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 KI-CHUL CHA, a Director of InBody 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]	InBody CO., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer[b]	InBody CO., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand[c]	InBody	Model[d]	BPBIO320N

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]	InBody CO., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Manufacturer[b]	InBody CO., LTD.	*Address*	625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
Brand[c]	InBody	Model[d]	BPBIO320

Existing validated blood pressure measuring device.

which has previously passed the ESH-IP2(2010) protocol, the results of which were published as follows:
Anastasios Kollias, Emelina Stambolliu, Konstantinos G. Kyriakoulis, Stamatis S. Papadatos and George S. Stergiou. Validation of the single-cuff oscillometric blood pressure monitor InBody BPBIO320 for public use according to the 2010 European Society of Hypertension International Protocol Blood Pressure Monitoring 2018, 00:000–000
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) Model name is changed to BPBIO320N from BPBIO320.

15) BPBIO320N has not print facility.

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 _____

Name KI-CHUL CHA

Date 02/05/2019

Signature of Witness _____

Name DAE-SEOK KIM

Address 625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA

Company Stamp/Seal

InBody Co., Ltd.
625, Eonju-ro, Gangnam-gu, Seoul 06106 KOREA
TEL:(82-2)501-3939 FAX:(82-2)501-3978

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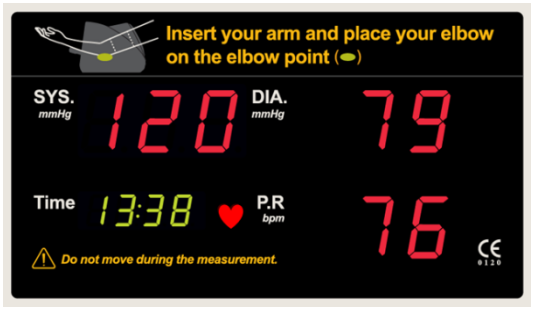
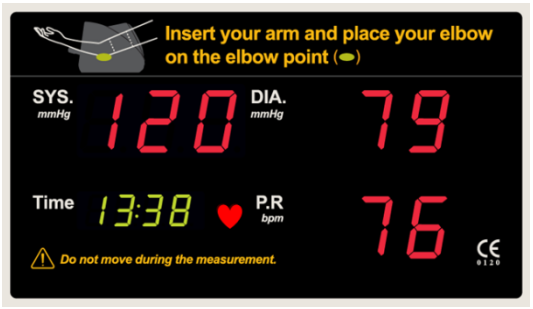
Comparison of the InBody BPBIO320N with the InBody BPBIO320

Devices – Item 9	BPBIO320N	BPBIO320
Pictures		
DisplayImage		
Validation	Equivalence	ESH IP2010
Category	Blood pressure monitor	Blood pressure monitor
Casing – Item 10	*Dimensions* 489(W) x 409(D) x 284(H) mm *Ports* RS-232C D-Sub terminal AC Inlet *Features* Measurement guide panel is separate. Fully automatic device. (The Cuff is built inside the device)	*Dimensions* 489(W) x 409(D) x 284(H) mm *Ports* RS-232C D-Sub terminal AC Inlet *Features* Measurement guide panel is separate. Fully automatic device. (The Cuff is built inside the device)

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Display – Item 11	*Type* 3-digit display LED(7-Segment LED)	*Type* 3-digit display LED(7-Segment LED)
Carrying/Mounting Facilities – Item 12	Dedicated Desk	Dedicated Desk
Software other than Algorithm – Item 13	Voice guidance on measurement methods and results.	Voice guidance on measurement methods and results. Print the result value and Pulse graph and other information.
Memory Capacity Item 14	N/A	N/A
Printing Facilities Item 15	N/A	2.5” Thermal Printer
Communication Facilities – Item 16	PC connection function for data transfer via RS232 Cable	PC connection function for data transfer via RS232 Cable
Power Supply Item 17	Switching AC Power supply unit, 100-240V AC 50-60Hz	Switching AC Power supply unit, 100-240V AC 50-60Hz
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* Print function
Same Criteria	***Measurement*** *Accuracy* Pressure: ±2 mmHg Pulse: ±1.5 % of reading *Method* Oscillometric measurement method *Ranges* Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute *Inflation* Automatic inflation by air pump *Deflation* Automatic deflation by solenoid valve *Cuffs (Please state sizes and materials used)* Winding mechanism operated by geared motor	***Measurement*** *Accuracy* Pressure: ±2 mmHg Pulse: ±1.5 % of reading *Method* Oscillometric measurement method *Ranges* Pressure: 0 - 300 mmHg Pulse: 30 - 240 beats/minute *Inflation* Automatic inflation by air pump *Deflation* Automatic deflation by solenoid valve *Cuffs(Please state sizes and materials used)* Winding mechanism operated by geared motor

	Bladder size: 125(w) x 310(L) mm Applicable arm circumference :7 inches(18.0 cm) to 16.5 inches(42.0 cm) *Sensors* Pressure sensor: Gauge type pressure transducer *Measurement Records* Last Measurement *Measurements other than Blood Pressure* PULSE(= Heart rate) ***Buttons/Switches*** *Power* ON/OFF Power Switch *Measurement Records* Start/Stop *Function* [▲]button: used to change function [▼]button: used to change function Emergency stop: All function are stopped *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* “0” lighting	Bladder size: 125(w) x 310(L) mm Applicable arm circumference :7 inches(18.0 cm) to 16.5 inches(42.0 cm) *Sensors* Pressure sensor: Gauge type pressure transducer *Measurement Records* Last Measurement *Measurements other than Blood Pressure* PULSE(= Heart rate) ***Buttons/Switches*** *Power* ON/OFF Power Switch *Measurement Records* Start/Stop Print *Function* [▲]button: used to change function [▼]button: used to change function Emergency stop: All function are stopped *Analysis* N/A *Event Marking* N/A *Communication* N/A ***Display/Symbols/Indicators*** *Preparation* “0” lighting

	Measurement Procedure Display the pressure value during measurement. The Heart LED twinkle synchronized to the Heartbeat. *Post Measurement* Systolic blood pressure(SYS) Diastolic blood pressure(DIA) Pulse(P.R) *Measurement Records* Systolic blood pressure(SYS) Diastolic blood pressure(DIA) Pulse(P.R) *Date and Time* Display Time *Power* N/A *Function* N/A *Communication* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* N/A *Diagnostic* N/A *Communication* N/A	*Measurement Procedure* Display the pressure value during measurement. The Heart LED twinkle synchronized to the Heartbeat. *Post Measurement* Systolic blood pressure(SYS) Diastolic blood pressure(DIA) Pulse(P.R) *Measurement Records* Systolic blood pressure(SYS) Diastolic blood pressure(DIA) Pulse(P.R) *Date and Time* Display Time Print date and time *Power* N/A *Function* N/A *Communication* N/A *Not described* N/A ***Algorithms*** *Averages and Differences* N/A *Diagnostic* N/A *Communication* N/A

Comparable Criteria	***Measurement*** Press the  button to display the last measurement on the display unit.	**Printing function** Press the Print button to print the result.

Office use only.

Comments		
Recommendation	**Recommended**	
Date	**21 May 2019**	