

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items.

I **Thomas Fässler,** a Director of **B.Well Swiss AG,**
Name of a Company Director Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Maker^a	B.Well Swiss AG	Address	Bahnhofstrasse 24, 9443 Widnau, Switzerland
Manufacturer^b	B.Well Swiss AG	Address	Bahnhofstrasse 24, 9443 Widnau, Switzerland
Brand^c	B.Well	Model^d	MED-55 (REF: MED-55 (G.IV))

Blood pressure measuring device for which validation is claimed. If alternative model names are used, include all.

blood pressure measuring device and the validated blood pressure measuring device

Maker^a	B.Well Swiss AG	Address	Bahnhofstrasse 24, 9443 Widnau, Switzerland
Manufacturer^b	B.Well Swiss AG	Address	Bahnhofstrasse 24, 9443 Widnau, Switzerland
Brand^c	B.Well	Model^d	TH-75

Existing validated blood pressure measuring device.

which has previously passed the **ISO 81060-2:2018 +A2:2024** protocol, the results of which were published as follows:

https://journals.lww.com/bpmonitoring/abstract/9900/validation_of_the_b_well_th_75_oscillometric.190.aspx

Full reference

The only differences between the devices involve the following components:

Tick one box for each item 1-18.

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A ^e <input type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	3	Artefact/Error Detection	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^f <input checked="" type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	6	Cuffs or Bladders	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 type="checkbox"/>	No <input checked="" type="checkbox"/>	
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" 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"/>	N/A ^g <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A ^g <input checked="" 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"/>	N/A ^g <input checked="" type="checkbox"/>

An explanation of each item ticked "Yes" must be included in Section B or on a separate sheet.

- Notes:
- a Provide the name and address of the actual maker of the device.
 - b Provide the name and address of the legal manufacturer of the device, even if it is the same as that of the maker.
 - c Provide the name of the brand under which it is sold, even if it is the same as that of the manufacturer or maker.
 - d Provide the model name. If alternative or internal model names are used, include all. Each device must be uniquely identifiable.
 - e Only tick N/A (Not Applicable) if neither device measures blood pressure using the oscillometric method.
 - f Only tick N/A (Not Applicable) if neither device measures blood pressure using the auscultatory method.
 - g Only tick N/A (Not Applicable) if neither device provides printing, communication or other facilities, as appropriate.

SECTION B An explanation for each item, 1 to 18, ticked "Yes" in Section A must be provided here or in an attached document. All differences between the devices must be described.

Refer to document: DET9 Device Equivalence Comparison Form 2026 (MED-55 tfav1)

SECTION C Please check that the following are included with the application

- A manual for the validated device
- A manual for the device for which equivalence is being sought
- Completed DET9 Form
- An image of the device for which equivalence is being sought
- An image of the screen layout of validated device*
- An image of the screen layout of the device for which equivalence is being sought*

* Screen layouts shown complete, and without obscuring labels or lines, in manuals need not be included separately.

SECTION D Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original to our address below. Please email a signed copy of this form, together with the manuals and images for both devices, to info@dableducational.org.

Signature of Director 

Name Thomas Fässler

Date 01.05.2026

Signature of Witness 



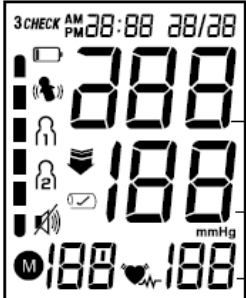
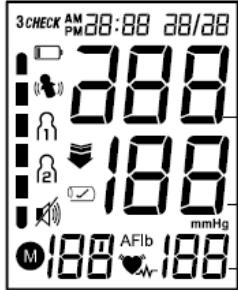
Name Mario Ivic

Address Bahnhofstrasse 24, 9443, Widnau, Switzerland

Company Stamp/Seal



Comparison of the B.Well MED-55 (REF: MED-55 (G.IV)) with the B.Well TH-75

Devices – Item 9	B.Well MED-55 (REF: MED-55 (G.IV))	B.Well TH-75
Pictures		
Display Image		
Validation	Equivalence	ISO 81060-2:2018+A2:2024
Category	Non-invasive oscillometric blood pressure monitor	Non-invasive oscillometric blood pressure monitor
Casing – Item 10	<p><i>Dimensions</i></p> <ul style="list-style-type: none"> - N/A <p><i>Ports</i></p> <ul style="list-style-type: none"> - N/A <p><i>Features</i></p> <ul style="list-style-type: none"> - N/A 	<p><i>Dimensions</i></p> <ul style="list-style-type: none"> - N/A <p><i>Ports</i></p> <ul style="list-style-type: none"> - N/A <p><i>Features</i></p> <ul style="list-style-type: none"> - N/A
Display – Item 11	<p><i>Type</i></p> <p>LCD, Layout <u>without</u> AFIB</p>	<p><i>Type</i></p> <p>LCD, Layout <u>with</u> AFIB</p>
Carrying/Mounting	- N/A	- N/A

