NIHON KOHDEN

Declaration No.: 3005

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: **Business Address:**	NIHON KOHDEN CORPORATION 1-31-4 Nishiochiai, Shinjuku-ku Tokyo 161-8560, Japan
European Representative: **Address:**	NIHON KOHDEN EUROPE GmbH 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

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NIHON KOHDEN

Declaration No.: 1088

EC/MDD DECLARATION OF CONFORMITY

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:		
	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

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

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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 / 5 April 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division

NIHON KOHDEN

Declaration No.: 20079

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) :

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
Main unit	MU-631RK
Main unit	MU-651RK
Main unit	MU-671RK
Interface	QI-631P
Interface	QI-632P
Interface	QI-634P
Interface	QI-671P
Interface	QI-672P
Memory unit	QM-600P
Software Kit	QS-028PK
Software Kit	QS-042P
Recorder Module	WS-671P
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
Neuro Unit	AE-918P

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Declaration No.: 20079

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

Authorised Signatory:

Tokyo, Japan/ 11 June 2021
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division