OMRON

No: OHQ(CS)-QS-091260D

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 Rule11)

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:

M. Yasui

Name: Shigeru Makita

Position: Senior General Manager
Customer Satisfaction Management Division