

EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Address: 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto
615-0084 JAPAN

European Representative: OMRON HEALTHCARE EUROPE B.V.
Address: Kruisweg 577, 2132 NA Hoofddorp, The Netherlands

Product Category: Electronic Sphygmomanometers / Blood Pressure Monitor
Model Name(-code): M6 Comfort (HEM-7223-E)
Classification: Class IIa (MDD Annex IX Rule10)

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.

Directives

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

Standards:

- EN 980:2008
- EN 1041:2008
- EN 1060-1:1995+A2:2009
- EN 1060-3:1997+A2:2009
- EN 60601-1:1990+A1:1993+A2:1995
- EN 60601-1-2:2007
- EN 60601-1-4:1996+A1:1999
- EN 62304:2006
- EN 62366:2008
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2009
- EN ISO 14971:2009

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 60018171 0001

Place / Date: Kyoto, Japan / June 21, 2011

Signature:



Name: Norikazu Yasue

Position: General Manager
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