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EC/R&TTE DIRECTIVE DECLARATION OF CONFORMITY 適合宣言書

This is a declaration made in accordance with the requirements of DIRECTIVE 1999/5/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity



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

hasato Samba

Equipment Classes:

Class 1.22, Wideband Data Transmission Systems

RF-Radiated Power under 10mW e.i.r.p.

Each kind of medical device complies with the applicable provisions of the essential requirements, the classification rules before being supplied.

Standard Applied:

EN 60950-1: 2006

EN 60950-1 Amendment 11: 2009 EN 60950-1 Amendment 1: 2010 EN 60950-1 Amendment 12: 2011

EN 60601-1: 2005

EN 60601-1 Amendment 1: 2012

EN 60601-1-2: 2007 EN 300 328 V1.9.1: 2015 EN 301 489-1 V1.9.2: 2011 EN 301 489-17 V2.2.1: 2012

EN 62479: 2010

Authorized Signatory:

Tokyo, Japan / 18 September 2015

Place and date of issue

Masato Semba General Manager

Quality Management Division