OMRON

No: OHQ(CS)-DoC(MDD)-9520534D

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 Monitors
Product Description:	Blood Pressure Monitor Cuff
Model(code):	HEM-RML30 (HEM-RML30-E)
Classification:	Class I (MDD Article 9 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 at 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:	93/42/EEC Medical Device Directive(MDD)
Standards:	EN ISO 15223-1:2016 EN 1041:2008 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 14971:2012
Place / Date:	Kyoto / November 5, 2018
Signature:	
Name:	Takefumi Nakanishi
Position:	General Manager Regulatory Affairs Department