

## 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: Mask (PVC) for Inhaler / Nebuliser

Model: Adult Mask (PVC)

MDD Classification: Class IIa  
(MDD Annex IX Rule2)

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

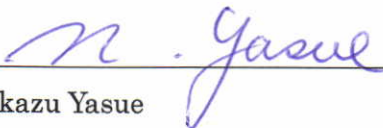
Standards: EN 60601-1:1990+A1:1993+A2:1995  
EN 980:2008  
EN 1041:1998  
EN 13544:1:2007  
EN ISO 14971:2007  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2009

Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nuremberg, Germany  
Notified under number 0197 to the EC Commission

Certificate: Annex II: HD 60018171 0001

Place / Date: Kyoto, Japan / March 23, 2010

Signature:

Name:   
Norikazu Yasue

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