

## 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): M6 Comfort IT(HEM-7322U-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  
EN60601-1:2006  
EN60601-1-2:2007  
IEC60601-1-6:2010  
EN ISO14971:2012  
EN ISO10993-1:2009  
EN ISO10993-5:2009  
EN ISO10993-10:2010  
EN62304:2006  
EN62366:2008  
EN60601-1-11:2010  
EN80601-2-30:2010

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 60100203 0001

Place / Date: Kyoto / May 29, 2015

Signature:



Name: Norikazu Yasue  
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