NIHON KOHDEN

**Declaration No.:** 1211

# 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 2797

**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)**

**Notified Body**

**Name and No. :** BSI Group The Netherlands B.V.; 2797

**Certificate No. (Conformity assessment procedure):** MDR 743465 (Annex IX Chapter I and III)
MDR 773832 (Annex IX Chapter II)

☑ **Directive 2011/65/EU and 2015/863/EU (RoHS)**

**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:**

| | |
|---|---|
| Health and Safety<br>Article 3.1 (a) | IEC 60601-1: 2005 +A1: 2012 +A2: 2020<br>IEC 60601-1-6: 2010 +A1: 2013 +A2: 2020<br>IEC 60601-1-11: 2010<br>IEC 60601-1-11: 2015 +A1: 2020<br>IEC 60601-1-12: 2014 +A1: 2020<br>IEC 60601-2-4: 2010 +A1: 2018<br>EN 62479: 2010 |
| EMC<br>Article 3.1 (b) | IEC 60601-1-2: 2014 +A1: 2020<br>IEC 60601-1-11: 2010<br>IEC 60601-1-11: 2015 +A1: 2020<br>IEC 60601-2-4: 2010 +A1: 2018<br>EN 301 489-1 V2.2.3: 2019<br>EN 301 489-17 V3.2.4: 2020 |
| Spectrum<br>Article 3.2 | EN 300 328 V2.2.2: 2019 |

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| | |
|---|---|
| Cybersecurity<br>Article 3.3 (d), (e), (f) | NA |

The device referenced in this declaration is subject to the provisions of Regulation (EU) 2017/745.
Pursuant to Article 2.1 of Commission Delegated Regulation (EU) 2022/30, the essential requirements outlined in Article 3.3(d), (e), and (f) of Directive 2014/53/EU shall not apply to the device.

**Device Information:**

| Product Name | Model Number | Class[1] | Basic UDI-DI | MDR | RoHS | RED |
|---|---|---|---|---|---|---|
| Automated External Defibrillator | AED-3100 | III | 4931921MD30011BY | × | × | × |

**Intended purpose:** The AED-3100 automated external defibrillator treats ventricular fibrillation or pulseless ventricular tachycardias by automatically detecting the patient's arrhythmia and delivering a short-duration high-current electrical shock to the heart. The defibrillator analyzes the electrocardiogram and gives auditory/visual instructions to the operator when an electric shock is needed.
The operator then follows the instructions to energize the patient's heart for a short period of time to defibrillate the heart muscle.
The defibrillator is intended to eliminate cardiac arrhythmias (ventricular fibrillation/ pulseless ventricular tachycardias).
The defibrillator is available for use by trained medical professionals and the general public on all patient populations. The defibrillator can be used in medical facilities, general facilities, ambulances, and outdoors.

**Additional Information:** NA

Signed by:
Hiroko Hagiwara
Signer Name: Hiroko Hagiwara
Signing Reason: I approve this document
Signing Time: 2025-10-03 | 2:56:32 PM JST
53BD6864AB2F44ADA8739632B5F04E38

**Authorized Signatory:**

Tokyo, Japan/ 2025-10-03
Place and date of issue

General Manager
Clinical Development & Regulatory Affairs Division

[1] *According to Annex VIII of the Regulation (EU) 2017/745 (MDR)*