

## 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 Name(-code): RS3(HEM-6130-E)

Classification: Class IIa(MDD 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 under 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**

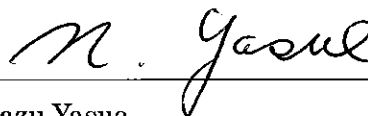
General applicable directives: Medical Device Directive (MDD) 93/42/EEC

Standards:  
EN980:2008  
EN1041:2008  
EN1060-1:1995+A2:2009  
EN1060-3:1997+A2:2009  
EN60601-1:1990+A1:1993+A2:1995  
EN60601-1-2:2007  
EN60601-1-4:1996+A1:1999  
EN ISO14971:2007  
EN ISO10993-1:2009  
EN ISO10993-5:2009  
EN ISO10993-10:2009  
EN62304:2006  
EN62366:2008

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 60041154 0001

Place / Date: Kyoto / November 26, 2012

Signature:



Name: Norikazu Yasue  
Position: General Manager  
Customer Satisfaction Management Division