OMRON

No: OHQ(CS)-DoC(MDD)-9546063D

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):	RS1 (HEM-6160-E)
Classification for MDD:	Class IIa (MDD Article 9 Annex IX Rule 10)

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 and the notified body.
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 1041:2008	EN ISO 10993-1:2009/AC:2010
	EN 1060-1:1995+A2:2009	EN ISO 10993-5:2009
	EN 1060-3:1997+A2:2009	EN ISO 10993-10:2013
	EN 60601-1:2006+A1:2013	EN ISO 14971:2012
	EN 60601-1-2:2015	EN ISO 15223-1:2016
	EN 60601-1-6:2010+A1:2015	EN ISO 81060-2:2014
	EN 60601-1-11:2015	
	EN 62304:2006+A1:2015	
	EN 62366-1:2015	
	EN 80601-2-30:2010+A1:2015	
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 2102042-1	

General applicable directives:	RoHS Directive 2011/65/EU
Product Category for RoHS:	Category 8 (Medical devices)
Standards:	EN 50581:2012

Place / Date:	Kyoto / February 9, 2021
Signature:	
Name:	Takefumi Nakanishi
Position:	General Manager Regulatory Affairs Department