

## 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: Accessory for Blood Pressure Monitor  
Model Name(-code): CW Wide Range Cuff (HEM-RML30)  
Classification: Class I (MDD Annex IX Rule 12)

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.

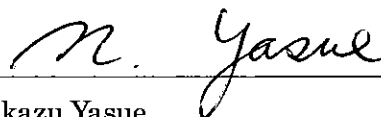
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

### Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC  
Standards: 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 62366:2008  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2009  
EN ISO 10993-12:2009  
EN ISO 14971:2009

Place / Date: Kyoto, Japan / January 6, 2012

Signature:



Name:

Norikazu Yasue

Position:

General Manager

Customer Satisfaction Management Division

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