

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): HeartGuide (HEM-6411T-MAE)
Classification for MDD: Class IIa (MDD Article 9 Annex IX Rule 10)
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 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: Standards	Medical Device Directive 93/42/EEC EN 1041:2008+A1:2013 EN 1060-1:1995+A2:2009 EN 60601-1:2006+A1:2013 EN 60601-1-6:2010+A1:2015 EN 62304:2006+A1:2015 EN 80601-2-30:2010+A1:2015 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223-1:2016 EN ISO 81060-2:2014
Notified Body: Address: ID No: Certificate Registration No:	TÜV Rheinland LGA Products GmbH Tillystrasse 2, 90431 Nuremberg, Germany Notified under number 0197 to the EC Commission Annex II : HD 60100990 0001
General applicable directives: Standards:	EN 1060-3:1997+A2:2009 EN 60601-1-2:2015 EN 60601-1-11:2015 EN 62366-1:2015

General applicable directives: Standards:	Radio Equipment Directive 2014/53/EU EN 300 328 V2.1.1 EN 301 489-17 V3.1.1 EN 62368-1:2014+A11:2017
General applicable directives: Standards	EN 301 489-1 V2.1.1 EN 62479:2010
General applicable directives: Standards	RoHS Directive 2011/65/EU EN50581:2012

Place / Date: Kyoto / October 3, 2019
Signature:

Name: 
Position: Takefumi Nakanishi
General Manager
Regulatory Affairs Department