

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 Category: Nebulizers
Model Name(-code): U22 (NE-U22-E)
Classification: Class IIa (MDD Annex IX Rule 11)

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.

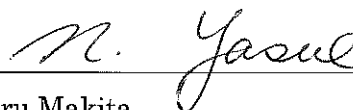
Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC
Standards: EN 980:2008
EN 1041:2008
EN 60601-1:1990+A1:1993+A2:1995
EN 60601-1-2:2007
EN 60601-1-4:1996+A1:1999
EN 60601-1-6:2007
EN 62304:2006
EN 62366:2008
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2009
EN 13544-1:2007+A1:2009
EN ISO 14971:2009

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 60018171 0001

Place / Date: Kyoto, Japan / June 23, 2011

Signature:



Name: Shigeru Makita

Position: Senior General Manager
Customer Satisfaction Management Division