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 Patrick Chow, (Name of a Company Director) a Director of Grandway Technology (Shenzhen) Limited, (Company name)

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

Maker[a]	Beurer GmbH	*Address*	Beurer GmbH, Söflinger Strasse 218, 89077 Ulm/ Germany
Manufacturer[b]	Grandway	*Address*	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Brand[c]	Beurer	Model[d]	BM67

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]	Grandway	*Address*	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Manufacturer[b]	Grandway	*Address*	No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen
Brand[c]	G.LAB	Model[d]	MD2680

Existing validated blood pressure measuring device.

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

Validation of the G.LAB MD2680(Grandway Technology Limited, Shenzhen, China) digital automatic blood pressure monitor according to the European Society of Hypertension International Protocol.

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.

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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.

(10) Button arrangement: Start/Stop button, M button, SET button, + button and - button

(11) LCD can display User 3 and User 4, BLE icon built-in

(13) BLE transmission, All measuring record will transmit to mobile phone

(14) Stores 30*4 readings

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 Patrick Chow

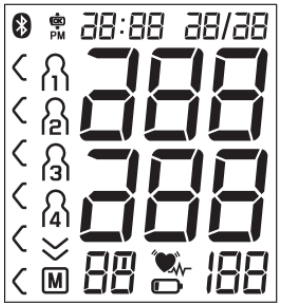
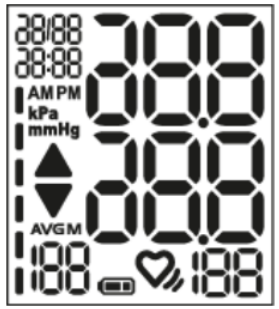
Date 7-Apr, 2020

Signature of Witness _____

Name Eric Wong

Address No.5, the Second Industrial Zone, Zhukeng Community, Longtian Street, Pingshan District, Shenzhen

Comparison of the Beurer BM67 with the G.LAB MD2680

Devices – Item 9	Beurer BM67	G.LAB MD2680
Pictures		
Display Image		
Validation		**ESH-IP 2010, BHS and AAMI**
Category	***Blood Pressure Monitor Device***	***Blood Pressure Monitor Device***
Casing – Item 10	*Dimensions* **139 (L) x 103(W) x 54(H) cm** *Ports* ***N/A*** *Features* ***Systolic and diastolic blood pressure measurement*** ***Pulse rate measurement*** ***Irregular heartbeat (IHB) detection and indication*** ***WHO blood pressure classification scale (WHO Guidelines 1999)*** ***Cuff tightness indicator*** ***Bluetooth LE***	*Dimensions* **160 (L) x 99(W) x 56(H) cm** *Ports* ***N/A*** *Features* ***Systolic and diastolic blood pressure measurement*** ***Pulse rate measurement*** ***Irregular heartbeat (IHB) detection and indication*** ***WHO blood pressure classification scale (WHO Guidelines 1999)***

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Display – Item 11	*Type* ***Single Screen Display*** ***Segment LCD*** *Measurement Procedure* ***During Measurement: BP level & Heartbeat*** *Post Measurement* ***SBP, DBP and Pulse*** ***Measurement error: E1, E2, E3, E4, E5, E6 and Er7*** ***Memory-Zone mean (A symbol)*** ***7- day morning memory-zone mean (AM symbol)*** ***7- day evening memory-zone mean (PM symbol)***	*Type* ***Single Screen Display*** ***Segment LCD*** *Measurement Procedure* ***During Measurement: BP level & Heartbeat*** *Post Measurement* ***SBP, DBP and Pulse*** ***Measurement error: E1, E2, E3, E4, E5 and E6*** ***Memory-Zone mean (A symbol)*** ***7- day morning memory-zone mean (AM symbol)*** ***7- day evening memory-zone mean (PM symbol)***
Carrying/Mounting Facilities – Item 12	***N/A***	***N/A***
Software other than Algorithm – Item 13	***Memory zone means*** ***7- day morning memory-zone mean*** ***7- day evening memory-zone mean*** ***WHO Guidelines 1999***	***Memory zone means*** ***7- day morning memory-zone mean*** ***7- day evening memory-zone mean*** ***WHO Guidelines 1999***
Memory Capacity Item 14	***60 memories x 4 users***	***120 memories x 2 users***
Printing Facilities Item 15	***N/A***	***N/A***
Communication Facilities – Item 16	***N/A***	***N/A***
Power Supply Item 17	***6.0Vdc, 600mA (supplied by a separate approved AC/DC adaptor)*** ***Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)*** ***Battery Life ~ 200 measurements***	***Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)*** ***Battery Life ~ 500 measurements***
Other differences	***Nil***	***Nil***
Same Criteria	***Measurement*** *Accuracy* **BP accuracy ± 3mmHg** **Pulse accuracy ± 5%** *Method* ***Oscillometric method made during cuff deflation***	***Measurement*** *Accuracy* **BP accuracy ± 3mmHg** **Pulse accuracy ± 5%** *Method* ***Oscillometric method made during cuff deflation***

