

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: 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	4931921BR-903PDS	×	×	—
Electrode Lead 3	BR-903PA	4931921BR-903PABX	×	×	—
Electrode Lead 6	BR-906P	4931921BR-906PE3	×	×	—
Electrode Lead 6	BR-906PA	4931921BR-906PACE	×	×	—
Electrode Lead 3	BR-923P	4931921BR-923PE4	×	×	—
Electrode Lead 6	BR-926P	4931921BR-926PED	×	×	—
Electrode Lead 3	BR-963P	4931921BR-963PEQ	×	×	—
ECG Patient Cable	BJ-900P	4931921BJ-900PA9	×	×	—
ECG Patient Cable	BJ-900PA	4931921BJ-900PA78	×	×	—
ECG Connection Cord 10	JC-900P	4931921JC-900PBN	×	×	—
ECG Connection Cord 10	JC-900PA	4931921JC-900PA89	×	×	—
ECG Connection Cord 6	JC-906P	4931921JC-906PC8	×	×	—
ECG Connection Cord 6	JC-906PA	4931921JC-906PA97	×	×	—
IBP Connection Cord	JP-900P	4931921JP-900PGX	×	×	—
IBP Connection Cord	JP-910P	4931921JP-910PH4	×	×	—
IBP Interface Isolation Cable	JP-911P	4931921JP-911PH7	×	×	—
IBP Connection Cord	JP-920P	4931921JP-920PH9	×	×	—
IBP Connection Cord	JP-921P	4931921JP-921PHC	×	×	—
SpO2 connection cord	JL-900P	4931921JL-900PFB	×	×	—
Temperature Connection Cord	JT-900P	4931921JT-900PJK	×	×	—
CO Connection Cord	JT-950P	4931921JT-950PKC	×	×	—
EEG Connection Cord	JE-905P	4931921JE-905PCX	×	×	—
EEG Connection Cord	JE-906P	4931921JE-906PD2	×	×	—
Disk Electrode	BE-910P	4931921BE-910P8D	×	×	—
Collodion Electrode	BE-920P	4931921BE-920P8J	×	×	—

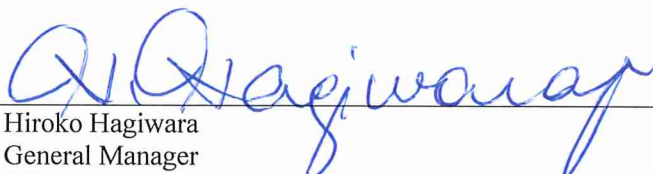
EEG Electrode Lead	BE-930P	4931921BE-930P8P	×	×	—
ECG/BP Output Cable	YJ-910P	4931921YJ-910PNM	×	×	—
ECG/BP Output Cable	YJ-920P	4931921YJ-920PNS	×	×	—
Air Hose Adult 1.5m	YN-900P	4931921YN-900PQ4	×	—	—
Air Hose Adult 3.5m	YN-901P	4931921YN-901PQ7	×	—	—
Air Hose Neonatal 1.5m	YN-924P	4931921YN-924PQS	×	—	—
Air Hose Neonatal 3.5m	YN-925P	4931921YN-925PQV	×	—	—
Extension cord	BM-918B	4931921BM-918BBH	×	×	—
Adapter	JC-990P	4931921JC-990PD3	×	×	—
Electrode lead	BR-975P	4931921BR-975PF3	×	×	—
Electrode lead	BR-973P	4931921BR-973PEV	×	×	—
Multi-link cable	YS-096P5	4931921YS-096P5QS	×	×	—
Unit connection cable	YS-096P3	4931921YS-096P3QN	×	×	—
Unit connection cable	YS-096P2	4931921YS-096P2QL	×	×	—
Accessory Set	YO-60IY2	4931921YO-60IY2S8	×	×	—
Accessory Set	YO-60IY1	4931921YO-60IY1S6	×	×	—
SpO2 connection cord	JL-650P	4931921JL-650PFF	×	×	—
SpO2 connection cord	JL-630P	4931921JL-630PF5	×	×	—
SpO2 connection cord	JL-631P	4931921JL-631PF8	×	×	—
SpO2 connection cord	JL-632P	4931921JL-632PFB	×	×	—
BISx connection cord	YJ-671P	4931921YJ-671PNZ	×	×	—
Nurse Call Cable	YJ-672P	4931921YJ-672PP4	×	×	—
Battery Pack	SB-671P	4931921SB-671PGK	×	—	—

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

Additional Information: NA

Authorized Signatory:Tokyo, Japan/ 31 August 2022

Place and date of issue


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