NIHON KOHDEN

Declaration No.: 1131

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 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:	EEG Head Set AE-120A
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 EN 1041: 2008 EN 1041 Amendment 1: 2013 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 IEC 62304: 2006 IEC 62366: 2007 IEC 62366 Amendment 1: 2014 ISO 10993-1: 2009

Authorized Signatory:

Tokyo, Japan / 15 March 2019
Place and date of issue

Yoshiyuki Fujita
General Manager
Quality Management Division

様式 MDD7-1

NIHON KOHDEN

Declaration No.: 1131

EC/MDD DECLARATION OF CONFORMITY
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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, Germany
Product Name and Model Name:	Accessory set YZ-003A4 EEG disk electrode NE-118A
Classification:	I

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

Standard Applied:

EN ISO 13485: 2016
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2008
EN 1041 Amendment 1: 2013
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
IEC 62304: 2006
IEC 62366: 2007
IEC 62366 Amendment 1: 2014
ISO 10993-1: 2009

Authorized Signatory:

Tokyo, Japan/ 15 March 2019
Place and date of issue

Y. Fujita

Yoshiyuki Fujita
General Manager
Quality Management Division

様式 MDD7-2