



Declaration of Conformance

BRAND **NISSEI**
Manufacture **NIHON SEIMITSU SOKKI CO.,LTD.**
Address 2508-13 Nakago, Shibukawa, Gunma
377-0293 JAPAN

European **JPI Inc EU Office**
Representative **Neubertstrasse 32**
22087 Hamburg Germany

Product **Non Invasive Blood Pressure Monitor**
Model Code: **DSK-1031**
Design Code: **DSK-1031-02**
Classification (MDD, Annex IX): **II a**

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directives and standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE **93/42/EEC** OF 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Harmonized Standards applicable to this product are:

ISO 13485, ISO 14971, EN 1060-1, EN 1060-3, EN 1060-4, IEC 60601-1, IEC 60601-1-2
EN-60601-1-2-30, EN 980, IEC 62304, IEC 62366, IEC/TR 60878, IEC 80601-2-30

Notified Body: **TÜV SÜD Product Service GmbH**, Ridlerstrasse. 65, 80339
München, Germany
ID Number **0123**

Date CE mark will be affixed: Oct , 2011

From serial No.(SN2011-101031-000001)and all successive following numbers.

Place, Date Oct 28 2011

Signature Kenju Seki

Name: Kenju Seki
Position: Quality Assurance, Management Representative



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Product **Non Invasive Blood Pressure Monitor**
Model Code: **WSK-1011**
Design Code: **WSK-1011-02**
Classification (MDD, Annex IX): **II a**

We herewith declare that the above mentioned product meet the provisions of the following EC Council Directives and standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE **93/42/EEC** OF 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Harmonized Standards applicable to this product are:

ISO 13485、ISO 14971、EN 1060-1、EN 1060-3、EN 1060-4、IEC 60601-1、IEC 60601-1-2
EN-60601-1-2-30、EN 980、IEC 62304、IEC 62366、IEC/TR 60878、IEC 80601-2-30

Notified Body: **TÜV SÜD Product Service GmbH**, Ridlerstrasse. 65, 80339
München, Germany
ID Number **0123**

Date CE mark will be affixed: Oct , 2011

From serial No.(SN2011-2P1011-000001)and all successive following numbers.

Place, Date Oct 28 2011

Signature 

Name: **Kenju Seki**
Position: **Quality Assurance, Management Representative**