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
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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

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様式 MDD7-1