

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

### SECTION A - Please complete all items.

I **Liu Yi,**  
Name of a Company Director

a Director of **Andon Health Co.,Ltd.,**  
Company name

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

Maker<sup>a</sup> **CITIZEN** Address **6-1-12 Tanashi-cho, Nishi-Tokyo-shi, Tokyo 188-8511, Japan**  
 Manufacturer<sup>b</sup> **Andon** Address **Andon Health Co., Ltd. No.3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China**  
 Brand<sup>c</sup> **CITIZEN** Model<sup>d</sup> **CHUD514**  
 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<sup>a</sup> **Andon** Address **Andon Health Co., Ltd. No.3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China**  
 Manufacturer<sup>b</sup> **Andon** Address **Andon Health Co., Ltd. No.3 Jin Ping Street, Ya An Road, Nankai District, Tianjin 300190, China**  
 Brand<sup>c</sup> **Andon** Model<sup>d</sup> **KD-595**  
 Existing validated blood pressure measuring device.

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

Wua N, Zhangb X, Wangb W and Zhangb H. Validation of the Andon KD595 for clinical use and self-measurement according to the European Society of Hypertension International Protocol. Blood Pressure Monitoring. 2016 Apr;21(2):124-7  
 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 <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <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 <sup>f</sup> <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 checked="" type="checkbox"/>	No <input type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>

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 actual maker 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 changed to CITIZEN CHUD514 from Andon KD-595;
- (10) The new device has a different industrial design.
- (11) No symbol for "inflate to measure".
- (13) The new device can show the average value of the last three measurements.
- (14) Stores 99 readings instead of 2\*60 readings.
- (18) No voice 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
- 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](mailto:info@dableducational.org).

Signature of Director   Company Stamp/Seal

Name Liu Yi





Date 24 May 2018

Signature of Witness 

Name Zhang Fei

Address Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China

Comparison of the CITIZEN CHUD514 with the Andon KD-595

Devices – Item 9	CITIZEN CHUD514	Andon KD-595
Pictures		
Display Image		
Validation		ESH 2010
Category	Upper Arm for Clinical Use and Self Measurement	Upper Arm for Clinical Use and Self Measurement
Casing – Item 10	<p><i>Dimensions</i></p> <p>137mm × 62mm × 118</p> <p><i>Ports</i></p>	<p><i>Dimensions</i></p> <p>153mm × 60mm × 108</p> <p><i>Ports</i></p>

	Cuff port and Adapter port  <i>Features</i> N/A	Cuff port and Adapter port  <i>Features</i> N/A
<b>Display – Item 11</b>	<i>Type</i> Segment LCD	<i>Type</i> Segment LCD
<b>Carrying/Mounting Facilities – Item 12</b>	N/A	N/A
<b>Software other than Algorithm – Item 13</b>	N/A	N/A
<b>Memory Capacity Item 14</b>	<i>Number of stored measurements</i> 1 × 99 readings	<i>Number of stored measurements</i> 1 × 60 readings
<b>Printing Facilities Item 15</b>	N/A	N/A
<b>Communication Facilities – Item 16</b>	N/A	N/A
<b>Power Supply Item 17</b>	4 × 1.5V AA batteries	4 × 1.5V AA batteries
<b>Other differences</b>	<i>Other Details on Equivalent device that are different to Validated device</i> No voice function	<i>Other Details on Validated device that are different to Equivalent device</i> Voice function

<p><b>Same Criteria</b></p>	<p><b>Measurement</b></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 – 300 mmHg</p> <p>Systolic: 60 – 260 mmHg</p> <p>Diastolic: 40 –199 mmHg</p> <p>Pulse rate: 40-180 beats/minute</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>Cuff circumference range:22cm-30cm</p>	<p><b>Measurement</b></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 – 300 mmHg</p> <p>Range of measurement:30-280mmHg</p> <p>Pulse rate: 40-180 beats/minute</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>Cuff circumference range:22cm-30cm</p>
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	<p>Bladder dimension:120mm × 240mm</p> <p><i>Sensors</i></p> <p>KD-2107-006GA</p> <p><i>Measurement Records</i></p> <p>1 × 99 readings</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse rate and IHB</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>Start/Stop button</p> <p><i>Measurement Records</i></p> <p>Memory button M</p> <p><i>Function</i></p> <p>Date and Time setting</p> <p><i>Analysis</i></p> <p>N/A</p>	<p>Bladder dimension:120mm × 240mm</p> <p><i>Sensors</i></p> <p>KD-2107-006GA</p> <p><i>Measurement Records</i></p> <p>1 × 60 readings</p> <p><i>Measurements other than Blood Pressure</i></p> <p>Pulse rate and IHB</p> <p><b>Buttons/Switches</b></p> <p><i>Power</i></p> <p>Start button</p> <p><i>Measurement Records</i></p> <p>Memory button MEM</p> <p><i>Function</i></p> <p>Date and Time setting</p> <p><i>Analysis</i></p> <p>N/A</p>
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	<p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Preparation</i></p> <p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Measuring during deflation</p> <p><i>Post Measurement</i></p> <p>Upper arm</p> <p><i>Measurement Records</i></p> <p>1 × 99 readings</p> <p><i>Date and Time</i></p> <p>Displayed on LCD</p>	<p><i>Event Marking</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><b><i>Display/Symbols/Indicators</i></b></p> <p><i>Preparation</i></p> <p>N/A</p> <p><i>Measurement Procedure</i></p> <p>Measuring during deflation</p> <p><i>Post Measurement</i></p> <p>Upper arm</p> <p><i>Measurement Records</i></p> <p>1 × 60 readings</p> <p><i>Date and Time</i></p> <p>Displayed on LCD</p>
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	<p><i>Power</i></p> <p>4 × 1.5V AA batteries</p> <p><i>Function</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>N/A</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>Average value of the last three measurements</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p>	<p><i>Power</i></p> <p>4 × 1.5V AA batteries</p> <p><i>Function</i></p> <p>N/A</p> <p><i>Communication</i></p> <p>N/A</p> <p><i>Features</i></p> <p>N/A</p> <p><i>Not described</i></p> <p>N/A</p> <p><b>Algorithms</b></p> <p><i>Averages and Differences</i></p> <p>None</p> <p><i>Diagnostic</i></p> <p>N/A</p> <p><i>Functions</i></p>
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	N/A  <i>Communication</i>  N/A	N/A  <i>Communication</i>  N/A
<b>Comparable Criteria</b>	N/A	N/A

<b>Comments</b>		
<b>Recommendation</b>	<b>Recommended</b>	
<b>Date</b>	<b>31<sup>st</sup> July 2018</b>	