NIHON KOHDEN

Declaration No.: 3044

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:	Defibrillator EMS-1052
Notified Body's Name and No.:	Telefication B.V., Inc., No.0560 (Module B+C)
EU-Type examination Certificate No.:	No.192140071/AA/01
Standard Applied:	IEC 60601-1: 2005 IEC 60601-1 Amendment 1: 2012 IEC 60601-1-2: 2014 EN 62311: 2008 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 300 328 V2.1.1 EN 301 893 V2.1.1

Authorized Signatory:

Tokyo, Japan / 17 July 2019
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

様式 RE4A

NIHON KOHDEN

Declaration No.: 1147

EC/MDD DECLARATION OF CONFORMITY

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:	Defibrillator EMS-1052
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:	EN ISO 13485: 2016 EN ISO 14971: 2012 IEC 60601-1: 2005 IEC 60601-1 Amendment 1: 2012 IEC 60601-2-4: 2010 IEC 60601-2-4 Amendment 1: 2018 IEC 60601-1-6: 2010 IEC 60601-1-6 Amendment 1: 2013 IEC 60601-1-8: 2008 IEC 60601-1-8 Amendment 1: 2012 IEC 60601-2-27: 2011 IEC 80601-2-30: 2009 IEC 80601-2-30 Amendment 1: 2013 IEC 60601-2-34: 2011 IEC 60601-2-49: 2011 IEC 62304: 2015 IEC 62366: 2007 IEC 62366 Amendment 1: 2014 ISO 80601-2-55: 2011 ISO 80601-2-56: 2009 ISO 80601-2-61: 2011 EN 1041: 2008 EN 1041 Amendment 1: 2013

NIHON KOHDEN

Declaration No.: 1147

EN 1789: 2007
EN 1789 Amendment 2: 2014
EN ISO 15223-1: 2016

Authorized Signatory:

Tokyo, Japan / 17 July 2019
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

NIHON KOHDEN

Declaration No.: 20159

RoHS DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 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 2011/65/EU for six regulated substances listed below.

Product Name(s):		
	Defibrillator	EMS-1052
	AC ADAPTER	SC-101V
	EXTERNAL PADDLES HOLDER	DP-101V
	PAD ADAPTER	JC-165V
	BATTERY CHARGER	SB-101V

List of environmentally hazardous substances:

1) **Lead**
2) **Mercury**
3) **Cadmium**
4) **Hexavalent Chromium**
5) **Polybrominated biphenyls (PBB)**
6) **Polybrominated diphenyl ethers (PBDE)**

Harmonised Standards Applied: EN 50581: 2012

Authorised Signatory:

Tokyo, Japan/ 17 July 2019
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division