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. Bill Huang,  
Name of a Company Director

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

Maker\# Beurer  
Address Beurer GmbH, Söflinger Strasse 218, 89077 Ulm/ Germany

Manufacturers\# AVITA Corporation  
Address 9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.

Brand\# Beurer  
Model\# BC51

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\# AVITA Corporation  
Address 9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.

Manufacturer\# AVITA Corporation  
Address 9F, NO.78, SEC.1, KWANG-FU RD. , SAN –Chung District, New Taipei City 24158 Taiwan R.O.C.

Brand\# AVITA  
Model\# BPM17

Existing validated blood pressure measuring device.

which has previously passed the ESH-2010 protocol, the results of which were published as follows:


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\# ☐
         2 Algorithm for Auscultatory Measurements  Yes ☐ No ☒ N/A\# ☐
         3 Artefact/Error Detection  Yes ☐ No ☒ N/A\# ☐
         4 Microphone(s)  Yes ☐ No ☒ N/A\# ☐
         5 Pressure Transducer  Yes ☐ No ☒ N/A\# ☐
         6 Cuffs or Bladders  Yes ☐ No ☒ N/A\# ☐
         7 Inflation Mechanism  Yes ☐ No ☒ N/A\# ☐
         8 De\‘flation Mechanism  Yes ☐ No ☒ N/A\# ☐

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 ☒ N/A\# ☒
         15 Printing Facilities  Yes ☐ No ☒ N/A\# ☒
         16 Communication Facilities  Yes ☐ No ☒ N/A\# ☒
         17 Power Supply  Yes ☐ No ☒ N/A\# ☒
         18 Other Facilities  Yes ☐ No ☒ N/A\# ☒

An explanation of each item ticked “Yes” must be included in Section B or on a separate sheet.

Notes:
\# Provide the name and address of the manufacturer of the device.
\# Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
\# Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
\# Provide the model name, if alternative or internal model names are used, include all. Each device must be uniquely identifiable.
\# Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
\# Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
\# 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 different. Beurer BC51 for new device and validated device is BPM17

10) The designs of the case are different.

11) The size and displayed data are different.

12) Carrying/Mounting Facilities are different.

14) Beurer BC51 has 2*120 memories

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  [Signature]

Name  Bill Huang

Date  2020.9.21

Signature of Witness  [Signature]

Name  Jonathan Chen

Address  9F, NO.78, SEC.1, KWANG-FU RD., SAN-Chung District, New Taipei City 24158 Taiwan R.O.C.
Comparison of the Beurer BC51 wrist blood pressure monitor with the AViTA BPM17

<table>
<thead>
<tr>
<th>Devices – Item 9</th>
<th>Beurer BC51</th>
<th>AViTA BPM17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictures</td>
<td><img src="image1" alt="Beurer BC51 Picture" /></td>
<td><img src="image2" alt="AViTA BPM17 Picture" /></td>
</tr>
<tr>
<td>Display Image</td>
<td><img src="image3" alt="Beurer BC51 Display" /></td>
<td><img src="image4" alt="AViTA BPM17 Display" /></td>
</tr>
</tbody>
</table>

**Validation**

- ESH 2010 IP2

**Category**

- Wrist Type Blood Pressure Monitor

**Casing – Item 10**

<table>
<thead>
<tr>
<th>Dimensions</th>
<th>Beurer BC51</th>
<th>AViTA BPM17</th>
</tr>
</thead>
<tbody>
<tr>
<td>approx. 94.8mm x 68mm x 20mm (W x H x D)</td>
<td></td>
<td>approx. 94.5mm x 68mm x 15mm (W x H x D)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Features</th>
<th>Beurer BC51</th>
<th>AViTA BPM17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cuff Port</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABS plastic part</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printing</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Form DET9 140527
<table>
<thead>
<tr>
<th></th>
<th>Item 11</th>
<th>Item 12</th>
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</thead>
<tbody>
<tr>
<td>Display – Item 11</td>
<td>LCD</td>
<td>LCD</td>
</tr>
<tr>
<td>Carrying/Mounting</td>
<td>Storage Box</td>
<td>Storage Box</td>
</tr>
<tr>
<td>Facilities – Item 12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software other than</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Algorithm – Item 13</td>
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<td></td>
</tr>
<tr>
<td>Memory Capacity Item 14</td>
<td>2*120 times with date and time</td>
<td>1*90 times with date and time</td>
</tr>
<tr>
<td>Printing Facilities</td>
<td>Artwork logo, gift box and manual is different from AVITA BPM1 for different functions</td>
<td>Artwork logo, gift box and manual is different for different functions</td>
</tr>
<tr>
<td>Item 15</td>
<td></td>
<td></td>
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<tr>
<td>Communication Facilities – Item 16</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Power Supply Item 17</td>
<td>2 * AAA Batteries</td>
<td>2 * AAA Batteries</td>
</tr>
<tr>
<td>Other differences</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Same Criteria**

