OMRON

No: OHQ(CS)-DoC(MDD)-9911730B

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:	Accessory for Electronic Sphygmomanometers/Blood Pressure Monitor
Model:	HEM-FL31
Classification:	Class I(MDD Annex IX Rule 1)

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 (MDD) 93/42/EEC
Standards:	EN980:2008 EN1041:2008 EN ISO10993-1:2009 EN ISO10993-5:2009 EN ISO10993-10:2010 EN62366:2008 EN ISO14971:2012 EN60601-1:1990+A1:1993+A2:1995 EN1060-1:1995+A2:2009 EN1060-3:1997+A2:2009 EN60601-1-6 : 2010
Place / Date:	Kyoto / July 7, 2014
Signature:	
Name:	Norikazu Yasue
Position:	General Manager Customer Satisfaction Management Division