dabl®Educational Trust — Declaration of Equivalence Form

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 Liu Zhiqing, (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]	Peroxfarma, S.A.	*Address*	Carrer Provença 328. 08037 Barcelona (Spain)
Manufacturer[b]	Andon	*Address*	No.3 JinPing Street,YaAn Road,Nankai District,Tianjin 300190,China.
Brand[c]	ICO	Model[d]	MT-20

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*	No.3 JinPing Street,YaAn Road,Nankai District,Tianjin 300190,China.
Manufacturer[b]	Andon	*Address*	No.3 JinPing Street,YaAn Road,Nankai District,Tianjin 300190,China.
Brand[c]	Andon	Model[d]	KD-5965

Existing validated blood pressure measuring device.

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

Validation of the Andon KD-5965 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 ☐	
	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 Name is changed to ICO MT-20 from Andon KD-5965;

(10) The new device has a different industrial design.

(11)please see the attachment.

(13)Just changing the way of the code written, not the software scheme

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

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 _____ Company Stamp/Seal

Name Liu Zhiqing

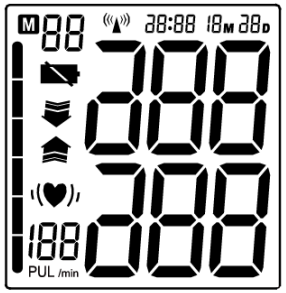
Date May 12,2022

Signature of Witness _____

Name SunGuimei

Address No.3 JinPing Street,YaAn Road,Nankai District,Tianjin 300190,China

Comparison of the ICO MT-20 with the Andon KD-5965

Devices – Item 9	ICO MT-20	Andon KD-5965
Pictures		
Display Image		
Validation	*N/A*	ESH 2010
Category	SBPM	*SBPM*
Casing – Item 10	*Dimensions* 118*97*175cm *Ports* Cuff port and Adapter port	*Dimensions* 177*100*118 *Ports* Cuff port and Adapter port

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	Features *N/A*	*Features* *N/A*
Display – Item 11	*Type* Segment LCD	*Type* Segment LCD
Carrying/Mounting Facilities – Item 12	N/A	N/A
Software other than Algorithm – Item 13	Just changing the way of the code written, not the software scheme	N/A
Memory Capacity Item 14	2*60	*60*
Printing Facilities Item 15	N/A	N/A
Communication Facilities – Item 16	N/A	N/A
Power Supply Item 17	4*size AA	4*size AA
Other differences	*Other Details on Equivalent device that are different to Validated device* N/A	*Other Details on Validated device that are different to Equivalent device* N/A
Same Criteria	***Measurement*** *Accuracy* Pressure: ±3mmHg Pulse rate: Less than 60: ±3bpm More than 60 (incl.) : ±5%	***Measurement*** *Accuracy* Pressure: ±3mmHg Pulse rate: Less than 60: ±3bpm More than 60 (incl.) : ±5%

	Method Oscillometric *Ranges* Cuff pressure: 0-300mmHg Systolic: 60-260mmHg Diastolic: 40-199mmHg Pulse rate: 40-180 beats/minute *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs (Please state sizes and materials used)* 22-30cm (identical to 20-34cm,only silk mark is different) 30-42cm (identical to 30-44cm,only silk mark is different) 42-48cm (identical to 40-48cm,only silk mark is different) Materials are Nylon and polyester *Sensors* KD-2107-006GA *Measurement Records* 2*60 readings	*Method* Oscillometric *Ranges* Cuff pressure: 0-300mmHg Systolic: 60-260mmHg Diastolic: 40-199mmHg Pulse rate: 40-180 beats/minute *Inflation* Automatic inflation by internal pump *Deflation* Automatic speed deflation system *Cuffs(Please state sizes and materials used)* 15-24cm 20-34cm 30-44cm 40-48cm Materials are Nylon and polyester *Sensors* KD-2107-006GA *Measurement Records* *60 readings*

	Measurements other than Blood Pressure Pulse rate and IHB ***Buttons/Switches*** *Power* Start/Stop button *Measurement Records* Memory button M1,M2 *Function* Date and Time setting *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Measuring during deflation	*Measurements other than Blood Pressure* Pulse rate and IHB ***Buttons/Switches*** *Power* Start/Stop button *Measurement Records* Memory button MEM *Function* Date and Time setting *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* N/A *Measurement Procedure* Measuring during deflation

	Post Measurement Upper arm *Measurement Records* 2*60 readings *Date and Time* Displayed on LCD *Power* 4*size AA *Function* N/A *Communication* N/A *Features* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* No such function	*Post Measurement* Upper arm *Measurement Records* *60 readings* *Date and Time* Displayed on LCD *Power* 4*size AA *Function* N/A *Communication* N/A *Features* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* No such function

	Diagnostic N/A *Functions* N/A *Communication* N/A	*Diagnostic* N/A *Functions* N/A *Communication* N/A
Comparable Criteria		

Comments		
Recommendation	**Recommended**	
Date	**May 2022**	