

**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:** Transmitter ZS-600P

**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: 2014  
EN 300 220-1 V3.1.1  
EN 300 220-2 V3.1.1  
EN 62479: 2010

**Authorized Signatory:**

Tokyo, Japan / 26 February 2019

Place and date of issue



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Yoshiyuki Fujita  
General Manager  
Quality Management Division

**EC/MDD DECLARATION OF CONFORMITY**  
**適合宣言書**

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:**

Software kit	QS-128P
Recorder module	WS-470P
Interface	QI-470P
Wireless LAN station	QI-520P
Transmitter	ZS-600P
Software Kit	QS-129P

**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.

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

**Standard Applied:**

- EN ISO 13485: 2016
- EN ISO 14971: 2012
- EN ISO 15223-1: 2016
- IEC 60601-1: 2005
- IEC 60601-1 Amendment 1: 2012
- IEC 60601-1-2: 2014
- 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 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

**Authorized Signatory:**

Tokyo, Japan / 31 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.

<b>Product Name(s) :</b>	Bedside Monitor	PVM-4763
	Bedside Monitor	PVM-4753
	Bedside Monitor	PVM-4733
	Bedside Monitor	PVM-4761
	Bedside Monitor	PVM-4751
	Bedside Monitor	PVM-4731
	Software kit	QS-128P
	Recorder module	WS-470P
	Interface	QI-470P
	Wireless LAN station	QI-520P
	Transmitter	ZS-600P

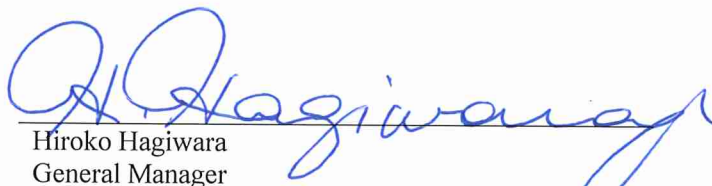
**List of environmentally hazardous substances:**

- 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