

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2011

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

SECTION A - Please complete all items.

I, _____, a Director of **Artsana s.p.a.**,
Name of a Company Director Company name

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

Manufacturer **Artsana spa** Brand **PiC Solution** Model **Mamy Check**

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

blood pressure measuring device and the

Manufacturer **Artsana spa** Brand **PiC Solution** Model **My Check**

Existing validated blood pressure measuring device. If alternative model names are used, include all.

blood pressure measuring device, which has previously passed the **ESH** protocol, the results of which were published as follows:

Gruseppe Germano; Angelos Psimenos; Francesco Sarullo; Alessandro Venditti; Valerio Pecchioli; Roland Asmar
Authors(s)

Validation of four automatic devices for self-measurement of blood pressure according to the international Protocol: **The PiC Indolor Personal Check, Comfort Check, My Check and Travel Check.**

Title

Blood Pressure **2009 - 18:1,15 - 23.**
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. It is necessary to provide details on each item ticked "Yes" in Section C or on a separate sheet.

| | | | | |
|---------|----|---|---|--|
| 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 type="checkbox"/> | No <input checked="" type="checkbox"/> |
| | 11 | Display | Yes <input type="checkbox"/> | No <input checked="" 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 type="checkbox"/> | No <input checked="" type="checkbox"/> |
| | 15 | Printing Facilities | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| | 16 | Communication Facilities | Yes <input type="checkbox"/> | No <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 checked="" type="checkbox"/> |

An explanation of each item ticked "Yes" must be included in **Section C** on the next page

SECTION B 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 manuals and images for both devices to info@dableducational.org.

Signature of Director _____

Company Stamp/Seal

Name **Mario Merlo**

ARTSANA S.p.A.

Date **9.02.2011**

Signature of Witness _____



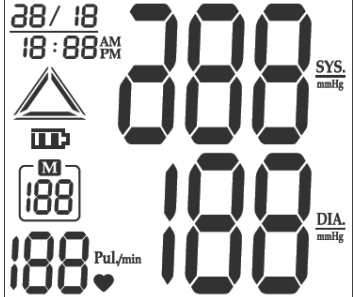
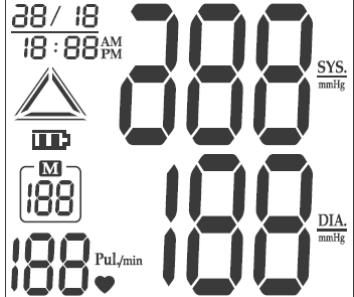
Name **Francesco Lo Piccolo**

Address **Artsana s.p.a. Via Saldarini Catelli 1, 22070, Grandate (Como), Italy**

SECTION C 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.

The Mamy Check model is the same as the My Check model, but with different name.

Comparison of the Artsana Pic Solution Mamy Check with the Artsana Pic Solution My Check

| Devices | Artsana Pic Solution Mamy Check | Artsana Pic Solution My Check |
|-------------------|---|---|
| Pictures |  |  |
| Display |  |  |
| Validation | | ESH |
| Device 1 Criteria | | |
| Same Criteria | <p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg – 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 199 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> | <p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p> <p>BP 30 mmHg – 260 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm – 199 bpm 1, 5, 8</p> <p>Manually initiated measurements 13</p> <p>Measurements are from single inflations 13</p> <p><i>Inflation</i></p> <p>Inflation 0 mmHg – 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> |

