

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2013

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

SECTION A - Please complete all items.

I **Stefano Chiesa,** a Director of **CA-MI Srl,**
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 **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Manufacturer^b **CA-MI Srl** Address **Via Ugo La Malfa 13 - 43010 Pilastro (PR) - Italy**
 Brand^c **CHIESI FARMACEUTICI SPA** Model^d **CHIESI 010000328 (DIESIS PLUS)**

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 **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Manufacturer^b **Nissei** Address **2508-13 Nakago Shibukawa Gunma 377-0293 Japan**
 Brand^c **Nissei** Model^d **DSK-1011**

Existing validated blood pressure measuring device.

which has previously passed the **ESH 2010** protocol, the results of which were published as follows:

Dublin:dablEducationalTrust;2011-Sep-01.-9p.

Available from: <http://www.dableducational.org/Publications/2011/ESH-IP 2010 Validation of Nissei DSK-1011.pdf>.

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 type="checkbox"/> | No <input checked="" 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 checked="" type="checkbox"/> | No <input 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"/> | 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 checked="" type="checkbox"/> | N/A ^g <input 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.

9) Model name - The model/reference name is different in accordance with requirement of MDD 93/42/EEC because of change in the identification code of new Manufacturer (in compliance with CE certification). The new model name is CHIESI 0100000328 (DIESIS PLUS) and replace the validated device name that is DSK-1011. On the validated device DSK-1011, the name was printed on front of device too, instead in the new model the name is printed on the rating label that is applied on the bottom (in compliance with CE certification).

Brief explanation of differences: Further details are shown on the attached "Section B comparison sheet".

10) Casing

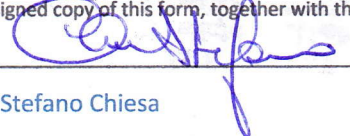
The company logo is different due to different company's brand.

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
- An image of the validated device
- 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@dablededucational.org.

Signature of Director 

Name Stefano Chiesa

Date 07 September 2015

Signature of Witness 





Name Mario Attolini

Address Via Ugo La Malfa 13 - 43010 Pilastro (PR) - Italy

Company Stamp/Seal

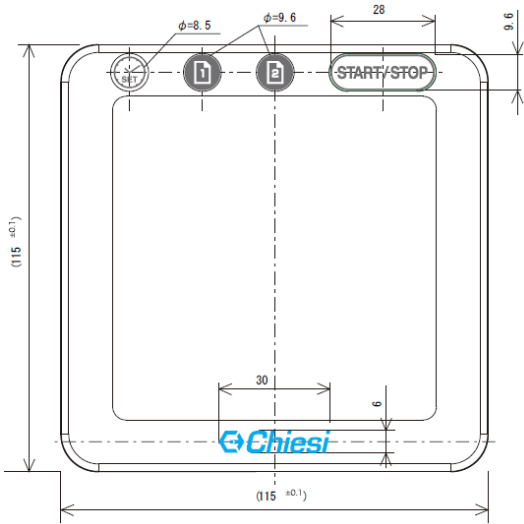
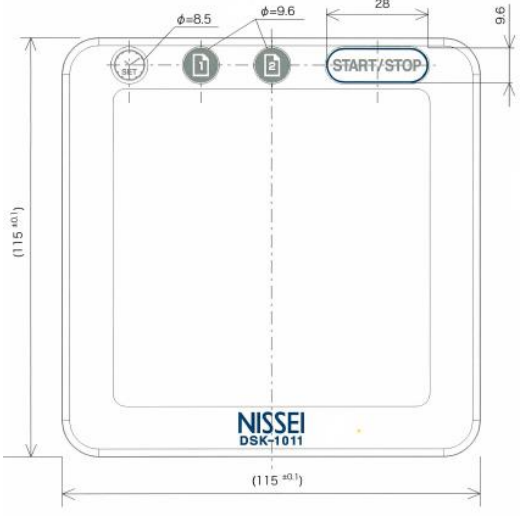
CA-MI S.r.l.
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 Cod. Fisc. e Part. IVA 00977090349
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 Fax +39 0521 639041

