

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

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 **Beurer GmbH, Söflinger Str.218, 89077 Ulm** Address **Building 2, No.202, Zhengzhong Rd., Westlake Econmy & Technology Zone, 310030, Hangzhou, China**
 Brand^c **Beurer** Model^d **BM35/1**

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 **No.365 , Wuzhou Road, HangzhouYuhang Economic Development Zone, Yuhang HANGZHOU, Zhejiang, 311100, Hangzhou, China**
 Manufacturer^b **Sejoy Electronics&Instruments Co., Ltd** Address **No.365 , Wuzhou Road, HangzhouYuhang Economic Development Zone, Yuhang HANGZHOU, Zhejiang, 311100, Hangzhou,**
 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" type="checkbox"/>

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.

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
- Completed DET9 Form
- 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 3th March, 2021



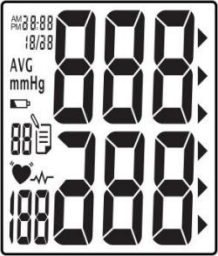
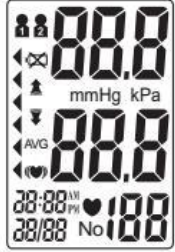
Signature of Witness Han Dongzheng

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

Name Han Dongzheng

Address 3th March, 2021

Comparison of the Beurer BM35/1 with the SEAJoy BP-1307

Devices – Item 9	Beurer BM35/1	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	<p><i>Dimensions</i></p> <p>Approx.135x105x53mm</p> <p><i>Ports</i></p>	<p><i>Dimensions</i></p> <p>Approx.166x114x72mm</p> <p><i>Ports</i></p>

	<p>Cuff port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p> <p>WHO Classification</p>	<p>Cuff port</p> <p>AC adapter port</p> <p><i>Features</i></p> <p>Blood pressure measurement</p> <p>Heart rate</p> <p>WHO Classification</p>
Display – Item 11	<i>Type</i> LCD	<i>Type</i> LCD
Carrying/Mounting Facilities – Item 12	no	no
Software other than Algorithm – Item 13	no	no
Memory Capacity Item 14	<p><i>Number of stored measurements</i></p> <p>2x60 measurements with date and time</p>	<p><i>Number of stored measurements</i></p> <p>2x60 measurements with date and time</p>
Printing Facilities Item 15	no	no
Communication Facilities – Item 16	no	no
Power Supply Item 17	no	no

Other differences	N/A	N/A
<p>Same Criteria</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure :±3mmHg</p> <p>Pulse rate: ±5%</p> <p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <p>22-42cm</p> <p>22~36cm</p> <p>PVC, Polyester</p> <p><i>Sensors</i></p> <p>Semi-conductive pressure</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>Pressure :±3mmHg</p> <p>Pulse rate: ±5%</p> <p><i>Method</i></p> <p>Oscillometric</p> <p><i>Ranges</i></p> <p>Cuff pressure 0-300mmHg</p> <p><i>Inflation</i></p> <p>Automatic inflation by internal pump</p> <p><i>Deflation</i></p> <p>Automatic speed deflation system</p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <p>22-42 cm</p> <p>PVC, Polyester</p> <p><i>Sensors</i></p> <p>Semi-conductive pressure</p>

	<p><i>Measurement Records</i></p> <p>2x60 measurements with date and time</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Heart rate</p> <p>WHO Classification</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>Start/Stop button</p> <p><i>Measurement Records</i></p> <p>Memory recall button – MEM button</p> <p><i>Function</i></p> <p>Date and time Setting– button “🕒” button</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p>	<p><i>Measurement Records</i></p> <p>2x60 measurements with date and time</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Heart rate</p> <p>WHO Classification</p> <p>Buttons/Switches</p> <p><i>Power</i></p> <p>Start/Stop button</p> <p><i>Measurement Records</i></p> <p>Memory recall button – M button</p> <p><i>Function</i></p> <p>Date and time setting– SET button</p> <p><i>Analysis</i></p> <p>N/A</p> <p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p>
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	<p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol</p> <p>Deflation symbol</p> <p>Heartbeat symbol during deflation</p> <p>Irregular Heartbeat symbol</p> <p><i>Post Measurement</i></p> <p>Systolic blood pressure</p> <p>Diastolic blood pressure</p> <p>Pulse rate</p> <p>WHO indicator</p> <p><i>Measurement Records</i></p> <p>Memory recall number</p> <p><i>Date and Time</i></p> <p>Date and Time</p> <p><i>Power</i></p> <p>Low battery detection symbol</p> <p><i>Function</i></p> <p>Average</p> <p><i>Communication</i></p>	<p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Inflation symbol</p> <p>Deflation symbol</p> <p>Heartbeat symbol during deflation</p> <p>Irregular Heartbeat symbol</p> <p><i>Post Measurement</i></p> <p>Systolic blood pressure</p> <p>Diastolic blood pressure</p> <p>Pulse rate</p> <p>WHO indicator</p> <p><i>Measurement Records</i></p> <p>Memory recall number</p> <p><i>Date and Time</i></p> <p>Date and Time</p> <p><i>Power</i></p> <p>Low battery detection symbol</p> <p><i>Function</i></p> <p>Average</p> <p><i>Communication</i></p>
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	<p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>N/A</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p>	<p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>N/A</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p>
Comparable Criteria		
Comments	This equivalence relates to the blood pressure measurement characteristics of both devices.	
Recommendation	Recommended	
Date	March 2021	