NIHON KOHDEN

Declaration No.: 3042

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 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

Yoshiyuki Fujita
General Manager
Quality Management Division

様式 RE4

NIHON KOHDEN

Declaration No.: 1145

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).

CE
2797

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

NIHON KOHDEN

Declaration No.: 1145

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

様式 MDD7-1

NIHON KOHDEN

Declaration No.: 20157

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	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

NIHON KOHDEN

Declaration No.: 20157

Authorised Signatory:

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

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division