

## EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.  
 Single Registration Number: JP-MF-000007213  
 Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN  
 European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.  
 Single Registration Number: NL-AR-000002683  
 Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands  
 Product Category: Electronic Sphygmomanometers/Blood Pressure Monitors  
 Model (code): M2 Basic (HEM-7121J-E)  
 Basic UDI-DI: 4015672112234T  
 MDR Classification: Class IIa (MDR Annex VIII Rule 10)

We herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer and the European Authorized Representative.

This Declaration of Conformity is valid in connection with all the shipping inspection reports for the respective batch of produced devices.

|                                 |                                                 |                             |
|---------------------------------|-------------------------------------------------|-----------------------------|
| General applicable regulations: | Medical Device Regulation (EU) 2017/745         |                             |
| Standards:                      | EN 1041:2008+A1:2013                            | EN ISO 10993-1:2020         |
|                                 | EN 1060-1:1995+A2:2009                          | EN ISO 10993-5:2009         |
|                                 | EN 1060-3:1997+A2:2009                          | EN ISO 10993-10:2013        |
|                                 | EN 60601-1:2006+A1:2013                         | EN ISO 13485:2016           |
|                                 | EN 60601-1-2:2015                               | EN ISO 14971:2019           |
|                                 | EN 60601-1-6:2010+A1:2015                       | EN ISO 15223-1:2016         |
|                                 | EN 60601-1-11:2015                              | EN ISO 81060-2:2019+A1:2020 |
|                                 | EN 62304:2006+A1:2015                           |                             |
|                                 | EN 62366-1:2015                                 |                             |
|                                 | EN IEC 80601-2-30:2019                          |                             |
|                                 |                                                 |                             |
| Notified Body:                  | TÜV Rheinland LGA Products GmbH                 |                             |
| Address:                        | Tillystrasse 2, 90431 Nuremberg, Germany        |                             |
| ID No:                          | Notified under number 0197 to the EC Commission |                             |
| Certificate Registration No:    | Annex IX: HZ 2102042-1                          |                             |

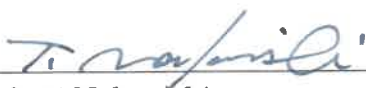
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|--------------------------------|-----------------------------------------------------------|
| General applicable directives: | RoHS Directive 2011/65/EU, (EU)2015/863 and (EU)2017/2102 |
| Product Category for RoHS:     | Category 8 (Medical devices)                              |
| Standards:                     | EN IEC 63000:2018                                         |

Place / Date: Kyoto / February 28, 2023

Signature:

Name:

Position:

  
 Takefumi Nakanishi  
 General Manager  
 Regulatory Affairs Department

Attachment to EC Declaration of Conformity No. OHQ(ĈS)-DoC(MDR)-3275334

**Intended purpose of the model:**

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and indicates this via a symbol with readings. It is mainly designed for general household use.