OMRON

No: OHQ(CS)-DoC(MDD)-4601141C

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):	RS3 Intelli IT (HEM-6161T-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

General applicable directives:	Medical Device Directive 93/42/EEC
Standards	EN ISO 15223-1:2016 EN 1041:2008+A1:2013 EN 1060-1:1995+A2:2009 EN 1060-3:1997+A2:2009 EN 60601-1:2006+A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 60601-1-11:2015 EN 80601-2-30:2010+A1:2015 EN 62304:2006+A1:2015 EN 62366-1:2015 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 81060-2:2014
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 II : HD 60100990 0001

General applicable directives:	Radio Equipment Directive 2014/53/EU
Standards:	EN 300 328 V2.1.1 EN 301 489-1 V2.1.1 EN 301 489-17 V3.1.1 EN 62479:2010 EN 62368-1:2014+A11:2017
General applicable directives:	RoHS Directive 2011/65/EU
Standards	EN50581:2012

Place / Date: Kyoto / March 29, 2019

Signature:

T. Nakanishi

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department