By Royal Charter

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, CO2 monitors for medical application, pulse oximeters, defibrillators, internal defibrillator paddles, electrocardiographs, electroencephalographs, evoked potential measuring systems, ventilators and accessories.
Those aspects of Annex II related to securing and maintaining sterility in the design and manufacture of Laryngoscope Blade.

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 2797):

Digitally signed by Matei Vasile
Date: 2022.01.25 11:25:21 EET
Reason: MoldSign Signature
Location: Moldova

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1996-07-01** Date: **2021-04-29** Expiry Date: **2024-05-26**

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai
Shinjuku-ku
Tokyo
161-8560
Japan

Facility ID Number: F000334

Holds Certificate No: **MDSAP 680668**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-15 Effective Date: 2021-04-06 Expiry Date: 2022-04-05

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 680668**

Registered Scope:

Design, development, manufacture and service provision of defibrillators, non-active non-implantable devices for anaesthesia, emergency and intensive care, active non-implantable respiratory devices, active non-implantable devices for stimulation or inhibition, other active non-implantable surgical devices, active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport, active non-implantable imaging devices utilising non-ionizing radiation, active non-implantable devices for monitoring of vital physiological parameters, hematology analyzer, lead for intracranial electrodes, injection and puncture device, catheter with active function, catheter with non-active function, catheter, non-active instruments, hearing aid, other active non-implantable devices for monitoring and/or diagnosis, active non-implantable devices utilising hyperthermia/hypothermia, and their accessories, software, in vitro diagnostic reagents (hemoglobin, CRP, HbA1c), healthcare information systems, patient plates, electrodes.

Inspection, storage, distribution of probes.

Original Registration Date: 2018-10-15 Effective Date: 2021-04-06 Expiry Date: 2022-04-05