

Declaration	No.:	3031	

EU/RE DIRECTIVE DECLARATION OF CONFORMITY

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.



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

Notified Body's Name and No.:

UL Japan, Inc., No.1731(Module B)

EU-Type examination Certificate

ULAR2006098

No.:

Standard Applied:

IEC 60601-1: 2005

IEC 60601-1 Amendment 1: 2012

IEC 60601-1-2: 2007 IEC 60601-2-26: 2012 EN 300 328 V2.2.2 EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4

Authorized Signatory:

Tokyo, Japan / 20 June 2022

Place and date of issue

Hiroko Hagiwara General Manager

Clinical Development & Regulatory Affairs Division