

EU DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of the following relevant Union harmonisation legislation. The manufacturer assures that the device that is covered by the present declaration is in conformity with this Regulation (EU) 2017/745 for Medical Devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The declaration of conformity is issued under the sole responsibility of the manufacturer.



Manufacturer's Name: NIHON KOHDEN CORPORATION

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SRN: JP-MF-000019022

European

Representative: NIHON KOHDEN EUROPE GmbH
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SRN: DE-AR-000010740

☒ **Regulation (EU) 2017/745(MDR)**

Classification/Risk Class: I

Conformity assessment procedure: Annex II and III

☒ **Directive 2011/65/EU and 2015/863/EU**

Standard Applied: EN IEC 63000: 2018

☐ **Directive 2014/53/EU (RED)**

Notified Body

Name and No. :

EU-Type Examination

Certificate No. :

Standard Applied:

Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Electrode Lead 3	BR-903P	4931921MD10004BD	×	×	—
Electrode Lead 3	BR-903PA	4931921MD10004BD	×	×	—
Electrode Lead 6	BR-906P	4931921MD10004BD	×	×	—
Electrode Lead 6	BR-906PA	4931921MD10004BD	×	×	—
Electrode Lead 3	BR-923P	4931921MD10004BD	×	×	—
Electrode Lead 6	BR-926P	4931921MD10004BD	×	×	—
Electrode Lead 3	BR-963P	4931921MD10004BD	×	×	—
ECG Patient Cable	BJ-900P	4931921MD10004BD	×	×	—
ECG Patient Cable	BJ-900PA	4931921MD10004BD	×	×	—
ECG Connection Cord 10	JC-900P	4931921MD10004BD	×	×	—
ECG Connection Cord 10	JC-900PA	4931921MD10004BD	×	×	—
ECG Connection Cord 6	JC-906P	4931921MD10004BD	×	×	—
ECG Connection Cord 6	JC-906PA	4931921MD10004BD	×	×	—
IBP Connection Cord	JP-900P	4931921MD10004BD	×	×	—
IBP Connection Cord	JP-910P	4931921MD10004BD	×	×	—
IBP Interface Isolation Cable	JP-911P	4931921MD10004BD	×	×	—
IBP Connection Cord	JP-920P	4931921MD10004BD	×	×	—
IBP Connection Cord	JP-921P	4931921MD10004BD	×	×	—
SpO2 connection cord	JL-900P	4931921MD10004BD	×	×	—
Temperature Connection Cord	JT-900P	4931921MD10004BD	×	×	—
CO Connection Cord	JT-950P	4931921MD10004BD	×	×	—
EEG Connection Cord	JE-905P	4931921MD10004BD	×	×	—
EEG Connection Cord	JE-906P	4931921MD10004BD	×	×	—
Disk Electrode	BE-910P	4931921MD10004BD	×	×	—
Collodion Electrode	BE-920P	4931921MD10004BD	×	×	—
EEG Electrode Lead	BE-930P	4931921MD10004BD	×	×	—
ECG/BP Output Cable	YJ-910P	4931921MD10004BD	×	×	—
ECG/BP Output Cable	YJ-920P	4931921MD10004BD	×	×	—
Air Hose Adult 1.5m	YN-900P	4931921MD10004BD	×	—	—
Air Hose Adult 3.5m	YN-901P	4931921MD10004BD	×	—	—
Air Hose Neonatal 1.5m	YN-924P	4931921MD10004BD	×	—	—
Air Hose Neonatal 3.5m	YN-925P	4931921MD10004BD	×	—	—
Extension cord	BM-918B	4931921MD10004BD	×	×	—
Adapter	JC-990P	4931921MD10004BD	×	×	—
Electrode lead	BR-975P	4931921MD10004BD	×	×	—
Electrode lead	BR-973P	4931921MD10004BD	×	×	—
Multi-link cable	YS-096P5	4931921MD10004BD	×	×	—
Unit connection cable	YS-096P3	4931921MD10004BD	×	×	—
Unit connection cable	YS-096P2	4931921MD10004BD	×	×	—
SpO2 connection cord	JL-650P	4931921MD10004BD	×	×	—
SpO2 connection cord	JL-630P	4931921MD10004BD	×	×	—
SpO2 connection cord	JL-631P	4931921MD10004BD	×	×	—
SpO2 connection cord	JL-632P	4931921MD10004BD	×	×	—
BISx connection cord	YJ-671P	4931921MD10004BD	×	×	—

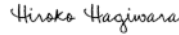
Declaration No.: 2238

Nurse Call Cable	YJ-672P	4931921MD10004BD	×	×	—
Battery Pack	SB-671P	4931921MD10004BD	×	—	—

Intended purpose: The products listed above are accessories of Bedside Monitor.

Additional Information: NA

Authorized Signatory:

DocuSigned by:

 Signer Name: Hiroko Hagiwara
 Signing Reason: I approve this document
 Signing Time: 2024-05-10 | 4:54:05 PM JST
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Tokyo, Japan/ 2024-05-10

Place and date of issue

Hiroko Hagiwara
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 Clinical Development & Regulatory Affairs Division