OMRON

No: OHQ(CS)-DoC(MDD)-9063683C

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):	RS8(HEM-6310F-E)
Classification for MDD:	(MDD Annex IX)
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 60601-1:1990+A1:1993+A2:1995, EN 60601-1-2:2007, EN 60601-1-4:1996+A1:1999, 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
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 301 489-1 V1.9.2, EN 301 489-3 V1.6.1, EN 300 330-1 V1.8.1, EN 300 330-2 V1.6.1

Place / Date: Kyoto / February 19, 2016

Signature:

M. Yasue

Name: Norikazu Yasue
Position: General Manager
Customer Satisfaction Management Division