

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:

Bedside Monitor	PVM-4763
Bedside Monitor	PVM-4753
Bedside Monitor	PVM-4733
Bedside Monitor	PVM-4761
Bedside Monitor	PVM-4751
Bedside Monitor	PVM-4731

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
- 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 / 20 February 2020

Place and date of issue


Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

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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

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Product Name and Model Name:

Battery Pack	SB-470P
Adapter	DH-470P
Holder	DI-470P
Holder	DI-471P
Hook	DZ-470P
Cart	KC-470P

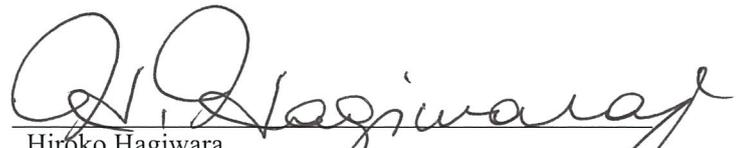
Classification: I

Each kind of medical device complies with the applicable provisions of the essential requirements, the classification rules before being supplied.

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