

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:

Accesory for Electronic Sphygmomanometers/Blood

Pressure Monitor

Model Name(-code):

AC ADAPTER-S(HEM-ACW5-E)

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:

EN ISO14971:2009 EN1041:2008

EN1041.2008 EN980:2008

EN60601-1:1990+A1:1993+A2:1995

EN60601-1-2:2007

Place / Date:

Signature:

Kyoto / March 19, 2012

Name:

M. Joseph Norikazu Yasue

Position:

General Manager

Customer Satisfaction Management Division