

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
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.


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

Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC
Standards: EN980:2008
EN1041:2008
EN60601-1:1990+A1:1993+A2:1995
EN60601-1-2:2007
EN60601-1-4:1996+A1:1999
EN60601-1-6:2007
EN ISO14971:2009
EN ISO10993-1:2009
EN ISO10993-5:2009
EN ISO10993-10:2010
EN62304:2006
EN62366:2008
EN13544-1:2007+A1:2009
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 60100203 0001

Place / Date: Kyoto / May 29, 2015

Signature:


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