

## DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

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

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

I Ty-Minh Tan Director of Microlife AG  
Name of a Company Director Company name

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

Microlife BP 3AC1-2  
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife BP 3 AC1-1  
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the BHS protocol, the results of which were published as follows

Topouchian JA, El Assad MA, Orobinskaia LV, El Feghali RN, Asmar RG  
Authors(s)

Validation of two devices for self-measurement of brachial blood pressure according to the International Protocol of the European Society of Hypertension: the Seinex SE-9400 and the Microlife BP 3AC1-1  
Title

Blood Pressure Monitoring, ISSN 1359-5237 2005, Vol 10 No 6 Page 325-331  
Publication Year Volume Pages

The only differences between the devices involve the following components:

(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences on the reverse of this form.)

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input 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"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" 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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input checked="" type="checkbox"/>	No <input 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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <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"/>

Further relevant details: 10) different colour

11) no 2 User indication

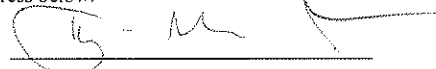
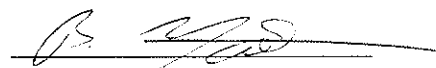
12) equipped with a wall holder

14) contains 60 Memory instead of 2x30



18) BP 3AC1-2 set includes AC Adapter, additional L Size cuff and Printer PR 1KA1

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**SECTION B** - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director		Company Stamp/Seal
Name	<u>Ty-Minh Tan</u>	<i>microlife</i>
Date	<u>July 7, 2006</u>	Microlife
Signature of Witness		Max Schmidheiny-Strasse 201
Name	<u>Bernd Jaenecke</u>	9435 Heerbrugg / Switzerland
Address	<u>Microlife AG, Max-Schmidheiny-Strasse 201, CH-9435 Heerbrugg</u>	Phone +41 / 71 727 70 00
		Fax +41 / 71 727 70 01

### Comparison of the Microlife BP 3AC1-2 with the Microlife BP 3AC1-1

Devices	Microlife BP 3AC1-2	Microlife BP 3AC1-1
<b>Pictures</b>		
<b>Validation</b>		BHS - A/A grading
<b>Device 1 Criteria</b>	Wall holder <span style="float: right;">12</span> Memory: 30 measurements <span style="float: right;">14</span>	
<b>Same Criteria</b>	MAM (average mode) or standard mode selection Oscillometric measuring method Fuzzy Logic Printer Port Error code (1, 2, 3, 5 & 6)	MAM (average mode) or standard mode selection Oscillometric measuring method Fuzzy Logic Printer Port Error code (1, 2, 3, 5 & 6)
<b>Comparable Criteria</b>	Colour <span style="float: right;">10</span> Cuffs: M & L <span style="float: right;">18</span> Mains adapter <span style="float: right;">18</span> Printer kit PR1KA1 <span style="float: right;">18</span>	Cuffs: M (L as accessory) <span style="float: right;">18</span> Optional mains adapter <span style="float: right;">18</span> Optional printer kit PR1KA1 <span style="float: right;">18</span>
<b>Device 2 Criteria</b>		Current user displayed <span style="float: right;">11</span> Memory: 2 x 30 measurements – 2 persons monitor <span style="float: right;">14</span>
<b>Web link</b>	<a href="http://mldata.ria.ch/detail.asp?Produkt_ID=208&amp;Sprach_ID=2">http://mldata.ria.ch/detail.asp?Produkt_ID=208&amp;Sprach_ID=2</a>	<a href="http://mldata.ria.ch/detail.asp?Produkt_ID=198&amp;Sprach_ID=2">http://mldata.ria.ch/detail.asp?Produkt_ID=198&amp;Sprach_ID=2</a>
<b>Comments</b>	The 3AC1-2 has both cuffs, the printer kit and mains adapter supplied. 3AC1-1 allows for 2 users.	
<b>Recommendation</b>	Accept.	