NIHON KOHDEN

Declaration No.: 1084

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 0086

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:

Electroencephalograph	EEG-1200K
PC unit	CC-120AK
Photic Stimulator Control Unit	LS-120AK
Analog Output Unit	QD-120AK
Input box converter	QI-123A
INTERFACE UNIT	QI-124A
Flash Lamp Assembly	LS-703A
Flash lamp assembly	LS-706A
Multiple Portable Socket Outlet	SD-120AK
Multiple Portable Socket Outlet	SD-903AK
EEG Trend program	QP-160AK
Switch box	PE-210AK
Electrode junction box	JE-921A
Electrode junction box	JE-921AG
Electrode junction box	JE-120A
Digital video software	QP-110AK
Review program	QP-112AK
EEG mapping program	QP-220AK
Spike detector software	QP-251AK
AMPLIFIER UNIT	QA-120A
EXTENSION UNIT	MS-120BK

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:	British Standard Institution
EC Certificate:	CE 01342

Standard Applied:

ISO 13485: 2016
EN ISO 14971: 2012
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 60601-2-26: 2012

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IEC 62304: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
EN 1041: 2008
EN 1041 Amendment 1: 2013
EN ISO 15223-1: 2016
ISO 10993-1: 2009

Authorized Signatory:

Tokyo, Japan / 30 January 2018
Place and date of issue

Masato Semba
General Manager
Quality Management Division

様式 MDD7-1

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Product Name and Model Name:

Adapter	DI-120A
LCD Pole	KH-121A
LCD Stand	KH-122A
Cart	KD-029A
Cart	KE-122A
Mini Flat Junction Box	JE-225AK
Mini Flat Junction Box	JE-226AK
Mini Flat Junction Box	JE-227AK
Mini Flat Junction Box	JE-125AK
Mini Flat Junction Box	JE-228AK
Holder	DI-121A
EEG ELECTRODE SET	BE-403A
Electrode pad sheet	-
O-ring guide and 50 O-ring	-
EEG electrode lead	BE-403B
EEG electrode set	BE-413AG
Switch Box Checker	AX-201A
Camera capture unit	QI-120A
Electrode G (with plastic holder)	BE-0005
Electrode (with plastic holder)	BE-0006
Headcap strap	BE-0007
Chin strap	BE-0008
Patient cable	BC-112B
Earlobe electrode	NE-313AG
EEG electrode lead (DIN)	-
MINI JUNCTION BOX	JE-922A
MINI JUNCTION BOX	JE-922AG
STIMULATION POD	JS-102B
MS-MEE CONNECTION CABLE	JW-121B
CART	KC-001A
EEG ELECTRODE	NE-113A
EEG ELECTRODE	NE-114A
EEG DISK ELECTRODE	NE-116A
EEG DISK ELECTRODE	NE-117A
EEG ELECTRODE	NE-133A
EEG ELECTRODE	NE-134A
EEG ELECTRODE	NE-136A
Visual stimulator adapter	YL-104A
EEG EARLOBE CLIP	NE-301B
EEG EAR CLIP ELECTRODE	NE-311A

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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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