

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 3AG1
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
Title

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 type="checkbox"/>	No <input checked="" type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input 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 type="checkbox"/>	No <input checked="" 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 <input checked="" type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>

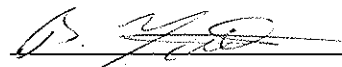
Further relevant details: 10) Different housing, smaller display

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 3AG1 with the Microlife BP 3BT0-A

Devices	Microlife BP 3AG1	Microlife BP 3BT0-A
Pictures		
Validation		BHS - A/A grading, Gütesiegel/Quality Seal, German Design Award
Device 1 Criteria	Different Case <i>10</i>	
Same Criteria	Memory: 1 measurement Error code (1, 2, 3 & 5) Cuffs: M (L as accessory) Optional mains adapter One-touch operation Fuzzy logic	Memory: 1 measurement Error code (1, 2, 3 & 5) Cuffs: M (L as accessory) Optional mains adapter One-touch operation Fuzzy logic
Comparable Criteria		
Device 2 Criteria		
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1098&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=156&Sprach_ID=2
Comments	These are essentially the same devices in different casing	
Recommendation	Accept	