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:	-
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany
SRN:	-

☑ **Regulation (EU) 2017/745(MDR)**

Classification/Risk Class:	I
Conformity assessment procedure:	Annex II and III

☐ **Directive 2011/65/EU (RoHS:6 substances)**

☑ **Directive 2011/65/EU and 2015/863/EU (RoHS:10 substances)**

Standard Applied:	EN 50581:2012

☑ **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 Name and Basic UDI-DI :

Product Name	Model Name	Basic UDI-DI	MDR	RoHS (6)	RoHS (10)	RED
Wireless LAN Module	QI-330D	4931921QI-330DG8	×	—	×	×

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

Additional Information NA

Authorized Signatory:
Tokyo, Japan/ 30 July 2021
Place and date of issue

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General Manager
Clinical Development & Regulatory Affairs Division