

### DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

A SIGNED COPY WILL BE POSTED ON THE [www.dableducational.org](http://www.dableducational.org) WEBSITE

#### SECTION A - Please complete all items.

I **Uriel Şulam,**  
Name of a Company Director

a Director of **Trimpeks İth. İhr. Tur. ve Tic. A.Ş.,**  
Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker <sup>a</sup>	<b>ONBO</b>	Address	<b>497 Dalang South Road, Longhu, Shenzhen, Guangdong, China</b>
Manufacturer <sup>b</sup>	<b>Trimpeks İth. İhr. Tur. ve Tic. A.Ş.</b>	Address	<b>Eski Büyükdere Cad. Yunus Emre Sok. No:1/12 Topcu Is Merkezi 4. Levent/İstanbul</b>
Brand <sup>c</sup>	<b>Plusmed</b>	Model <sup>d</sup>	<b>pM-NT-01</b>

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 <sup>a</sup>	<b>ONBO</b>	Address	<b>497 Dalang South Road, Longhu, Shenzhen, Guangdong, China</b>
Manufacturer <sup>b</sup>	<b>Microlife AG</b>	Address	<b>Espenstrasse 139, 9443 Widnau, Switzerland</b>
Brand <sup>c</sup>	<b>Microlife</b>	Model <sup>d</sup>	<b>BP3AS1-2</b>

Existing validated blood pressure measuring device.

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

**Annemarie de Greeff, Hannah Nathan, Nina Stafford, Bing Liu, Andrew Shennan - Development of an accurate oscillometric blood pressure device for low resource settings; BPM: Blood Pressure Monitoring, Vol13, N°6 pp.342-348, December 2008**

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A <sup>e</sup> <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>f</sup> <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	10	Casing	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	11	Display	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	13	Software other than Algorithm	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	14	Memory Capacity/Number of stored measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	18	Other Facilities	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <sup>g</sup> <input type="checkbox"/>

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.

**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.

6. Only Cuff textil color is different: PLUSMED pM-NT 01 is grey(pantone #cool grey 11C), Microlife BP 3AS1-2 is blue (pantone #210D). Both cuffs use the same bladder and tubing.

9. Model name PLUSMED pM-NT 01 Microlife BP 3AS1-2

18. Artwork (printing, colour) is different

**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 \_\_\_\_\_

Company Stamp/Seal

Name Uriel Şulam

Date 21.01.2015



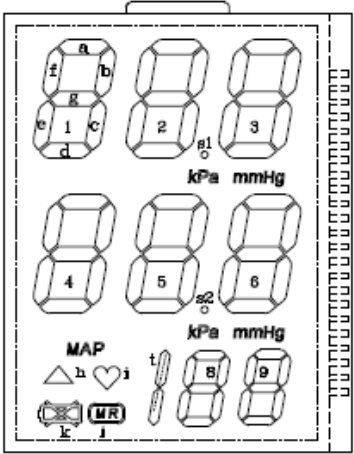
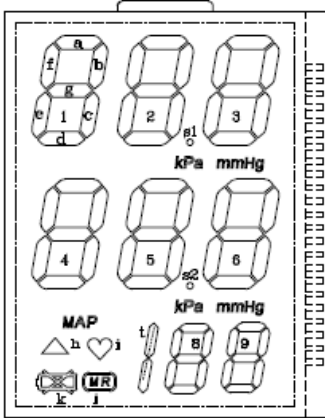
Signature of Witness \_\_\_\_\_



Name Dilek Metin


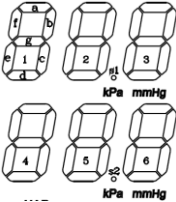
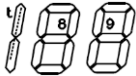



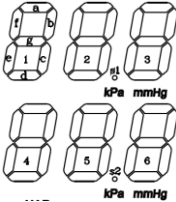
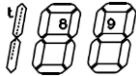


Address Trimpeks A.Ş. Eski Büyükdere Cad. Yunus Emre Sok. No:1/12 Topcu Is Merkezi 4. Levent/Istanbul

TRIMPEKS İTHALAT İHRACAT  
TURİZM ve TIC. A.Ş.  
Eski Büyükdere Cd. Yunus Emre Sk. No:1/12  
Topcu Is Merkezi 80650 4. Levent/İSTANBUL  
Tel: (0212) 319 50 00 Fax: 319 50 50  
Boğaziçi Kurumlar V.D. 859 040 5925

