

# 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  
1-31-4 Nishiochiai  
Shinjuku-Ku  
Tokyo  
161-8560  
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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **01 July 1996**

Date: **19 June 2016**

Expiry Date: **30 June 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.