NIHON KOHDEN

Declaration No.: 2246

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. :
EU-Type Examination Certificate No. :
Standard Applied:

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Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Disposable Pads	P-511	4931921P-511LV	×	×	—
Disposable Pads for infants	P-513	4931921P-513LZ	×	×	—
Disposable Pads	P-511X	4931921P-511XDY	×	×	—

Intended purpose: The products listed above are accessories of Defibrillator.

Additional Information: NA

Authorized Signatory:
Tokyo, Japan/ 31 August 2022
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division