NIHON KOHDEN

Declaration No.: 2223

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
IEC 60601-1-2: 2007
IEC 60601-1-6: 2010
IEC 60601-1-6 Amendment 1:2013
IEC 60601-1-12: 2014
EN 300 328 V2.2.2
EN 301 489-1 V2.2.3
EN 301 489-17 V3.2.4
EN 62311: 2008

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Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
CPR assist	CPR-1100	4931921MD10012BC	×	×	×

Intended purpose: The product listed above is used for assisting trained medical staff to perform CPR.

Additional Information: NA

Authorized Signatory:

DocuSigned by:
Hiroko Hagiwara
Signer Name: Hiroko Hagiwara
Signing Reason: I approve this document
Signing Time: 2024-04-03 | 6:35:16 PM JST
53BD6864AB2F44ADA8739632B5F04E38

2024-04-03
Tokyo, Japan/
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division