(Form-0419) 2016.8.29

NISSEI

Declaration of Conformity

BRAND	**NISSEI**
Manufacture	**NIHON SEIMITSU SOKKI CO., LTD.**
Address	2508-13 Nakago, Shibukawa, Gunma 377-0293 JAPAN
European Representative	**Nissei Healthcare (UK) Ltd.** **Rede House New Barn Lane Henfield** **West Sussex BN5 9SJ / United Kingdom**

Product **Non Invasive Blood Pressure Monitor**
Model Code: **DSK-1031**
Design Code: **DSK-1031-14**
Classification (MDD, Annex Ⅸ): **Ⅱa**
Conformity Assessment : **Annex V+VII**

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.

Directives

General applicable directives:
Medical Device Directive :
WE HEREWITH DECLARE THAT WE ARE EXCLUSIVELY RESPONSIBLE FOR THE STATED MEDICAL DEVICES TO MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES-AS AMENDED BY Directive 2007/47/EC ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

Harmonized Standards applicable to this product are:
SEE : "10. List of Standards applied for the device and appropriate proof to show conformance with the Directive in "Technical Documentation" of the above Design Code Model.

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

Date CE mark will be affixed: **November , 2012**

From serial No.(SN2012-1O1031-011001) and all successive following numbers.

Place, Date Gunma, JAPAN **January 15th 2019**

Signature H. Kobayashi
Name : Hideyuki Kobayashi
Position : Quality Assurance, Management Representative