

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-900PG

Notified Body's Name and No.: Telefication B.V., No.0560 (Module B)

EU-Type examination Certificate No.: 172140417/AA/00


Standard Applied: Safety: Depends on the device to which the transmitter is connected. Refer to the device manual.
(IEC 60601-1: 2005 + IEC 60601-1 Amendment 1: 2012)

EMC: Depends on the device to which the transmitter is connected. Refer to the device manual.
(IEC 60601-1-2: 2007)

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

Authorized Signatory:

Tokyo, Japan / 23 June 2017
Place and date of issue


Masato Semba
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:

Battery Pack	SB-671P
BISx connection cord	YJ-671P
Nurse Call Cable	YJ-672P
Network cable	YS-089P7
Cart	KC-600P
Handle	DH-600P
SpO2 connection cord	JL-650P
SpO2 connection cord	JL-630P
SpO2 connection cord	JL-631P
SpO2 connection cord	JL-632P
Unit connection cable	YS-096P2
Unit connection cable	YS-096P3
Multi-link cable	YS-096P5
Accessory Set	YO-60AY1
Accessory Set	YO-60AY2
Accessory Set	YO-60AY3
Accessory Set	YO-60AY4
Accessory Set	YO-60IY1
Accessory Set	YO-60IY2
Accessory Set	YO-60IY3
Accessory Set	YO-60IY4
Base	DH-691P
Holder	DH-692P
Adapter	DH-693P
Adapter	DI-630P
Adapter	DI-650P
Hook	DZ-630P
Counter Top Mount	KG-600P
Wireless LAN mounting set	YS-095P3
Electrode lead	BR-973P
Electrode lead	BR-975P
Adapter	JC-990P
Transmitter	ZS-900PG
Holder	DI-590P
Serial Cable	YS-089P2
Interface	QI-670P
Software Kit	QS-100P

Classification: I


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

Standard Applied:

- ISO 13485: 2003
- EN ISO 14971: 2012
- ISO 9919: 2005
- ISO 21647: 2004
- IEC 60601-1: 1988
- IEC 60601-1 Amendment 1: 1991
- IEC 60601-1 Amendment 2: 1995
- IEC 60601-1-1: 2000
- IEC 60601-1-2: 2001
- IEC 60601-1-2 Amendment 1: 2004
- IEC 60601-1-4: 1996
- IEC 60601-1-4 Amendment 1: 1999
- IEC 60601-1-6: 2010
- IEC 60601-1-8: 2006
- IEC 60601-2-27: 2005
- IEC 60601-2-30: 1999
- IEC 60601-2-34: 2000
- IEC 60601-2-49: 2001
- IEC 62366: 2007
- EN 12470-4: 2000
- EN 980: 2008
- EN 1041: 2008
- EN 1041 Amendment1: 2013
- ANSI/AAMI EC13: 2002

Authorized Signatory:

Tokyo, Japan/ 3 March 2017
Place and date of issue



Masato Semba
General Manager
Quality Management Division

RoHS DECLARATION OF CONFORMITY

RoHS 指令適合宣言書

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.



Manufacturer's Name/製造業者: NIHON KOHDEN CORPORATION/日本光電工業株式会社
Business Address/所在地: 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan
東京都新宿区西落合 1-31-4

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 2011/65/EU for six regulated substances listed below.

下記の対象製品が、電気電子機器における下記6種類の有害物質の使用を制限する RoHS 指令に適合することを証明致します。

Product Name(s) /対象製品:	Bedside Monitor	BSM-6301K
	Bedside Monitor	BSM-6501K
	Bedside Monitor	BSM-6701K
	Smart Expansion unit	AA-672P
	Smart Expansion unit	AA-674P
	Input unit	AY-631P
	Input unit	AY-633P
	Input unit	AY-660P
	Input unit	AY-661P
	Input unit	AY-663P
	Input unit	AY-671P
	Input unit	AY-673P
	Electrode lead	BR-973P
	Electrode lead	BR-975P
	Handle	DH-600P
	Base	DH-691P
	Holder	DH-692P
	Adapter	DH-693P
	Adapter	DI-630P
	Adapter	DI-650P
	Hook	DZ-630P
	Adapter	JC-990P
	SpO2 connection cord	JL-630P
	SpO2 connection cord	JL-631P
	SpO2 connection cord	JL-632P
	SpO2 connection cord	JL-650P
	APCO/IBP Processor	JP-600PK
	Cart	KC-600P
	Counter top mount	KG-600P
	Main unit	MU-631RK
	Main unit	MU-651RK
	Main unit	MU-671RK
	Wireless LAN Station	QI-320PA

Interface	QI-631P
Interface	QI-632P
Interface	QI-634P
Interface	QI-671P
Interface	QI-672P
Memory unit	QM-600P
Hemodynamics Review Program	QP-033P
esCCO Program	QP-034P
Software Kit	QS-028PK
Software Kit	QS-042P
Recorder Module	WS-671P
BISx connection cord	YJ-671P
Nurse Call Cable	YJ-672P
Accessory Set	YO-60AY1
Accessory Set	YO-60AY2
Accessory Set	YO-60AY3
Accessory Set	YO-60AY4
Accessory Set	YO-60IY1
Accessory Set	YO-60IY2
Accessory Set	YO-60IY3
Accessory Set	YO-60IY4
Network Cable	YS-089P7
Wireless LAN Mounting Set	YS-095P3
Unit connection cable	YS-096P2
Unit connection cable	YS-096P3
Multi-link cable	YS-096P5
Serial Connection Cable 10M	YS-089P2
Holder	DI-590P
Transmitter	ZS-900PG
Input unit	AY-651P
Input unit	AY-653P
Data Acquisition unit	JA-690PA
Data Acquisition unit	JA-694PA
Interface unit	QI-600P
Interface	QI-670P
SOFTWARE KIT	QS-100P

List of environmentally hazardous substances/対象環境負荷物質:

- 1) Lead /鉛
- 2) Mercury/水銀
- 3) Cadmium/カドミウム
- 4) Hexavalent Chromium/六価クロム
- 5) Polybrominated biphenyls (PBB) /ポリ臭化ビフェニール
- 6) Polybrominated diphenyl ethers (PBDE) /ポリ臭化ジフェニルエーテル

Harmonised Standards Applied/適用整合規格: EN 50581:2012

Authorised Signatory:

Tokyo, Japan/ 3 March 2017

Place and date of issue

発行日及び発行場所



Masato Semba

General Manager

Quality Management Division

日本光電工業株式会社

品質管理統括部 部長 仙波 正人