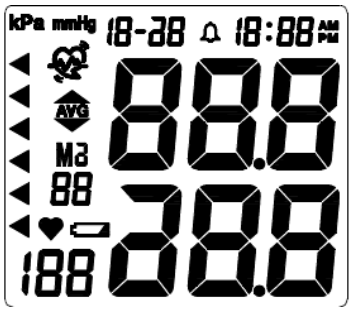
Signature of Witness _____

Name Jonathan Chen AVITA CORPORATION

Authorized Signature

Address 9F, NO.78, SEC.1, KWANG-FU RD., SAN-CHUNG District, New Taipei City 24158 Taiwan R.O.C.

Comparison with BRAUN BPW4500 and AViTA BPM17

Devices – Item 9	BRAUN BPW4500	AViTA BPM17
Pictures		
Display Image	Black & White OLED dot matrix display (128 x 32 pixels) with bitmap graphics and scrolling. Some examples given below: 	
Validation		ESH 2010 (IP2)
Category	Wrist Type Blood Pressure Monitor	Wrist Type Blood Pressure Monitor
Casing – Item 10	*Dimensions* 76.6mm x 67.2mm x 78.6mm (W x H x D) *Ports* Cuff Port *Features* *N/A*	*Dimensions* 94.5mm x 68.0mm x 18.5mm (W x H x D) *Ports* Cuff Port *Features* *N/A*

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

Display – Item 11	*Type* White OLED dot-matrix (graphic) display	*Type* Segment LCD
Carrying/Mounting Facilities – Item 12	N/A	Storage Case available
Software other than Algorithm – Item 13	New device has a simplified User Interface based on a single power button, a graphic display and a multi-colour LED (in heart shape). Measurement starts when wrist is positioned at the correct angle. User is prompted to find the correct wrist position with a “ball-in-the-hole” on the graphic display. Readings (memories) cannot be displayed on device – only by transfer to smartphone by Bluetooth. Visuals on display are different due to graphic dot-matrix display	N/A
Memory Capacity Item 14	*Number of stored measurements* 1*100 times with date and time	*Number of stored measurements* 2*90 times with date and time
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	Bluetooth LE (BT Smart 4.0) to transfer measurement data to smartphone (with dedicated APP)	N/A
Power Supply Item 17	2 * AAA Batteries (3V)	2 * AAA Batteries (3V)
Other differences	*Other Details on Equivalent device that are different to Validated device* Wrist positioning system (wrist angle) to ensure device is at heart level	*Other Details on Validated device that are different to Equivalent device* N/A
Same Criteria	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 4% *Method* Oscillometric *Ranges* Blood Pressure: 40~255mmHg	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 4% *Method* Oscillometric *Ranges* Blood Pressure: 40~255mmHg

	Pulse Rate: 40~199 beat/min. *Inflation* Automatic inflation by internal pump *Deflation* Automatic by exhaust valve *Cuffs (Please state sizes and materials used)* Cuff size: 12.5-21 cm Bladder dimension: 138x53mm Materials: • PVC « faux-leather » in white color on cuff outside • Stretchy Lycra in blue/purple color inside cuff • Velcro loop and hook in grey color *Sensors* US-9111-006-S (semiconductor) *Measurement Records* YES: SYS, DIA, Pulse, IHB (irregular heartbeat), Date & time *Measurements other than Blood Pressure* Pulse (heart rate) Irregular heartbeat Date & time ***Buttons/Switches*** *Power* START/POWER Button (on / off). Also used to abort measurement *Measurement Records* N/A *Analysis* N/A *Event Marking* N/A	Pulse Rate: 40~199 beat/min. *Inflation* Automatic inflation by internal pump *Deflation* Automatic by exhaust valve *Cuffs (Please state sizes and materials used)* Cuff size: 12.5-21 cm Bladder dimension: 138x53mm Materials: • Polyester in black color on cuff outside • Stretchy polyester in black color inside cuff • Velcro loop and hook in black color *Sensors* US-9111-006-S (semiconductor) *Measurement Records* YES: SYS, DIA, Pulse, IHB (irregular heartbeat), Date & time *Measurements other than Blood Pressure* Pulse (heart rate) Irregular heartbeat Date & time ***Buttons/Switches*** *Power* START/POWER Button (on / off). Also used to abort measurement *Measurement Records* Memory Recall Buttons – M1 for User 1 / M2 for User 2 *Analysis* N/A *Event Marking* N/A

	Communication N/A ***Display/Symbols/Indicators*** *Preparation* Zero pressure check: “Healthy heart” symbol  shows on OLED display for about 2 seconds *Measurement Procedure* Inflation: OLED display shows blinking “Healthy heart” symbol Deflation Display Results *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator (coloured LED – heart shape) Irregular Heartbeat symbol Errors, if any (ERROR 0, 1, 2, 3) *Measurement Records* N/A (measurement is recorded but not indication on display) *Date and Time* N/A (date & time not visible on device. Set internally when connected to smartphone) *Power* Low Battery symbol *Function* N/A *Features* N/A *Not described*	*Communication* N/A ***Display/Symbols/Indicators*** *Preparation* Zero pressure check: Up/Down arrow symbol  shows on LCD for about 2 seconds *Measurement Procedure* Inflation: LCD shows cuff pressure value and pulse symbol Deflation Display Results *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator Irregular Heartbeat symbol Errors, if any (Err 0, 1, 2, 3) *Measurement Records* Memory recall number *Date and Time* Yes, displayed on LCD *Power* Low Battery symbol *Function* AVG Symbol *Features* N/A *Not described*

	Algorithms *Averages and Differences* N/A *Diagnostic* N/A *Functions* N/A	***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* N/A *Functions* N/A
Comparable Criteria	*Measurement Records* Memory capacity: 100 measurements for 1 users (1*100) ***Buttons/Switches*** *Measurement Records* N/A *Function* N/A *Analysis* N/A *Event Marking* N/A *Communication* Long press on power button (> 5 seconds) to initiate Bluetooth pairing with smartphone (requires dedicated APP) ***Display/Symbols/Indicators*** *Post Measurement* WHO indicator with heart-shaped LED in 4 colours, with ESH 2013 hypertension level for home use (135/85mmHg) *Measurement Records*	*Measurement Records* Memory capacity: 90 measurements for 2 users (2*90) ***Buttons/Switches*** *Measurement Records* Memory Recall Buttons – M1 to select User 1, M2 to select User 2. Buttons also used to scroll thru readings *Function* Time & Date Setting (SET button) *Analysis* Last 3 readings average shown in memory mode *Event Marking* Delete all readings for User 1 or user 2: long press on M1 or M2 button when device is OFF *Communication* N/A ***Display/Symbols/Indicators*** *Post Measurement* WHO indicator, bar indicator with 6-levels (4-colours) *Measurement Records*

	N/A *Date and Time* N/A (date & time set internally when connected to smartphone – date & time not visible on device) *Communication* Bluetooth icon shows on display during BT pairing sequence. Transfer of readings to smartphone app is done in background w/o indication on display *Features* Wrist position indicator shows before measurement starts: user is prompted to position the wrist at correct angle using a “ball-in-the hole” game (dot in circle), as shown on OLED display. Measurement starts only when device is positioned is at heart level when seated. If wrist is not at correct angle for a given timeout, OLED display will show an Error message, then device will auto shut-off. User name displayed on OLED screen at power-up (if device was connected by Bluetooth with smartphone APP).	Memory recall number *Date and Time* Date and Time shown on LCD display and with each record *Communication* N/A *Features* AVG symbol for last 3 measurements

Comments		
Recommendation	**Recommended**	
Date	**23 March 2018**	