NIHON KOHDEN

Declaration No.: 3030

EU/RE DIRECTIVE DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Directive 2014/53/EU Of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment. The declaration of conformity is issued under the sole responsibility of the manufacturer.

CE

Manufacturer's Name:	NIHON KOHDEN CORPORATION
Business Address:	1-31-4 Nishiochiai, Shinjuku-ku Tokyo 161-8560, Japan
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany
Product Name and Model Name:	Automated External Defibrillator AED-3100
Notified Body's 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: 2014 IEC 60601-1-6: 2010 IEC 60601-1-6 Amendment 1: 2013 IEC 60601-11: 2010 IEC 60601-12: 2014 IEC 60601-2-4: 2010 EN 301 489-1 V2.2.3 EN 301 489-17 V3.1.1 EN 300 328 V2.2.2 EN 62479: 2010

Authorized Signatory:

Tokyo, Japan / 3 September 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

RE4A

NIHON KOHDEN

Declaration No.: 1122

EC/MDD DECLARATION OF CONFORMITY
適 合 宣 言 書

This is a declaration made in accordance with the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

CE
2797

Manufacturer's Name:	NIHON KOHDEN CORPORATION
Business Address:	1-31-4 Nishiochiai, Shinjuku-ku Tokyo 161-8560, Japan
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany
Product Name and Model Name:	Automated External Defibrillator AED-3100 Software Kit QS-011V
Classification:	IIb

Each kind of medical device to which the Full Quality Assurance Procedures (Annex II) have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Notified Body:	BSI Group The Netherlands B.V.
EC Certificate:	CE 01342
Standard Applied:	ISO 13485: 2016 EN ISO 14971: 2012 EN ISO 15223-1: 2016 IEC 60601-1: 2005 IEC 60601-1 Amendment 1: 2012 IEC 60601-2-4: 2010 IEC 60601-1-2: 2014 IEC 60601-1-6: 2010 IEC 60601-1-6 Amendment 1: 2013 IEC 62366: 2007 IEC 62366 Amendment 1: 2014 IEC 62304: 2006 ISO 10993-1: 2009 EN 1041: 2008 EN 1041 Amendment 1: 2013 EN 1789: 2007 EN 1789 Amendment 1: 2010

Authorized Signatory:

Tokyo, Japan / 18 November 2020
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

様式 MDD7-1

NIHON KOHDEN

Declaration No.: 20116

RoHS DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 and 2015/863/EU of 31 March 2015 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.

CE

Manufacturer's Name: **NIHON KOHDEN CORPORATION**
Business Address: **1-31-4 Nishiochiai, Shinjuku-ku,Tokyo 161-8560, Japan**

We hereby certify that following product(s) conform to the European Union's Restriction on Use of Hazardous Substances in Electrical and Electronic equipment (RoHS) Directive 2015/863/EU for ten regulated substances listed below.

Product Name(s) :

Automated External Defibrillator AED-3100

List of environmentally hazardous substances:

1) **Lead**
2) **Mercury**
3) **Cadmium**
4) **Hexavalent Chromium**
5) **Polybrominated biphenyls (PBB)**
6) **Polybrominated diphenyl ethers (PBDE)**
7) **Bis(2-ethylhexyl) phthalate (DEHP)**
8) **Butyl benzyl phthalate (BBP)**
9) **Dibutyl phthalate (DBP)**
10) **Diisobutyl phthalate (DIBP)**

Harmonised Standards Applied: EN 50581:2012

Authorised Signatory:

Tokyo, Japan/ 21 July 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division