NIHON KOHDEN

**Declaration No.:** 3035

# 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

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|---|---|
| **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:** | Wireless LAN Station QI-170P |
| **Notified Body's Name and No.:** | UL Japan, Inc., No.1731(Module B) |
| **EU-Type examination Certificate No.:** | ULAR2106094 |
| **Standard Applied:** | IEC 60601-1: 2005<br>IEC 60601-1 Amendment 1: 2012<br>IEC 60601-1-2: 2007<br>EN 300 328 V2.2.2<br>EN 301 893 V2.1.1<br>EN 62311: 2008<br>EN 62479: 2010 |

**Authorized Signatory:**

Tokyo, Japan / 29 June 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division



RE4A

NIHON KOHDEN

**Declaration No.:** 1113

# 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

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|---|---|
| **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:** | Wireless LAN Station QI-170P |
| **Classification:** | IIa |

**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.**

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| **Notified Body:** | BSI Group The Netherlands B.V. |
| **EC Certificate:** | CE 01342 |

**Standard Applied:**

IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2011
IEC 60601-1-6: 2010
IEC 60601-1-6 Amendment 1: 2013
IEC 60601-1-8: 2006
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
ISO 80601-2-55: 2011
ISO 80601-2-56: 2009
ISO 80601-2-61: 2011
IEC 62304: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN ISO 14971: 2012
EN ISO 13485: 2016
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016

NIHON KOHDEN

**Declaration No.:** 1113

**Authorized Signatory**

Tokyo, Japan / 31 March 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

NIHON KOHDEN

**Declaration No.:** 20104

# RoHS DECLARATION OF CONFORMITY

**This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 and 2015/863/EU of 31 March 2015 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 2015/863/EU for ten regulated substances listed below.**

| **Product Name(s) :** | | |
|---|---|---|
| | Bedside Monitor | BSM-1733 |
| | Bedside Monitor | BSM-1753 |
| | Bedside Monitor | BSM-1763 |
| | Bedside Monitor | BSM-1773 |
| | Software Kit | QS-065P |
| | Wireless LAN Station | QI-170P |

**List of environmentally hazardous substances:**

1) **Lead**
2) **Mercury**
3) **Cadmium**
4) **Hexavalent Chromium**
5) **Polybrominated biphenyls (PBB)**
6) **Polybrominated diphenyl ethers (PBDE)**
7) **Bis(2-ethylhexyl) phthalate (DEHP)**
8) **Butyl benzyl phthalate (BBP)**
9) **Dibutyl phthalate (DBP)**
10) **Diisobutyl phthalate (DIBP)**

**Harmonised Standards Applied**: EN 50581:2012

**Authorised Signatory:**

Tokyo, Japan/ 31 March 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division



MDA0023-4