

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.



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:

Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Airway Adapter	YG-111T	4931921YG-111TKZ	×	—	—
Airway Adapter	YG-111TW	4931921YG-111TWJN	×	—	—
Nasal Adapter	YG-120T	4931921YG-120TL3	×	—	—
Nasal Adapter	YG-121T	4931921YG-121TL6	×	—	—
Nasal Adapter	YG-122T	4931921YG-122TL9	×	—	—
Nasal Adapter	YG-125T	4931921YG-125TLJ	×	—	—
Pediatric Nasal Adapter	YG-135T	4931921YG-135TLP	×	—	—
Nasal Adapter	YG-120TW	4931921YG-120TWJQ	×	—	—
Nasal Adapter	YG-121TW	4931921YG-121TWJV	×	—	—
Nasal Adapter	YG-122TW	4931921YG-122TWK2	×	—	—
Nasal Adapter	YG-125TW	4931921YG-125TWKH	×	—	—
Pediatric Nasal Adapter	YG-135TW	4931921YG-135TWKQ	×	—	—

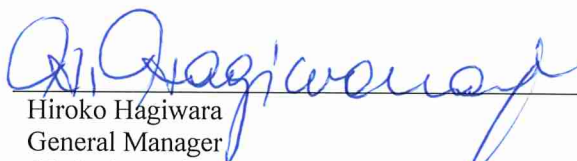
Intended purpose: The products listed above are accessories of CO2 SENSOR KIT.

Additional Information: NA

Authorized Signatory:

Tokyo, Japan/ 31 August 2022

Place and date of issue



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