NIHON KOHDEN

Declaration No.: 2260

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.

CE

Manufacturer's Name: NIHON KOHDEN CORPORATION

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

SRN: JP-MF-000019022

European Representative: NIHON KOHDEN EUROPE GmbH

Address: Raiffeisenstrasse 10, 61191 Rosbach, Germany

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:
IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
EN 60601-1-2: 2015
IEC 60601-2-25: 2011
EN 60950-1: 2006
EN 60950-1 Amendment 1: 2010
EN 60950-1 Amendment 2: 2013
EN 60950-1 Amendment 11: 2009
EN 60950-1 Amendment 12: 2011
EN 62311: 2011
EN 300 328 V2.2.2
EN 301 893 V2.1.1

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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:

DocuSigned by:
Hiroko Hagiwara
Signer Name: Hiroko Hagiwara
Signing Reason: I approve this document
Signing Time: 2024-04-05 | 8:12:37 PM JST
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Tokyo, Japan/ 2024-04-05
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division