

**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.



**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

**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).



**Manufacturer's Name:** NIHON KOHDEN CORPORATION  
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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

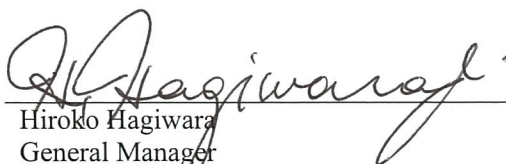
Each kind of medical device to which the Full Quality Assurance Procedures (Annex II) have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

**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

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

**Authorized Signatory:**Tokyo, Japan / 17 July 2019Place and date of issue

Hiroko Hagiwara  
General Manager

Clinical Development & Regulatory Affairs Division

**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.



**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.

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

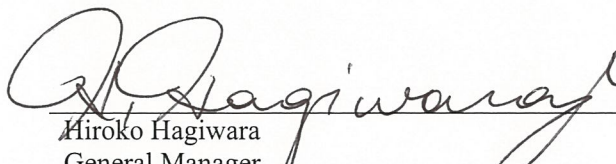
**List of environmentally hazardous substances:**

- 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