OMRON

No. OHQ(CS)-QS-05345

# Declaration of Conformity

We,

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

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

**Cuff Medium (OMRON 4997086-7)**

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** medical device, and complies with

**Annex I, 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 60006688 0001,**
**Report No.: 12002566 003,**
**Dated on: 1 January, 2004,**

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, EN 60601-1-2, EN 980, EN 1041, EN 14971, EN 1060-1 and EN 1060-3.**

Kyoto, April 6, 2006

Osamu Nakao
Managing Officer
Customer Satisfaction Management Division