

## EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.  
Address: 24, Yamanouchi Yamanoshita-cho, Ukyo-ku, Kyoto  
615-0084 JAPAN

European Representative: OMRON HEALTHCARE EUROPE B.V.  
Address: Kruisweg 577, 2132 NA Hoofddorp, The Netherlands  
Product: Small Cuff and Inflation Bulb Cuff HEM-CS24-BE  
Model: CSB2 (HEM-CS24-BE)  
MDD Classification: Class I  
(MDD Annex IX Rule12)

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.

### Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC

Standards: EN 60601-1:1990+A1:1993+A2:1995  
EN 980:2008  
EN 1041:2008  
EN 1060-1:1995+A1:2002  
EN 1060-3:1997+A1:2005  
EN ISO 14971:2007  
EN 62366:2008  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2009  
EN ISO 10993-12:2009

Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nuremberg, Germany

Place / Date: Kyoto, Japan / July 14, 2010

Signature:



Name: Norikazu Yasue  
Position: General Manager  
Customer Satisfaction Management Division  
OMRON HEALTHCARE Co., Ltd.