OMRON

No: OHQ(CS)-DoC(MDD)-9074142C

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 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 under 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	
	EN 1060-1:1995+A2:2009	EN 1060-3:1997+A2:2009
	EN 60601-1:2006	EN 60601-1-2:2007
	EN 60601-1-6:2010	
	EN 62304:2006	
	EN 62366:2008	
	EN ISO 10993-1:2009	EN ISO 10993-5:2009
	EN ISO 10993-10:2010	
	EN ISO 14971:2012	
	ISO 81060-2:2013	
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 60100203 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 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013	
General applicable directives:	RoHS Directive 2011/65/EU	
Standards	EN50581:2012	

Place / Date: Kyoto / December 25, 2017

Signature:

T. Nakanishi

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

All for Healthcare

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN