

## 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
NIBP Cuff Infant	YP-710T	4931921YP-710TQV	×	—	—
NIBP Cuff Child Small	YP-711T	4931921YP-711TQY	×	—	—
NIBP Cuff Child	YP-712T	4931921YP-712TR3	×	—	—
NIBP Cuff Adult	YP-713T	4931921YP-713TR6	×	—	—
NIBP Cuff Adult Large	YP-714T	4931921YP-714TR9	×	—	—
NIBP Cuff Thigh	YP-715T	4931921YP-715TRC	×	—	—

**Intended purpose:** The products listed above are used to measure non-invasive blood pressure.

**Additional Information:** NA

**Authorized Signatory:**

Tokyo, Japan/ 31 August 2022

Place and date of issue

  
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