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 Gao Wendong, a Director of Sejoy Electronics & Instruments Co., Ltd,
Name of a Company Director — 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 Str.218, 89077 Ulm
Manufacturer[b]	Sejoy Electronics&Instruments Co., Ltd	*Address*	Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
Brand[c]	Beurer	Model[d]	BM95

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]	Sejoy Electronics&Instruments Co., Ltd	*Address*	Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
Manufacturer[b]	Sejoy Electronics&Instruments Co., Ltd	*Address*	Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China
Brand[c]	SEJOY	Model[d]	BP-1307

Existing validated blood pressure measuring device.

which has previously passed the ESH2010 protocol, the results of which were published as follows:

Validation of the Sejoy BP-1307 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 ☐	

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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.

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 model name is changed to BM95 from SEJOY BP-1307

(10) The casing of the device is with different appearnace

(11) The size of LCD display is different and the icons are different

(13) Additional software on Bluetooth Chip for transmission and software with USB transmission

(14) Stores 2*64 readings instead of 2*60

(16) The BM95 is with USB & bluetooth function

(17) Power supply changed to 4 * AAA Batteries instead of 4 * AA Batteries

(18) The BM95 is with ECG function

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 Gao Wendong ____ Company Stamp/Seal

Name Gao Wendong

Date 12 Dec, 2017

Signature of Witness Han Dongzheng ____

杭州世佳电子有限公司
HANGZHOU SEJOY ELECTRONICS & INSTRUMENTS CO.,LTD

Name Han Dongzheng

Address 12 Dec, 2017

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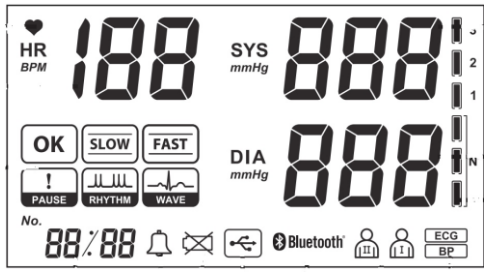
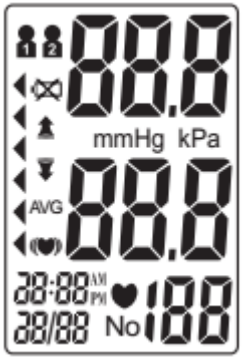
Comparison of the Beurer BM95 with the SEJOY BP-1307

Devices – Item 9	Beurer BM95	SEJOY BP-1307
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper arm blood pressure monitor for home blood pressure monitoring	Upper arm blood pressure monitor for home blood pressure monitoring
Casing – Item 10	*Dimensions* Main Unit Approx. 128x128x40 mm ECG Pen Approx. 25x125mm *Ports* Cuff port USB port *Features* Blood pressure measurement Heart rate WHO Classification	*Dimensions* Approx.166x114x72mm *Ports* Cuff port AC adapter port *Features* Blood pressure measurement Heart rate WHO Classification

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	ECG Measusurement	
Display – Item 11	*Type* LCD	*Type* LCD
Carrying/Mounting Facilities – Item 12	no	no
Software other than Algorithm – Item 13	Software on Bluetooth Chip for transmission, software with USB transmission	no
Memory Capacity Item 14	*Number of stored measurements* 2x64 measurements with date and time	*Number of stored measurements* 2x60 measurements with date and time
Printing Facilities Item 15	Printing by using PC software	no
Communication Facilities – Item 16	USB & Bluetooth transmission	no
Power Supply Item 17	no	no
Other differences	ECG measurement, PC software	N/A
Same Criteria	***Measurement*** *Accuracy* Pressure :±3mmHg Pulse rate: ±5% *Method* Oscillometric *Ranges* Cuff pressure 0-300mmHg Pulse 30-180 beats/min *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* 22-42 cm	***Measurement*** *Accuracy* Pressure :±3mmHg Pulse rate: ±5% *Method* Oscillometric *Ranges* Cuff pressure 0-300mmHg Pulse 30-180 beats/min *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* 22-42 cm

	PVC, Polyester *Sensors* Semi-conductive pressure *Measurement Records* 2x64 measurements with date and time *Measurements other than Blood Pressure* Heart rate WHO Classification ECG measurement ***Buttons/Switches*** *Power* Start/Stop button *Measurement Records* Memory recall button – M button *Function* Date and time Setting– Setting button"+" for 3 sec *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Heartbeat symbol during deflation *Post Measurement*	PVC, Polyester *Sensors* Semi-conductive pressure *Measurement Records* 2x60 measurements with date and time *Measurements other than Blood Pressure* Heart rate WHO Classification ***Buttons/Switches*** *Power* Start/Stop button *Measurement Records* Memory recall button – M button *Function* Date and time setting– SET 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

	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* N/A *Communication* Bluetooth+ bluetooth symbol *Features* ECG symbols *Not described* ***Algorithms*** *Averages and Differences* N/A *Diagnostic* N/A *Functions* N/A *Communication* N/A	*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* N/A *Diagnostic* N/A *Functions* N/A *Communication* N/A

Comparable Criteria		

Comments		This equivalence relates to the blood pressure measurement characteristics of both devices.
Recommendation	**Recommended**	
Date	**4th February 2018**	