

**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	BSM-6701K
Bedside Monitor	BSM-6501K
Bedside Monitor	BSM-6301K
Main unit	MU-671RK
Main unit	MU-651RK
Main unit	MU-631RK
Input unit	AY-671P
Input unit	AY-673P
Input unit	AY-660P
Input unit	AY-661P
Input unit	AY-663P
Input unit	AY-651P
Input unit	AY-653P
Input unit	AY-631P
Input unit	AY-633P
Smart Expansion Unit	AA-672P
Smart Expansion Unit	AA-674P
Software kit	QS-028PF
Software kit	QS-028PG
Software kit	QS-028PH
Software kit	QS-028PI
Software kit	QS-028PK
Software kit	QS-028PN
Software kit	QS-028PO
Software kit	QS-028PS
Software kit	QS-028PQ
Software kit	QS-028PD
Software kit	QS-028PU
Software kit	QS-028PW
Software kit	QS-028PR
Software kit	QS-042P
Hemodynamics Review Program	QP-033P
esCCO Program	QP-034P
BIS Processor	QE-910P
Neuro Unit	AE-918P

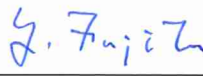
**Classification:** IIb

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: 2007  
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 60601-2-26: 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: 2006  
IEC 62366: 2007  
IEC 62366 Amendment 1: 2014  
EN 1041: 2008  
EN 1041 Amendment 1: 2013  
ISO 80601-2-55: 2011  
ISO 80601-2-56: 2009  
ISO 80601-2-61: 2011

**Authorized Signatory:**  
Tokyo, Japan / 15 March 2019  
Place and date of issue

  
Yoshiyuki Fujita  
General Manager  
Quality Management Division

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**Product Name and Model Name:**

Recorder Module	WS-671P
Interface	QI-671P
Interface	QI-672P
Interface	QI-631P
Interface	QI-632P
Interface	QI-634P
Interface Unit	QI-600P
Memory Unit	QM-600P
Data Acquisition unit	JA-690PA
Data Acquisition unit	JA-694PA
Transmitter	ZS-900PG

**Classification:** IIa

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<b>European Representative:</b>	NIHON KOHDEN EUROPE GmbH	
<b>Address:</b>	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany	
<b>Product Name and Model Name:</b>	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
	Electrode lead	BR-973P
	Electrode lead	BR-975P
	Adapter	JC-990P
	Holder	DI-590P
	Serial Cable	YS-089P2
	Interface	QI-670P
	Software Kit	QS-100P
	Remote Controller	RY-910PA
	Electrode Lead 3	BR-903P



Electrode Lead 3	BR-903PA
Electrode Lead 6	BR-906P
Electrode Lead 6	BR-906PA
Electrode Lead 3	BR-923P
Electrode Lead 6	BR-926P
Electrode Lead 3	BR-963P
ECG Patient Cable	BJ-900P
ECG Patient Cable	BJ-900PA
ECG Connection Cord 10	JC-900P
ECG Connection Cord 10	JC-900PA
ECG Connection Cord 6	JC-906P
ECG Connection Cord 6	JC-906PA
IBP Connection Cord	JP-900P
IBP Connection Cord	JP-910P
IBP Interface Isolation Cable	JP-911P
IBP Connection Cord	JP-920P
IBP Connection Cord	JP-921P
SpO2 Connection Cord	JL-900P
Temperature Connection Cord	JT-900P
CO Connection Cord	JT-950P
EEG Connection Cord	JE-905P
EEG Connection Cord	JE-906P
Disk Electrode	BE-910P
Collodion Electrode	BE-920P
EEG Electrode Lead	BE-930P
ECG/BP Output Cable	YJ-910P
ECG/BP Output Cable	YJ-920P
Air Hose Adult 1.5m	YN-900P
Air Hose Adult 3.5m	YN-901P
Air Hose Neonatal 1.5m	YN-924P
Air Hose Neonatal 3.5m	YN-925P
Extension cord	BM-918B

**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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- EN ISO 13485: 2016
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- EN ISO 15223-1: 2016
- IEC 60601-1: 2005
- IEC 60601-1 Amendment 1: 2012
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