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 Gary Hung, (Name of a Company Director) a Director of Rossmax International Ltd., (Company name)

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

Maker[a]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Manufacturer[b]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Brand[c]	Alvita	Model[d]	Blood Pressure Monitor – Arm (CG155f)

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]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Manufacturer[b]	Rossmax Swiss GmbH	*Address*	Tramstrasse 16, CH-9442 Berneck, Switzerland
Brand[c]	Rossmax	Model[d]	CF175

Existing validated blood pressure measuring device.

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

Zhang, Lu; Kang, Yuan-Yuan; Zeng, W. Validation of the Rossmax CF175 upper-arm 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 DETY 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.

9. The validated model is CF175 and the claimed model is Blood Pressure Monitor – Arm.

10. The appearance is different.

11. CF175 has talking speaker mark, but Blood Pressure Monitor – Arm not.

13. CF175 has talking speaker function, but Blood Pressure Monitor – Arm not.

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 Gary Hung Company Stamp/Seal

Name Gary Hung

Date May 15, 2015

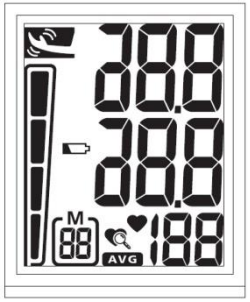
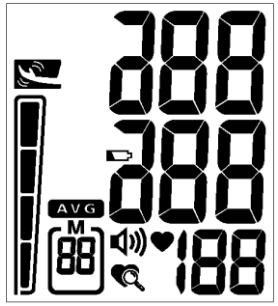
ROSSMAX INTERNATIONAL LTD.

Signature of Witness Mark Lin

Name Mark Lin

Address 12F, No.189, Kang Chien Rd., Taipei, 114, Taiwan

Comparison of the Alvita Blood Pressure Monitor – Arm with the Rossmax CF175

Devices	*Alvita Blood Pressure Monitor – Arm(CG155f)*	*Rossmax CF175*
Pictures		
Display		
Validation		ESH 2010
Device 1 Criteria		***Display/Symbols/Indicators*** Talking Speaker Mark ***Casing*** *Ports* Data Link Socket *Power* AC Adaptor(Optional)
Device 2 Criteria		
Same Criteria	***Measurement*** *Accuracy* Pressure: ± 3 mmHg Pulse: ± 5% of reading *Method* Oscillometric measurement method	***Measurement*** *Accuracy* Pressure: ± 3 mmHg Pulse: ± 5% of reading *Method* Oscillometric measurement method

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

	Inflation Automatic inflation Inflation: 0 mmHg - 299 mmHg Measurement Range; Pressure:30-260mmHg Pulse: 40-199 beats/minute *Deflation* Automatic deflation *Cuffs* Arm circumference: Adult: 24~40 cm (9.4”~15.7”) *Sensors* Semi conductor *Measurement Records* Memory capacity: 90 ***Buttons/Switches*** *Power* On/Off/Start (⏻ symbol) *Measurement Records* Memory(M symbol) ***Display/Symbols/Indicators*** *Preparation* “0” blinking *Measurement Procedure* Heartbeat symbol during deflation *Post Measurement* systolic blood pressure, diastolic blood pressure, and pulse Movement Detector (once a body movement has been detected) Hypertension Risk Indicator (JNC-7) Irregualr Heartbeat (IHB) Detector *Measurement Records* M symbol and Memory Sequence Memory Average Symbol *Power* Weak Battery Indicator ***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* Hypertension Risk Indicator (JNC-7) Irregular Heartbeat detection	*Inflation* Automatic inflation Inflation: 0 mmHg - 299 mmHg Measurement Range; Pressure:30-260mmHg Pulse: 40-199 beats/minute *Deflation* Automatic deflation *Cuffs* Arm circumference: Adult: 24~40 cm (9.4”~15.7”) *Sensors* Semi conductor *Measurement Records* Memory capacity: 90 ***Buttons/Switches*** *Power* On/Off/Start (⏻ symbol) *Measurement Records* Memory(M symbol) ***Display/Symbols/Indicators*** *Preparation* “0” blinking *Measurement Procedure* Heartbeat symbol during deflation *Post Measurement* systolic blood pressure, diastolic blood pressure, and pulse Movement Detector (once a body movement has been detected) Hypertension Risk Indicator (JNC-7) Irregualr Heartbeat (IHB) Detector *Measurement Records* M symbol and Memory Sequence Memory Average Symbol *Power* Weak Battery Indicator ***Algorithms*** *Averages and Differences* Average of the last 3 measurements *Diagnostic* Hypertension Risk Indicator (JNC-7) Irregular Heartbeat (IHB) detection

	Casing *Display* Single screen display Segment LCD *Power* Four AAA Batteries	***Casing*** *Display* Single screen display Segment LCD *Power* Four AAA Batteries
Comparable Criteria		

Comments		
Recommendation	***Recommended***	
Date	21 May 2015	