

## 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: Nebulizers  
Product Description: Mask  
Model (code): Mask Adapter(U22-2)  
Classification: Class IIa(MDD Annex IX Rule 2)

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.  
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

### Directives

General applicable directives: 93/42/EEC Medical Device Directive (MDD)  
Standards: EN 980:2008  
EN 1041:2008  
EN 13544-1:2007+A1:2009  
EN 60601-1:1990+A1:1993+A2:1995  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2010  
EN ISO 14971:2012

Notified Body: TÜV Rheinland LGA Products GmbH  
Address: Tillystrasse 2, 90431 Nuremberg, Germany  
ID No: Notified under number 0197 to the EC Commission  
Certificate Registration No: Annex II : HD 60100203 0001  
Place / Date: Kyoto / September 1, 2015  
Signature:

Name:   
Position: Norikazu Yasue  
General Manager  
Customer Satisfaction Management Division