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:	-
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 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

NIHON KOHDEN

Declaration No.: 2223

Product Name, Model Name and Basic UDI-DI :

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

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

Additional Information NA

Authorized Signatory:
Tokyo, Japan/ 9 June 2022
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division