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 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[a]	CITIZEN	*Address*	6-1-12 Tanashi-cho,Nishi-Tokyo-shi,Tokyo188-8511,Japan
Manufacturer[b]	Andon	*Address*	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Brand[c]	CITIZEN	Model[d]	CHU304

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]	Andon	*Address*	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Manufacturer[b]	Andon	*Address*	Andon Health Co.,Ltd.No.3 Jin Ping Street,Ya An Road,Nankai District,Tianjin 300190,China
Brand[c]	Andon	Model[d]	KD-5915

Existing validated blood pressure measuring device.

which has previously passed the ESH2002 protocol, the results of which were published as follows:

Huang QF, Wang J, Sheng CS, Zhang NN, Li Y, Wang JG. Validation of the ANDON KD-5915 blood pressure monitor for home blood pressure monitoring according to the European Society of Hypertension International Protocol. Blood Press Monit 2010;15(4)

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.
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.

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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 number is changed to CITIZEN CHU304 from ANDON KD-5915;

(10) They have the same botton but in the different position;

(11) No symbol for "find an error,please re-inflate";

(13)The average reading function is added(latest 3 readings in the memory);

(14) Stores 99 readings instead of 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 ☐
- 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 Liu Yi

Company Stamp/Seal

ANDON HEALTH CO.,LTD. 天津 九安医疗电子股份有限公司

Name Liu Yi

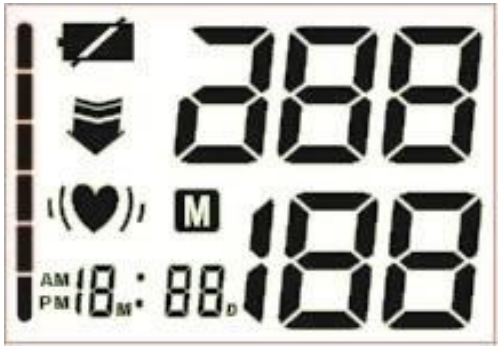
Date 22 Dec. 2014

Signature of Witness Zhang Fei

Name Zhang Fei

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

Comparison of the Andon KD-5915 with the Citizen CHU304

Devices	Citizen CHU304 (Device 2)	Andon KD-5915 (Device 1)
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria		*Memory* 60 Readings *Voice Function* Yes *Cuff Pressure* 0-295mmHg *Average Reading* No

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		Measurement Range SBP 60-280 mmHg DBP 30-199 mmHg *Dimension* Approximately 156mm x 101mm x 57mm *Weight* Approximately 280g (Excluding batteries)
Device 2 Criteria	*Memory* 99 Readings *Voice Function* No *Cuff Pressure* 0-300mmHg *Average Reading* Yes *Measurement Range* SBP 60-260 mmHg DBP 40-199 mmHg *Dimension* Approximately 138mm x 54mm x 95mm *Weight* Approximately 211g (Excluding batteries)	
Same Criteria	***Measurement*** *Accuracy* BP Accuracy ±3mmHg Pulse accuracy ±5mmHg	***Measurement*** *Accuracy* BP Accuracy ±3mmHg Pulse accuracy ±5mmHg

	Method Oscillometric Pulse Rate Range 40-180 pulse/min *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs* 22cm-30cm Upper Arm Location *Sensors* KD-2107-006G or KD-2107-006GR ***Display/Symbols/Indicators*** *Power* 4 AA Batteries ***Casing*** *Display* LCD	*Method* Oscillometric Pulse Rate Range 40-180 pulse/min *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs* 22cm-30cm Upper Arm Location *Sensors* KD-2107-006G or KD-2107-006GR ***Display/Symbols/Indicators*** *Power* 4 AA Batteries ***Casing*** *Display* LCD
Comparable Criteria		
Device 2 Criteria		

Recommendation	***Recommended***
Date	27 January 2015