| Devices | Artsana Pic Solution Mamy Check | Artsana Pic Solution My Check | |
|---|--|--|---|
| Same Criteria (continued) | Measurement (continued) | Measurement (continued) | |
| | <i>Inflation (continued)</i> | <i>Inflation (continued)</i> | |
| | Fuzzy Logic | 7 | Fuzzy Logic 7 |
| | Zero pressure check before inflation | 7 | Zero pressure check before inflation 7 |
| | <i>Deflation</i> | | <i>Deflation</i> |
| | Automatic Deflation | 8 | Automatic Deflation 8 |
| | Automatic safety release valve | 8 | Automatic safety release valve 8 |
| | <i>Cuffs</i> | | <i>Cuffs</i> |
| | Large (Arm circ. 34-46 cm) (Optional) | 6 | Large (Arm circ. 34-46 cm) (Optional) 6 |
| | Medium (Arm circ. 24 to 36 cm) | 6 | Medium (Arm circ. 24 to 36 cm) 6 |
| | Small (Arm circ. 18-26 cm) (Optional) | 6 | Small (Arm circ. 18-26 cm) (Optional) 6 |
| | <i>Sensors</i> | | <i>Sensors</i> |
| | Pressure sensor: semi conductor | 5 | Pressure sensor: semi conductor 5 |
| | <i>Measurement Records</i> | | <i>Measurement Records</i> |
| | Memory: 120 measurements | 14 | Memory: 120 measurements 14 |
| | Buttons/Switches | | Buttons/Switches |
| | <i>Power</i> | | <i>Power</i> |
| | On/Off with Start/Stop (O/I Label) | 10 | On/Off with Start/Stop (O/I Label) 10 |
| | <i>Measurement Records</i> | | <i>Measurement Records</i> |
| | Memory (shows average on first press) | 10 | Memory (shows average on first press) 10 |
| | <i>Settings</i> | | <i>Settings</i> |
| | Date/Time set (2 buttons: Mode & Plus) | 10 | Date/Time set (2 buttons: Mode & Plus) 10 |
| | Display/Symbols/Indicators | | Display/Symbols/Indicators |
| | <i>Measurement Procedure</i> | | <i>Measurement Procedure</i> |
| | Beeps before measurement | 18 | Beeps before measurement 18 |
| | During Measurement: BP Level & Heartbeat | 11 | During Measurement: BP Level & Heartbeat 11 |
| | Beeps after measurement | 18 | Beeps after measurement 18 |
| | <i>Post Measurement</i> | | <i>Post Measurement</i> |
| SBP, DBP and Pulse | 11 | SBP, DBP and Pulse 11 | |
| Measurement error EE , $E1$, $E2$, $E3$ & E_r | 11 | Measurement error EE , $E1$, $E2$, $E3$ & E_r 11 | |
| Hypertension (triangle) | 11, 13 | Hypertension (triangle) 11, 13 | |
| Average (\bar{H} symbol) | 11, 13, 14 | Average (\bar{H} symbol) 11, 13, 14 | |
| <i>Measurement Records</i> | | <i>Measurement Records</i> | |
| Memory "M" symbol | 11 | Memory "M" symbol 11 | |
| Memory recall number | 11 | Memory recall number 11 | |
| Delete memory (Press memory button for 5 s) | 11 | Delete memory (Press memory button for 5 s) 11 | |

| Devices | Artsana Pic Solution Mamy Check | Artsana Pic Solution My Check |
|----------------------------------|---|---|
| Same Criteria (continued) | <p>Display/Symbols/Indicators (continued)</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate (E_H displayed) 11, 18</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p><i>Diagnostic</i></p> <p>135 / 85 mmHg thresholds 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 4 min 17</p> | <p>Display/Symbols/Indicators (continued)</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Power</i></p> <p>Charged battery 11, 17</p> <p>Low battery 11, 17</p> <p><i>Settings</i></p> <p>Recalibrate (E_H displayed) 11, 18</p> <p>Algorithms</p> <p><i>Averages and Differences</i></p> <p>Last 3 measurements mean 13</p> <p><i>Diagnostic</i></p> <p>135 / 85 mmHg thresholds 13</p> <p>Casing</p> <p><i>Display</i></p> <p>Single screen display 10</p> <p>Segment LCD 10</p> <p><i>Ports</i></p> <p>Data port (Optional USB cable and PC software) 16, 18</p> <p><i>Power</i></p> <p>4 “AA” batteries 17</p> <p>AC adapter (Optional) 17</p> <p>Automatic switch-off when not used for 4 min 17</p> |
| Comparable Criteria | | |
| Device 2 Criteria | | <p>Case</p> <p><i>Features</i></p> <p>Lid 10</p> |

| | |
|-----------------------|--|
| Comments | The “Mamy Check” is the same as the “My Check” except for the lid. |
| Recommendation | Equivalence is recommended |
| Date | 16/03/2012 |