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:		
	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

NIHON KOHDEN

Declaration No.: 1145

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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Notified Body: BSI Group The Netherlands B.V.
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ISO 80601-2-56: 2009
ISO 80601-2-61: 2011
EN 1041: 2008

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Declaration No.: 1145

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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NIHON KOHDEN

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European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany

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.

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
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