

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-A(2)
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

Reinders A, Cuckson AC, Lee JTM, Shennan AH
Authors(s)

An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the

Microlife 3BTO-A
Title

RCOG 2005 BJOG: Int. Journal of Obstetrics
Publication

April 2005, Vol 112
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 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 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"/>

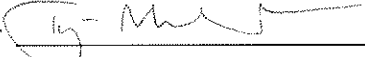

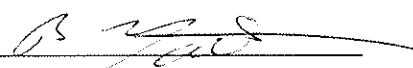
Further relevant details: 10) different colour, additional buttons for Date/Time and Memory

11) indication for Date/Time and Memory



14) BP 3BTO-A(2) contains 30 Memory

18) BP 3BTO-A(2) set contains additional L-size cuff and pacifier

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>	
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>	

Comparison of the Microlife BP 3BT0-A (2) with the Microlife BP 3BT0-A

Devices	Microlife BP 3BT0-A (2)	Microlife BP 3BT0-A
Pictures		
Validation		BHS - A/A grading, Gütesiegel/Quality Seal, German Design Award
Device 1 Criteria	Memory and Date/Time buttons <i>10</i> Memory and Date/Time <i>11</i> Memory: 30 measurements <i>14</i>	
Same Criteria	Oscillometric measuring method Optional mains adapter	Oscillometric measuring method Optional mains adapter
Comparable Criteria	Error code (1, 2, 3, 5, Hi & Lo) Cuffs: M and L <i>18</i>	Error code (1, 2, 3 & 5) Cuffs: M (L as accessory) <i>18</i>
Device 2 Criteria		Memory: 1 measurement <i>14</i>
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1154&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=156&Sprach_ID=2
Comments	This monitor is promoted as being especially for pregnancy. The declaration form indicated the addition of a “pacifier”. No such facility is mentioned in the manual. However, it does seem to be something additional to the monitor and therefore not connected to its validation.	
Recommendation	Accept.	