

## EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.  
Address: 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN  
European Representative: OMRON HEALTHCARE EUROPE B.V.  
Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands  
Product Category: Electronic Sphygmomanometers/Blood Pressure Monitors  
Model (code): M7 Intelli IT (HEM-7322T-E)  
Classification for MDD: Class IIa (MDD Article 9 Annex IX Rule 10)  
Product Category for RoHS: Category 8 (Medical devices)

We herewith declare that the above mentioned product meets the provisions of the following European Committee Council Directives and Standards. All supporting documentation are retained at the premises of the manufacturer and the notified body.  
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

### Directives

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| General applicable directives:<br>Standards                          | Medical Device Directive 93/42/EEC<br>EN ISO 15223-1:2016<br>EN 1041:2008<br>EN 1060-1:1995+A2:2009<br>EN 60601-1:2006+A1:2013<br>EN 60601-1-6:2010<br>EN 80601-2-30:2010+A1:2015<br>EN 62304:2006+A1:2015<br>EN 62366:2008<br>EN ISO 10993-1:2009/AC:2010<br>EN ISO 10993-10:2010<br>EN ISO 14971:2012<br>EN ISO 81060-2:2014 | EN 1060-3:1997+A2:2009<br>EN 60601-1-2:2015<br>EN 60601-1-11:2010 |
| Notified Body:<br>Address:<br>ID No:<br>Certificate Registration No: | TÜV Rheinland LGA Products GmbH<br>Tillystrasse 2, 90431 Nuremberg, Germany<br>Notified under number 0197 to the EC Commission<br>Annex II : HD 60100990 0001  |   |

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| General applicable directives:<br>Standards: | Radio Equipment Directive 2014/53/EU<br>EN 300 328 V2.1.1<br>EN 301 489-1 V2.1.1<br>EN 301 489-17 V3.1.1<br>EN 60950-1:2006 +A11:2009 +A1:2010 +A12:2011 +A2:2013 | EN 301 489-1 V2.1.1<br>EN 62479:2010 |
| General applicable directives:<br>Standards  | RoHS Directive 2011/65/EU<br>EN50581:2012   |                                      |

Place / Date: Kyoto / April 10, 2019

Signature:

Name:

Position:

*K. Shimose*

Kazuhiko Shimose  
Manager  
Regulatory Affairs Department

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