

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.
Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category: Electronic Sphygmomanometers/Blood Pressure Monitors
Model (code): M300 Intelli IT (HEM-7143T1-D)
Basic UDI-DI: 40156721130752
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 10993-1:2009/AC:2010 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 14971:2012 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

General applicable directives:	Radio Equipment Directive 2014/53/EU
Standards:	EN 300 328 V2.2.2 EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4 EN 62479:2010 EN IEC 62368-1:2020+A11:2020


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 / September 13, 2021

Signature:

Name:

Position:



Takefumi Nakanishi
General Manager
Regulatory Affairs Department