

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

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SRN: JP-MF-000019022

European

Representative: NIHON KOHDEN EUROPE GmbH

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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: EN IEC 63000: 2018

☐ **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-211T	4931921YG-211TL8	×	—	—
Airway Adapter	YG-211TW	4931921YG-211TWJZ	×	—	—
Neonatal/Infant Airway Adapter	YG-213T	4931921YG-213TLE	×	—	—
Neonatal/Infant Airway Adapter	YG-213TW	4931921YG-213TWKB	×	—	—
Neonatal/Infant Airway Adapter	YG-214T	4931921YG-214TLH	×	—	—
Neonatal/Infant Airway Adapter	YG-214TW	4931921YG-214TWKG	×	—	—
Pediatric cap-ONE MASK	YG-232T	4931921YG-232TLM	×	—	—
Pediatric cap-ONE MASK	YG-232TW	4931921YG-232TWKL	×	—	—
Infant cap-ONE MASK	YG-242T	4931921YG-242TLS	×	—	—
Infant cap-ONE MASK	YG-242TW	4931921YG-242TWKT	×	—	—
Adult cap-ONE MASK	YG-272T	4931921YG-272TM9	×	—	—
Adult cap-ONE MASK	YG-272TW	4931921YG-272TWLG	×	—	—
Large adult cap-ONE MASK	YG-282T	4931921YG-282TME	×	—	—
Large adult cap-ONE MASK	YG-282TW	4931921YG-282TWLP	×	—	—
Nasal Adapter	YG-225T	4931921YG-225TLR	×	—	—
Nasal Adapter	YG-225TW	4931921YG-225TWKU	×	—	—
Pediatric Nasal Adapter	YG-235T	4931921YG-235TLW	×	—	—
Pediatric Nasal Adapter	YG-235TW	4931921YG-235TWL3	×	—	—
Thermal Airflow Sensor	TR-190A	4931921TR-190AMS	×	×	—
Thermal Airflow Sensor	TR-190AW	4931921TR-190AWMC	×	×	—
Adult cap-ONE Biteblock	YG-227T	4931921YG-227TLX	×	—	—
Adult cap-ONE Biteblock	YG-227TW	4931921YG-227TWL6	×	—	—
Adult cap-ONE Nasal Adapter	YG-220T	4931921YG-220TLA	×	—	—
Adult cap-ONE Nasal Adapter	YG-220TW	4931921YG-220TWK3	×	—	—
Adult cap-ONE Nasal Adapter	YG-221T	4931921YG-221TLD	×	—	—

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Adult cap-ONE Nasal Adapter	YG-221TW	4931921YG-221TWK8	×	—	—
Pediatric cap-ONE Nasal Adapter	YG-230T	4931921YG-230TLF	×	—	—
Pediatric cap-ONE Nasal Adapter	YG-230TW	4931921YG-230TWKA	×	—	—
Pediatric cap-ONE Nasal Adapter	YG-231T	4931921YG-231TLJ	×	—	—
Pediatric cap-ONE Nasal Adapter	YG-231TW	4931921YG-231TWKF	×	—	—

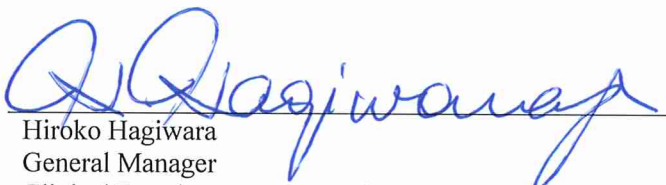
Intended purpose: The products listed above are accessories of CO₂ SENSOR KIT.

Additional Information: NA

Authorized Signatory:

Tokyo, Japan/ 31 August 2022

Place and date of issue



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