OMRON

OHQ(CS)-QS-091008

EC Declaration of Conformity

Manufacturer: Address:	OMRON HEALTHCARE Co., Ltd. 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto 615-0084 JAPAN
European Representative:	OMRON HEALTHCARE EUROPE B.V.
Address:	Kruisweg 577, 2132 NA Hoofddorp, The Netherlands
Product:	Blood Pressure Monitor HEM-759P-E2
Model:	705IT (HEM-759P-E2)
MDD Classification:	Class IIa (MDD Annex IX Rule10)

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.

Directives

General applicable directives:	Medical Device Directive (MDD) 93/42/EEC
Standards:	EN 60601-1:1990+A1:1993+A2:1995 EN 60601-1-2:2007 EN 1060-1:1995+A1:2002 EN 1060-3:1997+A1:2005 EN 980:2008 EN 1040:2008 EN ISO 14971:2007 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 10993-10:2009 EN ISO 10993-12:2009
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nuremberg, Germany Notified under number 0197 to the EC Commission
Certificate:	Annex II: HD 60018171 0001
Place / Date:	Kyoto, Japan / March 23, 2010
Signature:	
Name:	Norikazu Yasue
Position:	General Manager Customer Satisfaction Management Division OMRON HEALTHCARE Co., Ltd.