

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: Blood Pressure Monitor HEM-759P-E2

Model: 705IT (HEM-759P-E2)

MDD 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

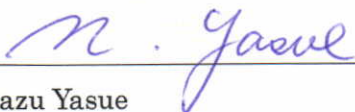
General applicable directives: Medical Device Directive (MDD) 93/42/EEC

Standards: EN 60601-1:1990+A1:1993+A2:1995
EN 60601-1-2:2007
EN 1060-1:1995+A1:2002
EN 1060-3:1997+A1:2005
EN 980:2008
EN 1040:2008
EN ISO 14971:2007
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 10993-12:2009

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nuremberg, Germany
Notified under number 0197 to the EC Commission

Certificate: Annex II: HD 60018171 0001

Place / Date: Kyoto, Japan / March 23, 2010

Signature: 

Name: Norikazu Yasue

Position: General Manager
Customer Satisfaction Management Division
OMRON HEALTHCARE Co., Ltd.