NIHON KOHDEN

Declaration No.: 2219

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. :

EU-Type Examination Certificate No. :

Standard Applied:

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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
Paste Holder Kit	YZ-025H0	4931921YZ-025H0RR	×	×	–	–
Battery Charger	SB-551V	4931921SB-551VGE	×	×	–	–
Rechargeable Battery Pack	NKB-301V(YZ-024H9)	4931921YZ-024H9S6	×	×	–	–
Test Load Unit	AX-250V	4931921AX-250VF2	×	×	–	–
Test Load Unit	AX-251V	4931921AX-251VF5	×	×	–	–
Pediatric Electrode Assy 44mm Dia.	ND-844V	4931921ND-844VFC	×	×	–	–
Top Cover	YZ-052H4	4931921YZ-052H4S7	×	×	–	–
External Paddles Electrodes (ERC)	ND-838V	4931921ND-838VFK	×	×	–	–
External Paddles (ERC)	ND-832V	4931921ND-832VEZ	×	×	–	–
Wall Mount	KG-561V	4931921KG-561VEC	×	×	–	–
Cart	KD-561V	4931921KD-561VD5	×	×	–	–
External Paddles Holder (ERC)	DP-562V	4931921DP-562VED	×	×	–	–
External Paddles Holder (STD)	DP-560V	4931921DP-560VE7	×	×	–	–

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

Additional Information NA

Authorized Signatory:

Tokyo, Japan/ 25 May 2020
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division