

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE 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 A100
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife BP A100 plus
Existing validated blood pressure measuring device

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

George S. Stergiou, Periklis P. Giovvas, Michalis S. Neofytou, Dionysios N. Adamopoulos
Authors(s)

Validation of the Microlife BPA100plus device for self-home blood pressure measurement according to the International Protocol

Blood Pressure Monitoring, ISSN 1359-5237 2006, Vol 11 No 3 Page 157-160
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 X
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No X
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No X
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No X
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No X
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No X
Part II	9	Model Name or Number	Yes X	No <input type="checkbox"/>
	10	Casing	Yes X	No <input type="checkbox"/>
	11	Display	Yes X	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes X	No <input type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes X	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No X
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Further relevant details: 10) Smaller housing, no Memory, MAM, Date/Time buttons

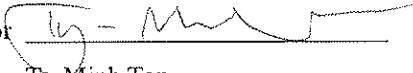
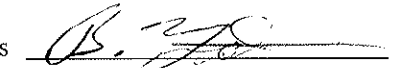
11) No Date/Time, traffic light and alarm times indication

13) No MAM Technology (Average Mode), no traffic light indication, no Alarm Times, no ERR 6 code (MAM relevant).



14) Only 1 memory (last reading) instead of 200 memories

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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 A 100 with the Microlife BP A 100 Plus

Devices	Microlife BP A 100	Microlife BP A 100 Plus
Pictures		
Validation		ESH - Pass
Device 1 Criteria	Memory: 1 measurement 14	
Same Criteria	Oscillometric measuring method Optional mains adapter Cuffs: S, M & L PAD – Pulse Arrhythmia Detection Cuff storage solution Rechargeable battery-friendly	Oscillometric measuring method Optional mains adapter Cuffs: S, M & L PAD – Pulse Arrhythmia Detection Cuff storage solution Rechargeable battery-friendly
Comparable Criteria	Error code (1, 2, 3, 5, Hi & Lo)	Error code (1, 2, 3, 5, 6, Hi & Lo)
Device 2 Criteria		Memory, MAM and Date/Time buttons 10 Traffic light, memory, date/time indication 11 2 Alarm times 13 MAM technology (automatic triple measurement) 13 Memory: 200 measurements 14
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1158&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=1159&Sprach_ID=2
Comments		
Recommendation	Accept	