

## Declaration of Conformity

We,

**OMRON HEALTHCARE Co., Ltd.,**  
**24 Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto 615-0084 Japan,**

as a manufacturer from 1 May, 2004, declare in sole responsibility that the medical device product,

**Accessory, AC Adapter for OMRON non-invasive Blood Pressure Monitor MIT Elite and MIT Elite Plus**  
**Model: AC Adapter E1600 (3094298-6)**

to which this declaration relates is in conformity with the determination of the Council of the European Communities on the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The product is classified as **Class I** in accordance with Annex IX, rule 12 and complies with Annex I, essential requirements of the Council Directive 93/42/EEC on Medical Devices.

This declaration is based on the Approval in accordance with

**Annex II, The Council Directive 93/42/EEC on Medical Devices (Section 4 excepted),**  
**Approval Registration No.: HD 60018171 0001,**  
**Dated on: 16 June, 2008**

granted by the Notified Body,

**TÜV Rheinland Product Safety GmbH,**  
**Am Grauen Stein D-51105 Köln,**  
**notified under number 0197 to the EC Commission.**

This declaration of conformity is in correspondence to the harmonized standards,

**EN 60601-1:1990+A1:1993+A2:1995, EN 60601-1-2:2001, EN980:2003,**  
**EN 1041:1998, EN 1060-1:1995+A1:2002, EN 1060-3:1997+A1:2005,**  
**EN ISO 14971:2000+A1:2003,**

Ranging from October, 2009 to October, 2011

21 August, 2009

OMRON HEALTHCARE Co., Ltd.



Koichi Tanaka  
General Manager  
Customer Satisfaction Management Division