**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