By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 743465 R000

Manufacturer: NIHON KOHDEN CORPORATION

Address:
1-31-4 Nishiochiai
Shinjuku-ku, Tokyo
161-8560
Japan

Single Registration Number: JP-MF-000019022

EU Authorised Representative: NIHON KOHDEN EUROPE GmbH

Address:
Raiffeisenstrasse 10
61191 Rosbach
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2022-04-13**

Current Issue Date: **2024-08-01**

Starting Validity Date: **2024-08-01**

Expiry Date: **2027-04-12**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Defibrillator	See MDR 773833

Class IIb	Intended purpose
Pulse Oximeter	The pulse oximeter is installed near the patient to display the patient's vital signs (SpO2, pulse rate, etc.) on the display and generate alarms.
Ventilator	The ventilator uses positive pressure to provide ventilation and ventilatory assistance as well as oxygen administration to adult or pediatric patients who have spontaneous breathing but need mechanical ventilation (patients with a tidal volume of 100 mL or more).
Bedside Monitor	This device is to be installed near the patient. The patient's vital signs can be monitored, and alarms are generated.
Central Monitor	This device is designed for use in various hospital environments, including the ICU, CCU, recovery room, and general ward. This device allows hospital staff to monitor several patients' vital signs.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Laryngoscope Blade	Class Is
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2022-04-13	3373731	Issued
2022-09-20	3717944	Supplemented – Addition of device category Pulse Oximeter Amended – Approval of significant subcontractors
2024-03-04	30072790	Supplemented – Addition device category Ventilators, and Defibrillators
2024-05-23	30164750	Supplemented – Addition of product category Bedside monitor Amended – Change of certificate history of 3717944 to anonymize significant subcontractor name
Current	30201108	Supplemented – Addition of device category / Central Monitor

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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