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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 Ken Zhai , 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]	Beurer GmbH	*Address*	Söflinger Strasse 218, 89077 Ulm, Germany
Manufacturer[b]	Guangdong Transtek Medical Electronics Co.,Ltd	*Address*	Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,528437,Guangdong,China
Brand[c]	Beurer	Model[d]	BC 54

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-988

Existing validated blood pressure measuring device.

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

Tian HY, Liu WJ, Li SG, Song Z, Gong W. Validation of the Transtek TMB-988 wrist blood pressure monitor for home blood pressure monitoring according to the International Protocol. Blood Press Monit 2010;15(6):326-8

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 ☐	

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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.

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 Ken Zhai

Company Stamp/Seal GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD 广东百胜医疗电子股份有限公司

Name Ken Zhai

Date June 1st, 2020

Signature of Witness Jingshang Liu. Haibin Huang

Name Jingshang Liu, Haibin Huang

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

Comparison of the Beurer BC 54 wrist blood pressure monitor with the Transtek TMB-988

Model Name or number– Item 9	Beurer BC54	Transtek TMB -988
Pictures		

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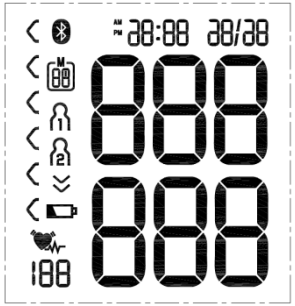
Display Image		
Validation	Same as Transtek TMB- 988	ESH 2002
Category	Wrist Blood Pressure Monitor	*Wrist Blood Pressure Monitor*
Casing – Item 10	*Dimensions* *Approx.80.5mm×69.5mm×25mm* *Ports* *Cuff port* *Features* *ABS Plastic Part* *Printing*	*Dimensions* *Approx.73mm×67.5mm×22.5mm* *Ports* *Cuff port* *Features* *ABS Plastic part* *Printing*

	LCD	*LCD*
Display – Item 11	LCD	LCD
Carrying/Mounting Facilities – Item 12	*Storage Box*	*None*
Software other than Algorithm – Item 13	Bluetooth transmission	*N/A*
Memory Capacity **Item 14**	*2*60 measurement records with date and time*	*60 measurement records with date and time*
Printing Facilities Item 15	N/A	*N/A*
Communication Facilities – Item 16	Bluetooth	*No BT model*
Power Supply **Item 17**	2*AAA Batteries	*2*AAA Batteries*
Other differences	*N/A*	*N/A*

Same Criteria	***Measurement***	***Measurement***
	Accuracy	*Accuracy*
	Blood Pressure: 5°C-40°C within±3mmHg(0.4kPa)	Pressure: 5°C-40°C within±3mmHg(0.4kPa)
	Pulse value:±5%	Pulse value:±5%
	Method	*Method*
	oscillography	*Oscillography*
	Ranges	*Ranges*
	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa)	*Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa)*
	Measurement pressure:	*Measurement pressure:*
	SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)	*SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)*
	DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)	*DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)*
	Pulse value: (40-199)beat/minute	*Pulse value: (40-199)beat/minute*
	Inflation	*Inflation*
	Automatic inflation by internal pump (Pump-924)	*Automatic inflation by internal pump (Pump-924)*
	Deflation	*Deflation*
	Automatic speed deflation system (JQF1-3C-60)	*Automatic Speed deflation system (JQF1-3C-60)*
	Cuffs (Please state sizes and materials used)	*Cuffs(Please state sizes and materials used)*
	Cuff Size: 13.5-21.5mm	Cuff size: 13.5-19.5mm
	Cuff Material: polyester	Cuff Material: polyester

	Bladder size: 130mm×55mm Material Bladder:PVC *Sensors* *MSP40-GSF* *Measurement Records* 2*60 measurement records with date and time *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power* START/STOP button *Measurement Records* M1 and M2 button *Function* START/STOP button for Setting *Analysis* N/A	Bladder size: 130mm×55mm Material Bladder : PVC *Sensors* *MSP40-GSF* *Measurement Records* 60 measurement records with date and time *Measurements other than Blood Pressure* *Pulse rate* ***Buttons/Switches*** *Power* START/STOP button *Measurement Records* MEM button *Function* SET button for Setting *Analysis* N/A *Event Marking*

	Event Marking N/A *Communication* Bluetooth 4.2 ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation* *Pressure value indication* *Current time* *Heart Beat Symbol during deflation* *Irregular Heartbeat Symbol* *Post Measurement* *Systolic blood pressure* *Diastolic Blood Pressure* *Pulse Rate* *WHO Indicator* *Measurement Records*	N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* *Automatic Zero setting* *Measurement Procedure* *Inflation* *Pressure value indication* *Current time* *Heart beat symbol during deflation* *Irregular Heartbeat Symbol* *Post Measurement* *Systolic blood pressure* *Diastolic Blood Pressure* *Pulse Rate* *WHO Indicator* *Measurement Records* *Systolic pressure (SYS)*

	Systolic pressure (SYS) *Diastolic pressure (DIA)* *Pulse rate* *Memory recall number* *Date and Time* Display measurement time in the upper right corner of LCD *Power* Low battery detection symbol *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* Bluetooth 4.2 data transmission *Features* Measuring during inflation *Not described* *N/A*	*Diastolic pressure (DIA)* *Pulse rate* *Memory Recall number* *Date and Time* Display measurement time in the lower left corner of LCD *Power* *Low battery detection symbol* *Function* Measure blood pressure and heart rate Recall measurement records Delete measurement records *Communication* N/A *Features* Measuring during inflation *Not described* *N/A*

	Algorithms *Averages and Differences* Average morning values (5:00AM – 9:00AM) of the last seven days measurements Average evening values (6:00PM – 8:00PM) of the last seven days measurements Average value of the last seven days measurements *Diagnostic* N/A *Functions* N/A	***Algorithms*** *Averages and Differences* Recall the average value of the last three measurements *Diagnostic* N/A *Functions* N/A
Comparable Criteria		

Comments		
Recommendation	**Recommended**	
Date	**17 September 2020**	