

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 Electronic Sphygmomanometers/Blood Pressure Monitor
Model: HEM-RML31
Classification: Class I(MDD Annex IX Rule 1)

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.

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
EN ISO10993-1:2009
EN ISO10993-5:2009
EN ISO10993-10:2010
EN62366:2008
EN ISO14971:2012
EN60601-1:1990+A1:1993+A2:1995
EN1060-1:1995+A2:2009
EN1060-3:1997+A2:2009
EN60601-1-6 : 2010

Place / Date: Kyoto / July 7, 2014

Signature:



Name:

Norikazu Yasue

Position:

General Manager
Customer Satisfaction Management Division