**Measurement**

**Accuracy**
- Blood Pressure Accuracy ± 3 mmHg
- Pulse Accuracy ± 4%

**Method**
Oscillometri

**Ranges**
- Cuff pressure 0 - 300 mmHg
- Systolic 60 mmHg – 255 mmHg
- Diastolic 40 mmHg – 200 mmHg

**Inflation**
- Automatic inflation by internal pump

**Deflation**
- Automatic speed deflation system

**Cuffs** (Please state sizes and materials used)
approx. 12.5 X 21 cm
<table>
<thead>
<tr>
<th>Bladder dimension: 138x64mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensors</td>
</tr>
<tr>
<td>Pressure sensor</td>
</tr>
<tr>
<td>Measurement Records</td>
</tr>
<tr>
<td>2*120 times with date and time</td>
</tr>
<tr>
<td>Measurements other than Blood Pressure</td>
</tr>
<tr>
<td>Pulse rate</td>
</tr>
<tr>
<td>Buttons/Switches</td>
</tr>
<tr>
<td>Power</td>
</tr>
<tr>
<td>START/POWER Button ( on / off )</td>
</tr>
<tr>
<td>Measurement Records</td>
</tr>
<tr>
<td>Memory Recall Buttons – User 1 / User 2</td>
</tr>
<tr>
<td>Function</td>
</tr>
<tr>
<td>Date and Time Setting– combination of button user 1+user2</td>
</tr>
<tr>
<td>Analysis</td>
</tr>
<tr>
<td>N/A</td>
</tr>
<tr>
<td>Event Marking</td>
</tr>
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<tr>
<td>Communication</td>
</tr>
<tr>
<td>N/A</td>
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<tr>
<td>Display/Symbols/Indicators</td>
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<tr>
<td>Preparation</td>
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<tr>
<td>N/A</td>
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<tr>
<td>Measurement Procedure</td>
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<tr>
<td>Inflation symbol</td>
</tr>
<tr>
<td>Deflation symbol</td>
</tr>
<tr>
<td>Heartbeat symbol during deflation</td>
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<tr>
<td>Irregular Heartbeat symbol</td>
</tr>
</tbody>
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<td>START/POWER Button ( on / off )</td>
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<tr>
<td>Measurement Records</td>
</tr>
<tr>
<td>Memory Recall Button - MEM</td>
</tr>
<tr>
<td>Function</td>
</tr>
<tr>
<td>Date and Time Set Button – SET</td>
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<tr>
<td>Mode (Alarm) Button - Mode</td>
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<tr>
<td>Analysis</td>
</tr>
<tr>
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<tr>
<td>Irregular Heartbeat symbol</td>
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<tr>
<td><strong>Systolic blood pressure</strong></td>
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<tr>
<td>-----------------------------</td>
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<tr>
<td><strong>Diastolic blood pressure</strong></td>
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<tr>
<td><strong>Pulse rate</strong></td>
</tr>
<tr>
<td><strong>WHO indicator</strong></td>
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</tbody>
</table>

**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**
- N/A

**Algorithms**
- Averages and Differences
  - Average of all measurement
  - Average morning values of the last seven days measurements between 5:00AM and 9:00AM
  - Average evening values of the last seven days measurements between 6:00PM and 8:00PM

**Diagnostic**
- N/A

**Functions**
- N/A
<table>
<thead>
<tr>
<th>Comparable Criteria</th>
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<tbody>
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<table>
<thead>
<tr>
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<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Recommended</th>
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<tbody>
<tr>
<td>Date</td>
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