**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      , a Director of      ,

 Name of a Company Director Company name

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

|  |  |  |  |
| --- | --- | --- | --- |
| Makera |       | *Address* |       |
| Manufacturerb |       | *Address* |       |
| Brandc |       | Modeld |       |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Makera |       | *Address* |       |
| Manufacturerb |       | *Address* |       |
| Brandc |       | Modeld |       |

Existing validated blood pressure measuring device.

which has previously passed the       protocol, the results of which were published as follows:

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 [ ]  No [ ]  N/Ae [ ]

 2 Algorithm for Auscultatory Measurements Yes [ ]  No [ ]  N/Af [ ]

 3 Artefact/Error Detection Yes [ ]  No [ ]

 4 Microphone(s) Yes [ ]  No [ ]  N/Af [ ]

 5 Pressure Transducer Yes [ ]  No [ ]

 6 Cuffs or Bladders Yes [ ]  No [ ]

 7 Inflation Mechanism Yes [ ]  No [ ]

 8 Deflation Mechanism Yes [ ]  No [ ]

Part II 9 Model Name or Number Yes [ ]  No [ ]

 10 Casing Yes [ ]  No [ ]

 11 Display Yes [ ]  No [ ]

 12 Carrying/Mounting Facilities Yes [ ]  No [ ]

 13 Software other than Algorithm Yes [ ]  No [ ]

 14 Memory Capacity/Number of stored measurements Yes [ ]  No [ ]

 15 Printing Facilities Yes [ ]  No [ ]  N/Ag [ ]

 16 Communication Facilities Yes [ ]  No [ ]  N/Ag [ ]

 17 Power Supply Yes [ ]  No [ ]

 18 Other Facilities Yes [ ]  No [ ]  N/Ag [ ]

**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.

**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 Company Stamp/Seal

Name

Date

Signature of Witness

Name

Address