EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 01342**

Issued To: **NIHON KOHDEN CORPORATION**
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Japan

In respect of:

The design, development and manufacture of patient monitoring systems, arrhythmia monitors, fetal monitors, CO2 monitors, pulse oximeters, cardiac catheterisation systems, defibrillators, internal defibrillator paddles, electrocardiographs, ambulatory ECG analysis systems, electroencephalographs and evoked potential measuring systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Digitally signed by Matei Vasile
Date: 2021.03.15 14:05:17 EET
Reason: MoldSign Signature
Location: Moldova

Frank Lee, EMEA Compliance & Risk Director

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