Facilities – Item 12		
Software other than Algorithm – Item 13	- N/A	- N/A
Memory Capacity Item 14	- 2 user, 90 memory each	- 2 user, 120 memory each
Printing Facilities Item 15	- N/A	- N/A
Communication Facilities – Item 16	- N/A	- N/A
Power Supply Item 17	- N/A	- N/A
Other differences	- Guest Mode	- N/A
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <ul style="list-style-type: none"> - Blood pressure: +/- 3mmHg - Pulse rate: <60: +/- 3bpm, ≥60: +/- 5% <p><i>Method</i></p> <p>Oscillometric measurement method</p> <p><i>Ranges</i></p> <p>SYS: 60-260mmHg, DIA:40-199mmHg</p> <p><i>Inflation</i></p> <p>Yes, inflation measurement mode</p> <p><i>Deflation</i></p> <p>No deflation measurement mode</p> <p><i>Cuffs (Please state sizes and materials used)</i></p> <ul style="list-style-type: none"> - Fan shape cuff for size: 22-42cm, PVC and TPU bladder option - Fan shape cuff for size: 22-32cm, PVC and TPU bladder option <p><i>Sensors</i></p> <ul style="list-style-type: none"> - DIP-6 mount pressure sensor <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - Difference, see comparison in item 14 	<p>Measurement</p> <p><i>Accuracy</i></p> <ul style="list-style-type: none"> - Blood pressure: +/- 3mmHg - Pulse rate: <60: +/- 3bpm, ≥60: +/- 5% <p><i>Method</i></p> <p>Oscillometric measurement method</p> <p><i>Ranges</i></p> <p>SYS: 60-260mmHg, DIA:40-199mmHg</p> <p><i>Inflation</i></p> <p>Yes, inflation measurement mode</p> <p><i>Deflation</i></p> <p>No deflation measurement mode</p> <p><i>Cuffs(Please state sizes and materials used)</i></p> <ul style="list-style-type: none"> - Fan shape cuff for size: 22-42cm, PVC and TPU bladder option - Fan shape cuff for size: 22-32cm, PVC and TPU bladder option <p><i>Sensors</i></p> <ul style="list-style-type: none"> - DIP-6 mount pressure sensor <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - 2 user, 120 memory each

	<p><i>Measurements other than Blood Pressure</i></p> <ul style="list-style-type: none"> - Pulse rate <p>Buttons/Switches</p> <p><i>Power</i></p> <ul style="list-style-type: none"> - Power key <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - “M” button <p><i>Function</i></p> <ul style="list-style-type: none"> - +/- for controlling - Switch on side for 1 or 3 check mode <p><i>Analysis</i></p> <ul style="list-style-type: none"> - No button/switch for analysis <p><i>Event Marking</i></p> <ul style="list-style-type: none"> - No button/switch for event marking <p><i>Communication</i></p> <ul style="list-style-type: none"> - No button/switch for communication <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <ul style="list-style-type: none"> - No symbols/indicators showed for preparation <p><i>Measurement Procedure</i></p> <ul style="list-style-type: none"> - Heartbeat Symbol flashing during measurement - Cuff placement indicator - Deflation of remaining air symbol <p><i>Post Measurement</i></p> <ul style="list-style-type: none"> - Result shown, if detected: Irregular heartbeat symbol shown <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - Difference, see comparison in item 14 <p><i>Date and Time</i></p> <ul style="list-style-type: none"> - Date & Time indication <p><i>Power</i></p> <ul style="list-style-type: none"> - Display: Low battery indication <p><i>Function</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed <p><i>Communication</i></p> <ul style="list-style-type: none"> - No Display/Symbol/Indicator for communication <p><i>Features</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed 	<p><i>Measurements other than Blood Pressure</i></p> <ul style="list-style-type: none"> - Pulse rate <p>Buttons/Switches</p> <p><i>Power</i></p> <ul style="list-style-type: none"> - Power key <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - “M” button <p><i>Function</i></p> <ul style="list-style-type: none"> - +/- for controlling - Switch on side for 1 or 3 check mode <p><i>Analysis</i></p> <ul style="list-style-type: none"> - No button/switch for analysis <p><i>Event Marking</i></p> <ul style="list-style-type: none"> - No button/switch for event marking <p><i>Communication</i></p> <ul style="list-style-type: none"> - No button/switch for communication <p>Display/Symbols/Indicators</p> <p><i>Preparation</i></p> <ul style="list-style-type: none"> - No symbols/indicators showed for preparation <p><i>Measurement Procedure</i></p> <ul style="list-style-type: none"> - Heartbeat Symbol flashing during measurement - Cuff placement indicator - Deflation of remaining air symbol <p><i>Post Measurement</i></p> <ul style="list-style-type: none"> - Result shown, if detected: Irregular heartbeat symbol shown or AFIB <p><i>Measurement Records</i></p> <ul style="list-style-type: none"> - Difference, see comparison in item 14 <p><i>Date and Time</i></p> <ul style="list-style-type: none"> - Date & Time indication <p><i>Power</i></p> <ul style="list-style-type: none"> - Display: Low battery indication <p><i>Function</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed <p><i>Communication</i></p> <ul style="list-style-type: none"> - No Display/Symbol/Indicator for communication <p><i>Features</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed
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	<p><i>Not described</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed <p>Algorithms</p> <p><i>Averages and Differences</i></p> <ul style="list-style-type: none"> - No differences to validated device <p><i>Diagnostic</i></p> <ul style="list-style-type: none"> - No differences to validated device <p><i>Functions</i></p> <ul style="list-style-type: none"> - No differences to validated device <p><i>Communication</i></p> <ul style="list-style-type: none"> - No communication to other devices 	<p><i>Not described</i></p> <ul style="list-style-type: none"> - No further symbols/indicators showed <p>Algorithms</p> <p><i>Averages and Differences</i></p> <ul style="list-style-type: none"> - Validated device <p><i>Diagnostic</i></p> <ul style="list-style-type: none"> - Validated device <p><i>Functions</i></p> <ul style="list-style-type: none"> - Validated device <p><i>Communication</i></p> <ul style="list-style-type: none"> - No communication to other devices
Comparable Criteria	N/A	N/A

Office Use Only

Comments		
Recommendation	Recommended	
Date	May 2026	