

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.



Manufacturer's Name: NIHON KOHDEN CORPORATION

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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 60601-1-8: 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

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

Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
ELECTRODE LEAD	BR-906V	4931921MD10009 BP	×	×	—
ELECTRODE LEAD	BR-906VA	4931921MD10009 BP	×	×	—
Bluetooth module (UR-0427)	QI-832V	4931921MD10009 BP	×	×	×
AC/DC Module	SC-831V	4931921MD10009 BP	×	×	—
Lithium Ion Battery	SB-831V	4931921MD10009 BP	×	—	—
AUXOUT Unit	QI-831V	4931921MD10009 BP	×	×	—
External paddles	ND-831V	4931921MD10009 BP	×	×	—
Adult Electrode Assy	ND-618V	4931921MD10009 BP	×	×	—
Pad Adaptor	JC-865V	4931921MD10009 BP	×	×	—
Pad Adaptor	JC-855V	4931921MD10009 BP	×	×	—
External ECG Cable	JC-831V	4931921MD10009 BP	×	×	—
External Paddles Holder	DP-831VK	4931921MD10009 BP	×	×	—
Patient cable	BJ-831VA	4931921MD10009 BP	×	×	—
Patient cable	BJ-831V	4931921MD10009 BP	×	×	—

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

Additional Information: NA

Authorized Signatory:

2024-04-03

Tokyo, Japan/

Place and date of issue

DocuSigned by:

Hiroko Hagiwara



Signer Name: Hiroko Hagiwara

Signing Reason: I approve this document

Signing Time: 2024-04-03 | 6:34:55 PM JST

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