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 Kevin Tan, a Director of Guangdong Transtek Medical Electronics 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]	Kaz Europe Sàrl	*Address*	Place Chauderon 18, 1003 Lausanne, Switzerland
Manufacturer[b]	Transtek	*Address*	
Brand[c]	Braun	Model[d]	BUA6350

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]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand[c]	TRANSTEK	Model[d]	TMB-986

Existing validated blood pressure measuring device.

which has previously passed the 2002 protocol, the results of which were published as follows:

Title: Validation of the TRANSTEK blood pressure monitor TMB-986 for home blood pressure monitoring according to the International Protocol

Authors: Wen Jun Liu; Su Gang Li; Zhe Song; Wei Gong

Publication: Blood Pressure Monitoring. 15(5):278-280, OCT 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.

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Carraig Court, Georges Avenue, Blackrock, Co. Dublin, Ireland. Tel + 353 1 278 0247 Email info@dableducational.org
Fax + 353 1 278 3835 Web www.dableducational.org

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.

Declaration of Equivalence Form

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.

See attached document

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 Ken Zhai

Company Stamp/Seal

Name Ken Zhai

Date February 13，2020

Signature of Witness Endless Chan

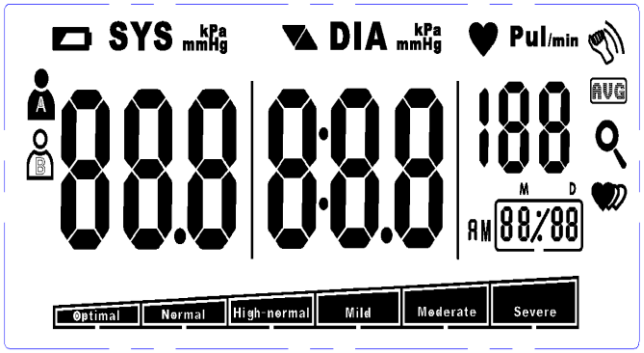
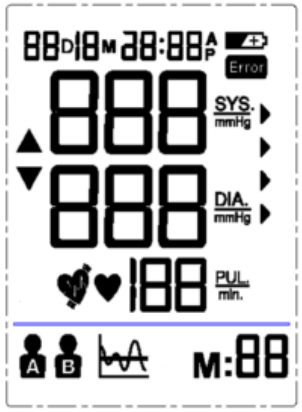
Name Endless Chan

Address Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, 528437, Guangdong, China

Comparison of the Braun BUA6350 with the TRANSTEK TMB-986

Model Name or number– Item 9	TRANSTEK TMB-986	Braun BUA6350
Pictures		

Carraig Court, George's Avenue, Blackrock, Co. Dublin, Ireland Tel +353 1 278 0247 Fax +353 1 278 0882 Email info@dableducational.org Web www.dableducational.org

Display Image		
Validation	ESH 2002	
Category	Upper arm device for self-measurement of blood pressure	Upper arm device for self-measurement of blood pressure
Casing – Item 10	*Dimensions* 182mm*100mm*39mm *Ports* *Cuff port* 22 –42 cm (standard: 22 –32 cm; large: 32 –42 cm) *Features* *User buttons: Start/stop, SET & MEM, User Select* *Cuff and DC adaptor connectors* *Model name printing & brand logo* *Display* *Battery compartment*	*Dimensions* 110mm*124mm*113mm *Ports* *Cuff port* 22 –42 cm (standard: 22 –32 cm; large: 32 –42 cm) *Features* *User buttons: start/stop, user selection (slide switch), average button, date & time setting buttons* *Cuff port* *Display with WHO colour indicator* *Branding logo and function printing on buttons* *Battery compartment*

Display – Item 11	*Type* *LCD (black on white background)*	*Type* *LCD (negative type – white on black background)*
Carrying/Mounting Facilities – Item 12	*N/A*	*N/A*
Software other than Algorithm – Item 13	*60 sets memories/per user (2*60)* *4 grade indicator* *mmHg unit*	*60 sets memories/per user (2*60)* *4 grade indicator* *mmHg unit*
Memory Capacity **Item 14**	*2*60*	*2*60*
Printing Facilities Item 15	NA	*NA*
Communication Facilities – Item 16	*None*	*None*
Power Supply **Item 17**	4*AAA DC power socket (6V)	*4*AA*
Other differences	*Other Details on Equivalent device that are different to Validated device*	*Other Details on Validated device that are different to Equivalent device*