Comparison of the New with the Old

Devices	<i>plusmed pM-NT 01</i>	<i>Microlife BP3AS1-2</i>
Pictures		
Display		
Validation		ESH 2002
Device 1 Criteria (Different Features)		None
Device 2 Criteria (Different Features)	None	

<p><b>Comparable Criteria</b></p>	<ul style="list-style-type: none"> <li>▪ Cuffs: Textile Colour is different - PLUSMED pM-NT 01 is grey (pantone #cool grey 11C). *Cuff bladder &amp; tubing are the same.</li> <li>▪ Artwork (printing, colour) is different</li> </ul>	<ul style="list-style-type: none"> <li>▪ Cuffs: Textile Colour is different - Microlife BP 3AS1-2 is blue (pantone #210D). *Cuff bladder and tubing are the same.</li> <li>▪ Artwork (printing, colour) is different</li> </ul>
<p><b>Same Criteria</b></p>	<p><b>Measurement</b>  <i>Accuracy</i>                  Pressure: within ± 3 mmHg                  Pulse: ± 5% of the reading</p> <p><i>Method</i>                  Oscillometric</p> <p><i>Inflation</i>                  Manual</p> <p><i>Deflation</i>                  Passive Deflation Valve</p> <p><i>Cuffs</i>                  Cuff Bladder &amp; Tubing; different textile &amp; printing</p> <p><i>Sensors</i>                  Capacitive Pressure Sensor</p> <p><i>Measurement Records</i>                  1 set Measurement Record</p> <p><i>Measurements other than Blood Pressure</i>                  Pulse Rate</p> <p><b>Buttons/Switches</b>  <i>Power</i>                  O/I Button</p> <p><i>Measurement Records</i>                  Press &amp; Hold O/I Button for 3 Seconds</p> <p><i>Function</i>                  Same as O/I Button</p> <p><b>Display/Symbols/Indicators</b>  <i>Measurement Procedure</i>                  Inflation Icon  </p>	<p><b>Measurement</b>  <i>Accuracy</i>                  Pressure: within ± 3 mmHg                  Pulse: ± 5% of the reading</p> <p><i>Method</i>                  Oscillometric</p> <p><i>Inflation</i>                  Manual</p> <p><i>Deflation</i>                  Passive Deflation Valve</p> <p><i>Cuffs</i>                  Cuff Bladder &amp; Tubing; different textile &amp; printing</p> <p><i>Sensors</i>                  Capacitive Pressure Sensor</p> <p><i>Measurement Records</i>                  1 set Measurement Record</p> <p><i>Measurements other than Blood Pressure</i>                  Pulse Rate</p> <p><b>Buttons/Switches</b>  <i>Power</i>                  O/I Button</p> <p><i>Measurement Records</i>                  Press &amp; Hold O/I Button for 3 Seconds</p> <p><i>Function</i>                  Same as O/I Button</p> <p><b>Display/Symbols/Indicators</b>  <i>Measurement Procedure</i>                  Inflation Icon  </p>

	<p>Pulse Detection Icon  </p> <p><i>Post Measurement</i>                  Blood Pressure (Systolic &amp; Diastolic)  </p> <p>Pulse Rate  </p> <p><i>Measurement Records</i>                  Measurement Record Icon  </p> <p><i>Power</i>                  Low Battery Icon  </p> <p><b>Algorithms</b>  <i>Functions</i>                  Same Oscillometric Algorithm</p> <p><b>Casing</b>  <i>Display</i>                  LCD Display</p> <p><i>Ports</i>                  Cuff Connector Port</p> <p><i>Power</i></p>	<p>Pulse Detection Icon  </p> <p><i>Post Measurement</i>                  Blood Pressure (Systolic &amp; Diastolic)  </p> <p>Pulse Rate  </p> <p><i>Measurement Records</i>                  Measurement Record Icon  </p> <p><i>Power</i>                  Low Battery Icon  </p> <p><b>Algorithms</b>  <i>Functions</i>                  Same Oscillometric Algorithm</p> <p><b>Casing</b>  <i>Display</i>                  LCD Display</p> <p><i>Ports</i>                  Cuff Connector Port</p> <p><i>Power</i></p>
--	---	---



	Battery Compartment (2x1.5V Batteries – Size AAA) <i>Features</i> O/I Button – Same design different colour	Battery Compartment (2x1.5V Batteries – Size AAA) <i>Features</i> O/I Button – Same design different colour
--	---	---

<b>Recommendation</b>	<b><i>Recommended</i></b>	
<b>Date</b>	29 January 2015	