NIHON KOHDEN

**Declaration No.:** 3015

# EU/RE DIRECTIVE DECLARATION OF CONFORMITY
# 適 合 宣 言 書

**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<br>Tokyo 161-8560, Japan |
| **European Representative:** | NIHON KOHDEN EUROPE GmbH |
| **Address:** | Raiffeisenstrasse 10, D - 61191 Rosbach, Germany |

**Product Name and Model Name:**

| | |
|---|---|
| Multiple Patient Receiver | ORG-9100K |
| Antenna | ZA-002P |
| Antenna Base | ZA-004P |
| Band pass filter | ZA-006P |
| Band pass filter | ZA-007P |
| Band pass filter | ZA-008P |
| Band pass filter | ZA-009P |
| Band pass filter | ZA-010P |
| Band pass filter | ZA-011P |
| Band pass filter | ZA-012P |
| Band pass filter | ZA-013P |
| Band pass filter | ZA-014P |
| Band pass filter | ZA-015P |
| Antenna Isolator | ZA-022P |
| Receiver | ZR-920P |

**Notified Body's Name and No.:** NA (Module A)

**EU-Type examination Certificate No.:** NA

**Standard Applied:**

IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
EN 300 220-1 V3.1.1
EN 300 220-2 V3.1.1

**Authorized Signatory:**

Tokyo, Japan / 23 June 2017
Place and date of issue

Masato Semba
General Manager
Quality Management Division



様式 RE4

NIHON KOHDEN

**Declaration No.:** 1083

# 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<br>Tokyo 161-8560, Japan |
| **European Representative:** | NIHON KOHDEN EUROPE GmbH |
| **Address:** | Raiffeisenstrasse 10, D - 61191 Rosbach, Germany |
| **Product Name and Model Name:** | Multiple Patient Receiver ORG-9100K<br>Software Kit QS-029PA |
| **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:** | IEC 60601-1: 2005<br>IEC 60601-1 Amendment 1: 2012<br>IEC 60601-1-2: 2007<br>IEC 60601-1-6: 2010<br>IEC 60601-1-6 Amendment 1: 2013<br>IEC 60601-1-8: 2006<br>IEC 62304: 2006<br>IEC 62366: 2007<br>IEC 62366 Amendment 1: 2014<br>EN ISO 13485: 2016<br>EN ISO 14971: 2012<br>EN 1041: 2008<br>EN 1041 Amendment 1: 2013<br>EN ISO 15223-1: 2016 |

**Authorized Signatory:**

Tokyo, Japan / 8 April 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division



MDD7-3A

NIHON KOHDEN

**Declaration No.:** 20046

# 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):** | Multiple Patient Receiver | ORG-9100K |
| | Software Kit | QS-029PA |

**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 / 8 April 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

NIHON KOHDEN

**Declaration No.:** 2258

# 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

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

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

**SRN:** -

**European Representative:** NIHON KOHDEN EUROPE GmbH

**Address:** Raiffeisenstrasse 10, D - 61191 Rosbach, Germany

**SRN:** -

☑ **Regulation (EU) 2017/745(MDR)**

**Classification/Risk Class:** I

**Conformity assessment procedure:** Annex II and III

☑ **Directive 2011/65/EU (RoHS:6 substances)**

☑ **Directive 2011/65/EU and 2015/863/EU (RoHS:10 substances)**

**Standard Applied:** EN 50581:2012

☐ **Directive 2014/53/EU (RED)**

**Notified Body Name and No. :** NA (Module A)

**EU-Type Examination Certificate No. :** NA

**Standard Applied:**

IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2007
EN 300 220-1 V3.1.1
EN 300 220-2 V3.1.1

NIHON KOHDEN

**Declaration No.:** 2258

**Product Name, Model Name and Basic UDI-DI :**

| Product Name | Model Name | Basic UDI-DI | MDR | RoHS (6) | RoHS (10) | RED |
|---|---|---|---|---|---|---|
| Receiver | ZR-920P | 4931921ZR-920PSK | × | × | × | × |
| Bandpassfilter | ZA-015P | 4931921ZA-015PHZ | × | × | × | × |
| Bandpassfilter | ZA-014P | 4931921ZA-014PHW | × | × | × | × |
| Bandpassfilter | ZA-013P | 4931921ZA-013PHT | × | × | × | × |
| Bandpassfilter | ZA-012P | 4931921ZA-012PHQ | × | × | × | × |
| Bandpassfilter | ZA-011P | 4931921ZA-011PHM | × | × | × | × |
| Bandpassfilter | ZA-010P | 4931921ZA-010PHJ | × | × | × | × |
| Bandpassfilter | ZA-009P | 4931921ZA-009PJ8 | × | × | × | × |
| Bandpassfilter | ZA-008P | 4931921ZA-008PJ5 | × | × | × | × |
| Bandpassfilter | ZA-007P | 4931921ZA-007PJ2 | × | × | × | × |
| Bandpassfilter | ZA-006P | 4931921ZA-006PHX | × | × | × | × |
| Antenna Base | ZA-019P | 4931921ZA-019PJD | × | × | × | × |

**Intended purpose:** The products listed above are accessories of Multiple Patient Receiver and Telemetry System.

**Additional Information** NA

**Authorized Signatory:**
Tokyo, Japan/ 30 March 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division