Comparison of the *CHIESI 0100000328(DIESIS PLUS)* with the *NISSEI DSK-1011*

| | | |
|-------------------|---|--|
| Devices | <i>CHIESI 0100000328(DIESIS PLUS)</i> (Device 2) | <i>NISSEI DSK-1011</i> (Device 1) |
| Pictures |  |  |
| Display |  |  |
| Validation | ESH 2010 | |
| Device 1 Criteria | | |

| Device 2 Criteria | | |
|-----------------------------|---|---|
| <p>Same Criteria</p> | <p>Measurement <i>Accuracy</i> Blood pressure accuracy \pm 3 mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i> Oscillo-Metric Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg Pulse rate 40 bpm - 160 bpm</p> <p><i>Inflation</i> Automatic Inflation System (Air Pump) Inflation 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> Universal cuff(Arm circ. 22 to 42cm)</p> <p><i>Sensors</i> CS-20A</p> <p><i>Measurement Records</i> 60 measurement \times 2 users</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> On/Off With Start</p> <p><i>Measurement Records</i> Memory \times 2, Clock set</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> Inflation symbol Deflation symbol</p> | <p>Measurement <i>Accuracy</i> Blood pressure accuracy \pm 3 mmHg Pulse accuracy \pm 5%</p> <p><i>Method</i> Oscillo-Metric Systolic blood pressure (SYS) 50 mmHg - 250 mmHg Diastolic blood pressure (DIA) 40 mmHg - 180 mmHg Pulse rate 40 bpm - 160 bpm</p> <p><i>Inflation</i> Automatic Inflation System (Air Pump) Inflation 0 mmHg - 300 mmHg</p> <p><i>Deflation</i> Automatic speed deflation system</p> <p><i>Cuffs</i> Universal cuff(Arm circ. 22 to 42cm)</p> <p><i>Sensors</i> CS-20A</p> <p><i>Measurement Records</i> 60 measurement \times 2 users</p> <p><i>Measurements other than Blood Pressure</i> Pulse rate</p> <p>Buttons/Switches <i>Power</i> On/Off With Start</p> <p><i>Measurement Records</i> Memory \times 2, Clock set</p> <p>Display/Symbols/Indicators <i>Measurement Procedure</i> Inflation symbol Deflation symbol</p> |

| | | |
|--|--|--|
| | <p>Heartbeat symbol during inflation Irregular pulse rhythm symbol Body motion Symbol</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate Average</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low Battery detection symbol</p> <p><i>Function</i> Memory1/2 symbol Measurement errors</p> <p><i>Features</i> WHO classification *WHO: World Health Organization</p> <p>Algorithms <i>Averages and Differences</i> All measurement mean</p> <p>Casing <i>Display</i> Segment LCD Single screen display</p> <p><i>Ports</i> Air connector DC Jack *AC adapter is optional</p> <p><i>Power</i> 4 "AA" batteries</p> | <p>Heartbeat symbol during inflation Irregular pulse rhythm symbol Body motion Symbol</p> <p><i>Post Measurement</i> Systolic blood pressure Diastolic blood pressure Pulse rate Average</p> <p><i>Measurement Records</i> Memory recall number</p> <p><i>Date and Time</i> Date and Time</p> <p><i>Power</i> Low Battery detection symbol</p> <p><i>Function</i> Memory1/2 symbol Measurement errors</p> <p><i>Features</i> WHO classification *WHO: World Health Organization</p> <p>Algorithms <i>Averages and Differences</i> All measurement mean</p> <p>Casing <i>Display</i> Segment LCD Single screen display</p> <p><i>Ports</i> Air connector DC Jack *AC adapter is optional</p> <p><i>Power</i> 4 "AA" batteries</p> |
|--|--|--|

| Comparable Criteria | | |
|----------------------|--|---|
| <p>Casing</p> | <p>Print</p> <p>Outline</p>  | <p>Print</p> <p>Outline</p>  |

| | |
|------------------------------|--|
| <p>Comments</p> | <p>Replies to queries; Accepted</p> |
| | |
| | |
| <p>Recommendation</p> | <p><i>Equivalence Recommended</i></p> |
| <p>Date</p> | <p>7 October 2015</p> |