

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.



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:

Telemetry System	WEP-5204K
Telemetry System	WEP-5208K
Antenna	ZA-002P
Antenna Base	ZA-004P
Antenna Base	ZA-019P
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

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 / 29 June 2017

Place and date of issue

A handwritten signature in blue ink that reads "Masato Semba".

Masato Semba
General Manager
Quality Management 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
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:

Telemetry System	WEP-5204K
Telemetry System	WEP-5208K
Software Kit	QS-039PK
Software Kit	QS-039PG
Software Kit	QS-039PI
Software Kit	QS-039PR
Software Kit	QS-039PS
Software Kit	QS-039PF

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 60601-1-2: 2007
- IEC 60601-1-6: 2010
- IEC 60601-1-6 Amendment 1: 2013
- IEC 60601-1-8: 2006
- IEC 60601-1-8 Amendment 1: 2012
- IEC 60601-2-27: 2011
- IEC 62304:2006
- IEC 62366: 2007
- IEC 62366 Amendment 1: 2014
- ISO 80601-2-61: 2011
- EN 1041: 2008
- EN 1041 Amendment 1: 2013
- 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

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.



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) :	Telemetry System	WEP-5204K
	Telemetry System	WEP-5208K
	Software Kit	QS-039PK
	Software Kit	QS-039PG
	Software Kit	QS-039PI
	Software Kit	QS-039PR
	Software Kit	QS-039PS
	Software Kit	QS-039PF
	Interface	QI-521P
	Memory Card	QM-601P

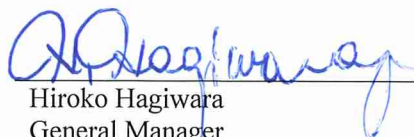
List of environmentally hazardous substances:

- 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/ 27 May 2021
Place and date of issue



Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

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.



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 NA (Module A)

Name and No. :

EU-Type Examination NA

Certificate No. :

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

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

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.



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) :	Antenna	ZA-002P
	Antenna Base	ZA-004P
	Antenna Isolator	ZA-022P
	QI RGB Cable (10m)	YS-080P3
	Serial Connection Cable 2.5M	YS-095P6
	VL Cable Set (Main)	YS-097P5
	VL Cable Set (Main)	YS-097P6
	VL Cable Set (Second)	YS-097P8
	VL Cable Set (Second)	YS-097P9
	VL Cable Set (Second)	YS-113P8
	VL Cable Set (Second)	YS-113P9
	Channel Writer	QI-901PK
	PVM-2700 Serial Cable	YS-100P6
	Network Connection Cable 0.2M	YS-100P7
	Test Load Unit	AX-250V
	Test Load Unit	AX-251V

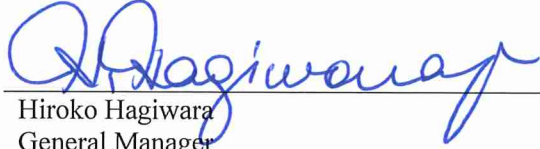
List of environmentally hazardous substances:

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- 10) Diisobutyl phthalate (DIBP)

Harmonised Standards Applied: EN 50581:2012

Authorised Signatory:

Tokyo, Japan/ 27 May 2021
Place and date of issue



Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division