dabl®Educational Trust

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 RM 100_____
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.)

			Yes	No
Part I	1	Algorithm for Oscillometric Measurements	☐	X
	2	Algorithm for Auscultatory Measurements	☐	☐
	3	Artefact/Error Detection	☐	X
	4	Microphone(s)	☐	☐
	5	Pressure Transducer	☐	X
	6	Cuff or Bladder	☐	X
	7	Inflation Mechanism	☐	X
	8	Deflation Mechanism	☐	X
Part II	9	Model Name or Number	X	☐
	10	Casing	X	☐
	11	Display	X	☐
	12	Carrying/Mounting Facilities	☐	☐
	13	Software other than Algorithm	X	☐
	14	Memory Capacity/Number of stored measurements	☐	X
	15	Printing Facilities	☐	☐
	16	Communication Facilities	☐	☐
	17	Power Supply	☐	X
	18	Other Facilities	☐	☐

Further relevant details: 10) different housing, different colour, additional buttons for Risk Factor input, Confirm Risk Factor, Time, MAM

11) indication for risk settings, risk classes, memory, date/time, MAM

13) Includes MAM technology (Microlife Average Mode),

additional error code: ERR 6 (MAM relevant),

includes "Risk Factor Input" to pre-select 7 risk factors according to the WHO

to categorize patients with high BP into 4 classes (see IB).

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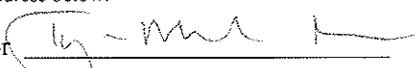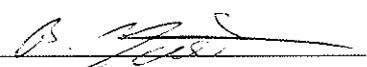
Address   Microlife AG, Max-Schmidheiny-Strasse 201, CH-9435 Heerbrugg

Comparison of the Microlife RM 100 with the Microlife BP 3BT0-A

Devices	Microlife RM 100	Microlife BP 3BT0-A
Pictures		
Validation	BHS - A/A grading	BHS - A/A grading, Gütesiegel/Quality Seal, German Design Award
Device 1 Criteria	Different case with extra buttons _10_ Risk, Memory, Date/Time, MAM display _11_ MAM (average mode) or standard mode selection _13_ Risk factor classification. _13_	
Same Criteria	Memory: 1 measurement (See comments) Oscillometric measuring method Cuffs: M (L as accessory) Optional mains adapter	Memory: 1 measurement Oscillometric measuring method 0 Cuffs: M (L as accessory) Optional mains adapter
Comparable Criteria	Error code (1, 2, 3, 5 & 6)	Error code (1, 2, 3 & 5)
Device 2 Criteria		
Web link	http://mldata.ria.ch/detail.asp?Produkt_ID=1100&Sprach_ID=2	http://mldata.ria.ch/detail.asp?Produkt_ID=156&Sprach_ID=2

Comments	This unit has quite a few extras. Some extra memory is required for the averaging facility but blood pressures stored for this reason cannot be recalled. The declared single measurement storage is therefore correct. _Only one measurement is stored for recall purposes. Quite separately, all measurements taken during the current day are stored. The average is stored elsewhere. Once the day changes, the list begins again and a new average is updated. Up to seven consecutive daily averages are stored. Data older than seven days are erased. The unit displays the average of the seven (or whatever available) daily averages._
Recommendation	Accept