NIHON KOHDEN

Declaration No.: 2220

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 60601-1-8: 2006
IEC 60601-1-8 Amendment 1: 2012
IEC 60601-1-12: 2014
IEC 60601-2-4: 2010
IEC 60601-2-27: 2011
IEC 60601-2-49: 2011
IEC 80601-2-30: 2009
IEC 80601-2-30 Amendment 1: 2013
IEC 80601-2-55: 2011
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
ISO 80601-2-61: 2011

NIHON KOHDEN

Declaration No.: 2220

EN 300 328 V2.2.2
EN 301 489-1 V2.2.3
EN 301 489-17 V3.2.4
EN 62479: 2010

NIHON KOHDEN

Declaration No.: 2220

Product Name, Model Name and Basic UDI-DI :

Product Name	Model Name	Basic UDI-DI	MDR	RoHS	RED
ELECTRODE LEAD	BR-906V	4931921BR-906VEF	×	×	—
ELECTRODE LEAD	BR-906VA	4931921BR-906VACY	×	×	—
Bluetooth module (UR-0427)	QI-832V	4931921QI-832VJM	×	×	×
AC/DC Module	SC-831V	4931921SC-831VH6	×	×	—
Lithium Ion Battery	SB-831V	4931921SB-831VGR	×	—	—
AUXOUT Unit	QI-831V	4931921QI-831VJJ	×	×	—
External paddles	ND-831V	4931921ND-831VEW	×	×	—
Adult Electrode Assy	ND-618V	4931921ND-618VET	×	×	—
Pad Adaptor	JC-865V	4931921JC-865VD8	×	×	—
Pad Adaptor	JC-855V	4931921JC-855VD3	×	×	—
External ECG Cable	JC-831V	4931921JC-831VCD	×	×	—
External Paddles Holder	DP-831VK	4931921DP-831VKD9	×	×	—
Patient cable	BJ-831VA	4931921BJ-831VA89	×	×	—
Patient cable	BJ-831V	4931921BJ-831VAY	×	×	—

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

Additional Information NA

Authorized Signatory:
Tokyo, Japan/ 6 June 2022
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division