



Declaration of Conformance

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

European **JPI Trading GmbH**
Representative Holzbrücke 7 D-20459, Hamburg, Germany
Makoto Ueno

Product **Non Invasive Blood Pressure Monitor**
Model Code: **DM-500**
Design Code: **DM-500-02**
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).

Standards:

Harmonized Standards applicable to this product are:

ISO 9001, ISO 13485, EN 1060-1, EN 1060-3

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

Certificate: **G2D 03 05 16512 011** (ANNEX V MDD)

Date CE mark will be affixed: April , 2008

From serial No.(SN2008-1k0500-000001)and all successive following numbers.

Place, Date May 2th, 2008

Signature

Name: **Kenju Seki**

Position: **Quality Assurance, Management Representative**