

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 3BTO-1
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

Microlife BP 3BTO-A
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

Cuckson AC, Reinders A, Shabeeh H, Shennan AH
Authors(s)

Validation of the Microlife BP 3BTO-A oscillometric blood pressure monitoring device according to a modified British Hypertension Society protocol

Blood Pressure Monitoring, ISSN 1359-5237 2002, Vol 7 No 6 Page 319-324
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 type="checkbox"/>	No <input type="checkbox"/>
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input 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 checked="" type="checkbox"/>	No <input type="checkbox"/>
	17	Power Supply	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Further relevant details: 10) additional buttons for MAM, Memory, User/Time and Printer

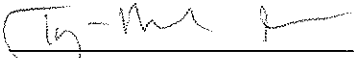
11) indication for Time/Date, User and MAM

13) BP 3BTO-1 includes MAM technology (Average Mode) and additional Error Code 6 (MAM relevant)

14) BP 3BTO-1 contains 2 sets of 14 memories

16) BP 3BTO-1 contains printer port

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 

Name Ty-Minh Tan

Date July 7, 2006

Signature of Witness 

Name Bernd Jaenecke

Address Microlife AG, Max-Schmidheiny-Strasse 201, CH-9435 Heerbrugg

Company Stamp/Seal

microlife

Microlife



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Comparison of the Microlife BP 3BT0-1 with the Microlife BP 3BT0-A

Devices	Microlife BP 3BT0-1	Microlife BP 3BT0-A
Pictures		
Validation		BHS - A/A grading, Gütesiegel/Quality Seal, German Design Award
Device 1 Criteria	Additional Buttons <i>10</i> Displays date, user, MAM <i>11</i> MAM (average mode) or standard mode selection <i>13</i> Memory: 2 x 14 measurements – 2 persons monitor <i>14</i> Printer Port <i>16</i>	
Same Criteria	Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter Fuzzy Logic	Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter Fuzzy logic
Comparable Criteria	Error code (1, 2, 3, 5 & 6)	Error code (1, 2, 3 & 5)
Device 2 Criteria		Memory: 1 measurement <i>14</i>
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=199&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=156&Sprach_ID=2
Comments	Communication facilities incorrectly ticked instead of Printing Facilities as only port is provided. Explanation clarifies issue.	
Recommendation	Accept	