

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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Tokyo 161-8560, Japan

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. : NA (Module A)

EU-Type Examination

Certificate No. : NA

Standard Applied:

Health and Safety Article 3.1 (a)	IEC 60601-1: 2005 IEC 60601-1 Amendment 1: 2012 IEC 60601-1 Amendment 2: 2020 IEC 60601-2-25: 2011 EN 62311: 2008
EMC Article 3.1 (b)	IEC 60601-1-2: 2014 IEC 60601-1-2 Amendment1:2020
Spectrum Article 3.2	EN 300 328 V2.2.2: 2019 EN 301 893 V2.1.1: 2017
Cybersecurity Article 3.3 (d), (e), (f)	NA

The device referenced in this declaration is subject to the provisions of Regulation (EU) 2017/745. Pursuant to Article 2.1 of Commission Delegated Regulation (EU) 2022/30, the essential requirements outlined in Article 3.3(d), (e), and (f) of Directive 2014/53/EU shall not apply to the device.

Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Wireless LAN Module	QI-330D	4931921MD10015BM	×	×	×

Intended purpose: The product listed above is accessory of Electrocardiograph.

Additional Information: NA

Authorized Signatory:

Tokyo, Japan/ 2025-12-25

Place and date of issue

Signed by:

Hiroko Hagiwara



Signer Name: Hiroko Hagiwara

Signing Reason: I approve this document

Signing Time: 2025-12-25 | 4:13:25 PM JST

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Hiroko Hagiwara

General Manager

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