NIHON KOHDEN

Declaration No.: 2252

EU DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of the following relevant Union harmonisation legislation. The manufacturer assures that the device that is covered by the present declaration is in conformity with this Regulation (EU) 2017/745 for Medical Devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The declaration of conformity is issued under the sole responsibility of the manufacturer.

CE

Manufacturer's Name: NIHON KOHDEN CORPORATION

Address: 1-31-4 Nishiochiai, Shinjuku-ku
Tokyo 161-8560, Japan

SRN: JP-MF-000019022

European Representative: NIHON KOHDEN EUROPE GmbH

Address: Raiffeisenstrasse 10, 61191 Rosbach, Germany

SRN: DE-AR-000010740

☑ **Regulation (EU) 2017/745(MDR)**

Classification/Risk Class: I

Conformity assessment procedure: Annex II and III

☐ **Directive 2011/65/EU and 2015/863/EU**

Standard Applied:

☐ **Directive 2014/53/EU（RED）**

Notified Body

Name and No. :

EU-Type Examination Certificate No. :

Standard Applied:

NIHON KOHDEN

Declaration No.: 2252

Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Paste for Defibrillation (Gelaid)	Z-101BA	4931921Z-101BABU	×	—	—

Intended purpose: The Elefix EEG paste is designed for attaching Nihon Kohden electrodes in EEG measuring.

Additional Information: NA

Authorized Signatory:
Tokyo, Japan/ 31 August 2022
Place and date of issue

Hiroko Hagiwara
General Manager
Clinical Development & Regulatory Affairs Division