NIHON KOHDEN

Declaration No.: 1095

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 v.d.H., Germany

Product Name and Model Name:		
	EMG/EP measuring system	MEB-2300K
	Main unit	DC-230BK
	Electrode junction box	JB-206B
	Electrode junction box	JB-212B
	Constant current stimulation unit	MS-230B
	Control panel unit	PV-230B
	Somato control box	RY-230B
	Active electrode cable	BM-230B
	PC unit	CC-230BK
	Power unit	SC-230BK
	Cart	KD-030AK
	Trend monitoring software	QP-258BK
	Autonomic nerve measurement software	QP-259BK
	Event related potential software	QP-260BK
	Review software	QP-219BK
	Review software	QP-219BG
	EMG playback software	QP-930B
	Headphone	DR-531B-10B
	Headphone	DR-531B-12B
	Concentric needle electrode	NM-121T
	Concentric needle electrode	NM-131T
	Concentric needle electrode	NM-151T
	Concentric needle electrode	NM-320T
	Bipolar concentric needle electrode	NM-220T
	Bipolar concentric needle electrode	NM-250T
	Single fiber electrode	NM-640T
	Single fiber macro EMG electrode	NM-640S
	Monopolar needle electrode	NM-710T
	Monopolar needle electrode	NM-715S
	Monopolar needle electrode	NM-730S
	Monopolar needle electrode	NM-830S
	Monopolar needle electrode	NM-850S
	LED goggles	LS-101J
	LED goggles	LS-102J
	Stimulus earphone	YE-102J
	Earphones	YE-103J
	Display	VD-403B

NIHON KOHDEN

Declaration No.: 1095

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 14971: 2007
ISO 13485: 2003
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: Amendment1:2004
IEC 60601-1-4: 1996
IEC 60601-1-4 Amendment 1: 1999
IEC 60601-1-6: 2010
IEC 60601-2-40: 1998
IEC 62366: 2007
EN/ISO 10993-10:1995
EN 1041: 2008
EN 980: 2008

Authorized Signatory:

Tokyo, Japan/ 29 March 2012
Place and date of issue

Masato Semba
General Manager
Quality Management Division

NIHON KOHDEN

Declaration No.: 1095

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

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 v.d.H., Germany

Product Name and Model Name:		
	Attachment	DI-230B
	Multi interface box	IJ-230B
	Arm	KH-230B
	Arm	KH-231B
	MEB-SEN connection cable	JW-230B
	Power cable N	YZ-001A3
	System power cable 0.5m	YZ-001A8
	System power cable 1.6m	YZ-001A9
	System power cable 2.5m	YZ-002A0
	EEG electrode	NE-114A
	Disk electrode	NE-136B
	Finger electrode	NM-451B
	Ground electrode	NM-505B
	Ground electrode	NM-506B
	Ground electrode	NM-551B
	Extension cord	BM-121S
	Extension cord	BM-710S
	Extension cord	BM-800S
	Extension cord	BM-840S
	Extension cord	BM-001B
	Extension cord	BM-002B
	Skin preparation gel	YZ-0019
	Cart	KC-001A
	LCD filter kit	-

Classification: I

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

NIHON KOHDEN

Declaration No.: 1095

Standard Applied:

ISO 14971: 2007
ISO 13485: 2003
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: Amendment1:2004
IEC 60601-1-4: 1996
IEC 60601-1-4 Amendment 1: 1999
IEC 60601-1-6: 2010
IEC 60601-2-40: 1998
IEC 62366: 2007
EN/ISO 10993-10:1995
EN 1041: 2008
EN 980: 2008

Authorized Signatory:

Tokyo, Japan/ 29 March 2012
Place and date of issue

Masato Semba
General Manager
Quality Management Division