

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

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 NA (Module A)

Name and No. :

EU-Type Examination NA

Certificate No. :

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

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 | × | — | × | × |

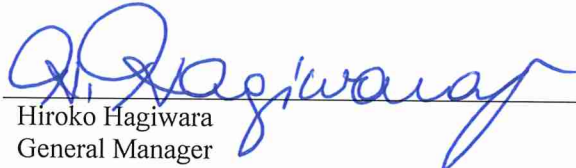
Intended purpose: The product listed above is accessory of Electrocardiograph.

Additional Information NA

Authorized Signatory:

Tokyo, Japan/ 30 July 2021

Place and date of issue



Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division