Same Criteria	***Measurement***	***Measurement***
	Accuracy *Pulse accuracy ± 5%* *Method* *Oscillometric measurement method* *Manually initiated measurement* *Measurements are from single inflations* *Ranges* *Rated cuff pressure: 0 mmHg – 300 mmHg* *Pulse 40 bpm – 199 bpm* *Inflation* *Automatic inflation by internal pump* *Zero pressure check before inflation* *Deflation* *Automatic Deflation* *Automatic safety release* *Cuffs (Please state sizes and materials used)* Nylon *Small/Medium (Arm circ. 22 cm to 32 cm) # AC2232-01* *Large/XLarge (Arm circ. 32-42 cm) # TMB-986-AC-05* *Sensors* *Piezo-resistive (semiconductor) pressure sensor*	*Accuracy* *Pulse accuracy ± 5%* *Method* *Oscillometric measurement method* *Manually initiated measurement* *Measurements are from single inflations* *Ranges* *Rated cuff pressure: 0 mmHg – 300 mmHg* *Pulse 40 bpm – 199 bpm* *Inflation* *Automatic inflation by internal pump* *Zero pressure check before inflation* *Deflation* *Automatic Deflation* *Automatic safety release* *Cuffs (Please state sizes and materials used)* Nylon *Small/Medium (Arm circ. 22 cm to 32 cm) # TMB-1250-02* *Large/XLarge (Arm circ. 32-42 cm) # TMB-1250-03* *Sensors* *Piezo-resistive (semiconductor) pressure sensor*

	Measurement Records *YES: SYS, DIA, Pulse, IHB, Date & time* *Measurements other than Blood Pressure* *Pulse (heart rate)* *Irregular heartbeat* *Date & time* ***Buttons/Switches*** *Power* *On/Off with Start/Stop (Start/Stop Label)* *Measurement Records* *Memory* *User ID (A or B)* ***Display/Symbols/Indicators*** *Preparation* *Zero pressure adjust - arrow down symbol* *Measurement Procedure* *During Measurement: cuff pressure level & heartbeat symbol* *Post Measurement* *SBP, DBP and Pulse* *BP classification (WHO)*	*Measurement Records* *YES: SYS, DIA, Pulse, IHB, Date & time* *Measurements other than Blood Pressure* *Pulse (heart rate)* *Irregular heartbeat* *Date & time* ***Buttons/Switches*** *Power* *On/Off with Start/Stop (Start Label)* *Measurement Records* *Memory* *User ID (A or B)* ***Display/Symbols/Indicators*** *Preparation* *Zero pressure adjust - arrow down symbol* *Measurement Procedure* *During Measurement: cuff pressure level & heartbeat symbol* *Post Measurement* *SBP, DBP and Pulse* *BP classification (WHO)*

	Measurement Records *Memory recall number* *User (A or B)* *Date and Time* *Date and Time (During memory recall)* *Power* *Low battery indicator* *Function* *N/A* *Communication* *N/A*	*Measurement Records* *Memory recall number* *User (A or B)* *Date and Time* *Date and Time (During memory recall)* *Power* *Low battery indicator* *Function* *N/A* *Communication* *Bluetooth module BT 4.2* *pairing to iOS and Android Braun Healthy Heart App (Smartphone)*
Comparable Criteria	***Measurement*** *Accuracy* *BP accuracy ± 3 mmHg (15 °C-25 °C) ± 6 mmHg otherwise* *Measurement Records* *Memory: 60 measurements × 2 users* ***Buttons/Switches*** *Settings* *Set*	***Measurement*** *Accuracy* *BP accuracy ± 3 mmHg (10 °C-40 °C)* *Measurement Records* *Memory: 60 measurements × 2 users* ***Buttons/Switches*** *Settings* *Date/Time set*

	Display/Symbols/Indicators *Post Measurement* *Measurement error E1, E2, E3, (E10, E11) → E4, E20, E21, Eexx* *Hypertension (Grading strip)* *Average (AVG)* *Measurement Records* *Memory icon (Magnifying glass)* *Date and Time* *Setting of Date and Time set but only display of Time* ***Casing*** *Power* *4 "AAA" batteries*	***Display/Symbols/Indicators*** *Post Measurement* *Measurement error E1, E2, E3, E4, Eexx* *Hypertension (Indicator strip)* *Average (Icon)* *Measurement Records* *Memory "M" symbol* *Date and Time* *Date and Time* ***Casing*** *Power* *4 "AA" batteries ~ 300 measurements*

Comments		BUA6350 is equivalent to BUA6150 BP6150 is already ESH approved by equivalence to Transtek TMB-986 BUA6350 is a BUA6150 with additional Bluetooth connectivity

Recommendation	**Recommended**	
Date	**March 2020**	