	Ranges ***Systolic pressure: 50 – 250mmHg*** ***Diastolic pressure: 30 – 200 mmHg*** ***Pulse rate: 40 – 180 pulse/minute*** ***Manually initiated measurements*** ***Measurements are from single inflations*** *Inflation* **Inflation 0 mmHg – 300 mmHg** **Automatic Inflation** **Zero pressure check before inflation** *Deflation* ***Automatic Deflation*** Cuffs(Please state sizes and materials used) **Nylon Material Standards Type: 22 – 36 cm (Original),** **Nylon Material Large: 35 – 44 cm (Optional),** **Nylon Material Universal: 22 – 44 cm (Optional)** *Sensors* **US9111 Resistance Type Pressure Sensors** *Measurement Records* **Memory Capacity: 30 memories x 4 users** *Measurements other than Blood Pressure* **N/A** ***Buttons/Switches*** *Power* **Power (**  **Symbol)** *Measurement records*	*Ranges* ***Systolic pressure: 50 – 250mmHg*** ***Diastolic pressure: 30 – 200 mmHg*** ***Pulse rate: 40 – 180 pulse/minute*** ***Manually initiated measurements*** ***Measurements are from single inflations*** *Inflation* **Inflation 0 mmHg – 300 mmHg** **Automatic Inflation** **Zero pressure check before inflation** *Deflation* ***Automatic Deflation*** Cuffs(Please state sizes and materials used) **Nylon Material Standards Type: 22 – 36 cm (Original),** **Nylon Material Large: 35 – 44 cm (Optional),** **Nylon Material Universal: 22 – 44 cm (Optional)** *Sensors* **US9111 Resistance Type Pressure Sensors** *Measurement Records* **Memory Capacity: 120 memories x 2 users** *Measurements other than Blood Pressure* **N/A** ***Buttons/Switches*** *Power* **User 1 (**  **Symbol)** **User 2 (**  **Symbol)**

	Memory (M Symbol) *User Selection* **Set (SET Symbol)** *Navigation* **Minus (– Symbol)** **Plus (+ Symbol)** *Measurement records* **User 1 (1 Symbol)** **User 2 (2 Symbol)** **User 3 (3 Symbol)** **User 4 (4 Symbol)** *Function* **Memory (M Symbol) – Memory mode** **Set (SET Symbol) – User Selection/ Set button** **Minus (– Symbol) - Navigation**	*Measurement records* **User 1 (1 Symbol)** **User 2 (2 Symbol)** *Function* **Clock (Symbol) – Set Clock Mode** **User 1 (1 Symbol) – Enter User 1 Memory Mode** **User 2 (2 Symbol) – Enter User 2 Memory Mode** *Analysis* **N/A** *Event Marking* **N/A** *Communication* **N/A** ***Display/Symbols/Indicators*** *Preparation* **Start to Inflate** **Zero pressure check used** *Measurement Procedure* **During Measurement: BP Level and Heartbeat** *Post Measurement* **SBP, DBP and Pulse** **Measurement error: E1, E2, E3, E4, E5, and E6** **Memory-Zone mean(A symbol)** ***7- day morning memory-zone mean (AM Symbol)*** ***7- day evening memory-zone mean (PM Symbol)***

	Plus (+ Symbol) - Navigation *Analysis* **N/A** *Event Marking* **N/A** *Communication* **N/A** ***Display/Symbols/Indicators*** *Preparation*  **Cuff tightness indicator**  **Zero pressure check used** *Measurement Procedure* **During Measurement: BP Level and Heartbeat** *Post Measurement* **SBP, DBP and Pulse** **Measurement error: E1, E2, E3, E4, E5,E6 and E7** **Memory-Zone mean(A symbol)** ***7- day morning memory-zone mean (AM Symbol)*** ***7- day evening memory-zone mean (PM Symbol)*** ***WHO blood pressure classification scale (WHO Guidelines 1999)*** **Irregular heartbeat (IHB) detection and indication** *Measurement Records* **Memory Capacity: 60 memories x 4 users** *Date and Time* **Date and Time** **Date and Time (During memory recall)**	***WHO blood pressure classification scale (WHO Guidelines 1999)*** **Irregular heartbeat (IHB) detection and indication** *Measurement Records* **Memory Capacity: 120 memories x 2 users** *Date and Time* **Date and Time** **Date and Time (During memory recall)** ***Algorithms*** *Averages and Differences* **Memory Zone Means** *Diagnostic* **WHO blood pressure classification scale (WHO Guidelines 1999)** **Irregular heartbeat (IHB) detection**

	Algorithms *Averages and Differences* **Memory Zone Means** *Diagnostic* **WHO blood pressure classification scale (WHO Guidelines 1999)** **Irregular heartbeat (IHB) detection**	
Comparable Criteria	**Casing** Power **Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)** **Battery Life ~ 200 measurements** ***Display/Symbols/Indicators*** *Preperation*  **Cuff tightness indicator**  **Zero pressure check used**	**Casing** Power **Alkaline Battery (DC 6V 600mA, LR06 (AA) 1.5V x 4 pcs)** **Battery Life ~ 500 measurements** ***Display/Symbols/Indicators*** *Preperation*  **Start to Inflate**  **Zero pressure check used**

Comments		
Recommendation	**Recommended**	
Date	**17 September 2020**	