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 Joe Zhao, (Name of a Company Director) a Director of Globalcare Medical Technology, (Company name)

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

Maker[a]	Paul Hartmann AG	*Address*	Paul Hartmann AG, Paul-Hartmann-Strasse 12, 89522 Heidenheim, Germany
Manufacturer[b]	Globalcare Medical Technology	*Address*	A7th Building 39 Middle Industrial Main Road European Industrial Zone, Xiaolan Town, Zhongshan City Guangdong Province 52815 CHINA
Brand[c]	Hartmann	Model[d]	HARTMANN Veroval BPU22

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]	Globalcare Medical Technology	*Address*	A7th Building 39 Middle Industrial Main Road European Industrial Zone, Xiaolan Town, Zhongshan City Guangdong Province 52815 CHINA
Manufacturer[b]	Globalcare Medical Technology	*Address*	A7th Building 39 Middle Industrial Main Road European Industrial Zone, Xiaolan Town, Zhongshan City Guangdong Province 52815 CHINA
Brand[c]	Globalcare Medical Technology	Model[d]	GCE603

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 Globalcare GCE603 automated blood pressure monitor for self-measurement according to the European Society of Hypertension International Protocol revision 2010

Cheng Songa, Yang Yub, Bao-Chuan Lua and Xi-Ling Yanc
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.

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

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Fax +353 1 278 3835 Web www.dableducational.org

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.

Declaration of Equivalence Form

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.

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 _____

Name

Date 2022-2-18

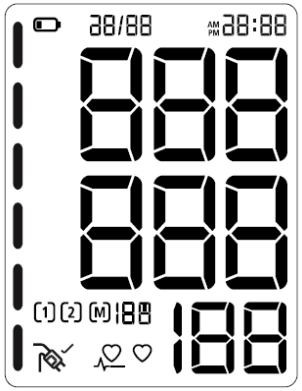
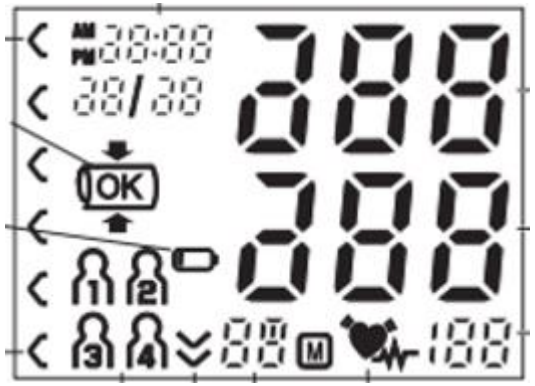
Signature of Witness _____

Name

Address

Company Stamp/Seal

Comparison of the HARTMANN Veroval BPU22 with the Globalcare - GCE603

Devices – Item 9	HARTMANN Veroval BPU22	Globalcare - GCE603
Pictures		
Display Image		
Validation	Equivalent to GCE603	ESH 2010 ESH 2002 BHS AAMI
Category	Arm Type Blood Pressure Monitor	Arm Type Blood Pressure Monitor

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Casing – Item 10	*Dimensions* 134 * 48 * 91 mm (W * H *D) *Ports* Cuff Port *Features* *NA*	*Dimensions* 112 * 110 * 58 mm (W * H *D) *Ports* Cuff Port *Features* *NA*
Display – Item 11	*Type* LCD	*Type* LCD
Carrying/Mounting Facilities – Item 12	NA	*NA*
Software other than Algorithm – Item 13	Different from GCE603 for different functions as 2 users, date and time setting, alarm, average	Different from bpu22 for different functions as 2 users, date and time setting, alarm, average
Memory Capacity Item 14	*Number of stored measurements* 2*100 times with date and time	*Number of stored measurements* 4*30 times with date and time
Printing Facilities Item 15	Artwork logo, gift box and manual is different from GCE603 for different functions	Artwork logo, gift box and manual is different for different functions
Communication Facilities – Item 16	NA	*NA*
Power Supply Item 17	4 * AA Batteries	4 * AA Batteries
Other differences	*Other Details on Equivalent device that are different to Validated device* *NA*	*Other Details on Validated device that are different to Equivalent device* NA
Same Criteria	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 5% *Method* Oscillometric *Ranges*	***Measurement*** *Accuracy* Blood Pressure Accuracy ± 3 mmHg Pulse Accuracy ± 5% *Method* Oscillometric *Ranges*

	Cuff pressure 0 -300 mmHg Systolic 50 mmHg – 280 mmHg Diastolic 30 mmHg – 200 mmHg *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs (Please state sizes and materials used)* 22-42 cm Bladder dimension: 140x250mm *Sensors* MSP40-GSF *Measurement Records* 2*100 times with date and time *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* START/POWER Button (on / off) *Measurement Records* Memory Recall Buttons – User 1 / User 2 *Function* Date and Time Setting– combination of button user 1+user2 *Analysis* N/A *Event Marking* N/A *Communication* N/A	Cuff pressure 0 -300 mmHg Systolic 50 mmHg – 280 mmHg Diastolic 30 mmHg – 200 mmHg *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* 22-42 cm Bladder dimension: 140x250mm *Sensors* MSP40-GSF *Measurement Records* 1*60 times with date and time *Measurements other than Blood Pressure* Pulse rate ***Buttons/Switches*** *Power* START/POWER Button (on / off) *Measurement Records* Memory Recall Button - M *Function* Date and Time Set Button – SET Function Button - +/- *Analysis* N/A *Event Marking* N/A *Communication* N/A

	Display/Symbols/Indicators *Preparation* N/A *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Average *Communication* N/A *Features* N/A *Not described* ***Algorithms*** *Averages and Differences* Average of all measurement Average morning values of the last seven days measurements between 5:00AM and 9:00AM	***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Inflation symbol Deflation symbol Heartbeat symbol during deflation Irregular Heartbeat symbol *Post Measurement* Systolic blood pressure Diastolic blood pressure Pulse rate WHO indicator *Measurement Records* Memory recall number *Date and Time* Date and Time *Power* Low Battery detection symbol *Function* Average Alarm *Communication* N/A *Features* N/A *Not described* ***Algorithms*** *Averages and Differences* Average of the last 3 measurements

	Average evening values of the last seven days measurements between 6:00PM and 8:00PM *Diagnostic* N/A *Functions* N/A *Communication* N/A	 *Diagnostic* N/A *Functions* N/A *Communication* N/A
Comparable Criteria		

Comments		
Recommendation	**RECOMMENDED**	
Date	**February 2023**	