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 Willis Chan, (Name of a Company Director) a Director of Microlife Corporation Co.,, (Company name)

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

Maker[a]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Manufacturer[b]	KAZ Home Appliances	*Address*	Flat 4B&4C,Productivity Building,2nd High Technology Road,Science and industy Park, NanShan District,Shenzhen,PRC
Brand[c]	BRAUN	Model[d]	BUA5000, BUA5000LA, BUA5000LAD1

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]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Manufacturer[b]	Microlife Corporation Co.,	*Address*	9F,431,RuiGuang Road,Nei-Hu,Taipei,114,Taiwan,R.O.C
Brand[c]	Microlife	Model[d]	BP A100 PLUS

Existing validated blood pressure measuring device.

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

Accuracy of the BP A100 blood pressure measuring device coupled with a single cuff with standard-size bladder over a wide range of arm circumferences; Elisa Bonso, Francesca Dorigatti and Paolo Palatini;

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.
(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.

Brief explanation of differences as below, further details are shown in the attachment "BUA5000, BUA5000LA, BUA5000LAD1 comparison table".

(6) Cuffs

New devie is equipped with universal cuff 22-42cm (soft) only and without S, M and L cuff.

(9) Model Name or Number

BRAUN BUA5000, BRAUN BUA5000LA, BRAUN BUA5000LAD1 are the model name for new device and Microlife BP A100 PLUS is the validated device model name.

(10) Casing

Two different housing design. New device has only one On/Off button.

(11) Display

Due to different casing of two models, the size of the LCD is different. Due to new device has less function there is only measurement values, memory, low battery and pulse detection symble shown on the display.

(14) Memory Capacity/ Number of stored measurements

New device has only one set of memory and the validated device has 200 sets of memories.

(18) Other Facilities

Compared to the validated device, new device has less function and without Irregular Heatbeat Indicator, Date and Time, MAM mode and Traffic light Display fucntions that the validated device has.

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 Willis Chan

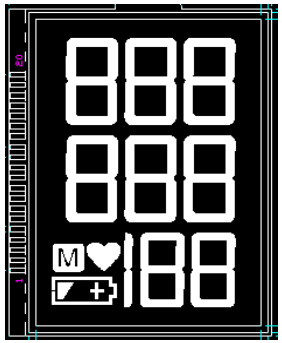
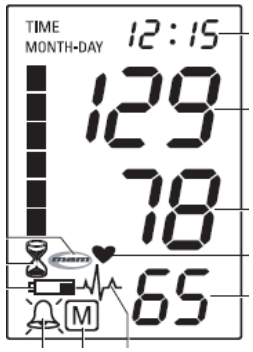
Date Feb. 10, 2015

Signature of Witness _____

Name Gerhard Frick

Address Microlife AG, 9443 Widnau, Switzerland

Comparison of the BRAUN BUA5000/BUA5000LA/BUA5000LAD1 with the Microlife BP A100 PLUS

Devices	BRAUN BUA5000/BUA5000LA/BUA5000LAD1	Microlife BP A100 PLUS
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria		***Memory Capacity*** 200 Sets shown with symbol "M" and date and time ***Display/Symbols/Indicators*** Irregular Heartbeat Indicator Date & time; 2 alarm times for medication. MAM mode Traffic light display ***Cuffs*** Small, Medium and Large cuffs. M-L cuff 22-42cm (soft) ***Power*** 4 x 1.5v Batteries; size AA

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

		Mains Adapter DC 6V, 600mA (optional)
Device 2 Criteria	***Memory Capacity*** 1 Set shown with symbol "M". ***Cuffs*** Small, Medium cuffs. (No large cuff) Universal cuff 22-42cm (soft) ***Power*** 4 x 1.5v Batteries; size AA	
Same Criteria	***Measurement*** *Accuracy* BP Accuracy ±3mmHg Pulse accuracy ±5% of the reading *Method* Oscillometric BP Range 30-280 mmHg Cuff Pressure 0-299 mmHg *Inflation* Automatic ***Casing*** *Display* LCD	***Measurement*** *Accuracy* BP Accuracy ±3mmHg Pulse accuracy ±5% of the reading *Method* Oscillometric BP Range 30-280 mmHg Cuff Pressure 0-299 mmHg *Inflation* Automatic ***Casing*** *Display* LCD
Comparable Criteria	***Measurement*** *Ranges* Pulse Rate Range 40-199 pulse/min	***Measurement*** *Ranges* Pulse Rate Range 40-200 pulse/min

Recommendation	***Recommended***
Date	11 February 2015