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

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.
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 980:2008 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
General applicable directives:	RoHS Directive 2011/65/EU
Standards	EN50581:2012
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:	R&TTE Directive 1999/5/EC
Standards:	EN 300 328 V1.9.1 EN 301 489-1 V1.9.2 EN 301 489-17 V2.2.1 EN 62479:2010 EN 60950-1:2006+A11:2009+A1:2010+A12:2011+A2:2013

Place / Date: Kyoto / April 28, 2016

Signature:

T. Nakanishi

Name: Takefumi Nakanishi
Position: General Manager
Customer Satisfaction Management Division

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