NIHON KOHDEN

Declaration No.: 1213

EU DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of the following relevant Union harmonisation legislation. The manufacturer assures that the device that is covered by the present declaration is in conformity with this Regulation (EU) 2017/745 for Medical Devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The declaration of conformity is issued under the sole responsibility of the manufacturer.

CE 2797

Manufacturer's Name: NIHON KOHDEN CORPORATION

Address: 1-31-4 Nishiochiai, Shinjuku-ku
Tokyo 161-8560, Japan

SRN: JP-MF-000019022

European Representative: NIHON KOHDEN EUROPE GmbH

Address: Raiffeisenstrasse 10, 61191 Rosbach, Germany

SRN: DE-AR-000010740

☑ **Regulation (EU) 2017/745 (MDR)**

Notified Body

Name and No. : BSI Group The Netherlands B.V.; 2797

Certificate No. (Conformity assessment procedure): MDR 743465 (Annex IX Chapter I and III)
MDR 743468 (Annex IX Chapter II)

☑ **Directive 2011/65/EU and 2015/863/EU (RoHS)**

Standard Applied: EN IEC 63000: 2018

☑ **Directive 2014/53/EU (RED)**

Notified Body

Name and No. : NA (Module A)

EU-Type Examination Certificate No. : NA

Standard Applied:

Health and Safety Article 3.1 (a)	IEC 60601-1: 2005 + A1: 2012 + A2: 2020 EN IEC 62311: 2020
EMC Article 3.1 (b)	IEC 60601-1-2: 2014 + A1: 2020 EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4
Spectrum Article 3.2	EN 300 328 V2.2.2
Cybersecurity Article 3.3 (d), (e), (f)	NA

The device referenced in this declaration is subject to the provisions of Regulation (EU) 2017/745. Pursuant to Article 2.1 of Commission Delegated Regulation (EU) 2022/30, the essential requirements outlined in Article 3.3(d), (e), and (f) of Directive 2014/53/EU shall not apply to the device.

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Device Information:

Product Name	Model Number	Class[1]	Basic UDI-DI	MDR	RoHS	RED
Defibrillator	EMS-1052	III	4931921MD30009CD	×	×	×

Intended purpose: The EMS-1052 defibrillator treats ventricular fibrillation and pulseless ventricular tachycardia by delivering a short-duration high-current electrical shock to the heart.
The defibrillator can perform synchronized cardioversion to treat certain arrhythmias such as atrial fibrillation. The defibrillator can also perform transcutaneous pacing which is used for temporary treatment of bradycardia.
In addition to manual defibrillation in Manual mode, the defibrillator provides easy to use semiautomatic defibrillation in AED mode.
The defibrillator also monitors the patient condition before and after defibrillation.
In addition to ECG measurement, noninvasive blood pressure (NIBP), body temperature and percutaneous oxygen saturation (SpO2) measurement are available.
End tidal CO2 partial pressure (ETCO2) and invasive blood pressure (IBP) measurement are also available by connecting a CO2 sensor kit and blood pressure transducer.
The defibrillator can be used in various sites, such as inside an ambulance/aircraft and indoors as well as outdoors.
The defibrillator is for use by trained medical professionals such as physicians, nurses and paramedics on all patient populations, including adult, adolescent, child, infant and neonate subgroups.

Additional Information: NA

Signed by:
Hiroko Hagiwara
Signer Name: Hiroko Hagiwara
Signing Reason: I approve this document
Signing Time: 2026-04-06 | 8:51:24 AM JST
53BD6864AB2F44ADA8739632B5F04E38

Authorized Signatory:
Tokyo, Japan/ 2026-04-06
Place and date of issue

General Manager
Clinical Development & Regulatory Affairs Division

[1] *According to Annex VIII of the Regulation (EU) 2017/745 (MDR)*