

## 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: Accessory for Nebulizers  
Product Description: AC Adapter  
Model: NEB-AC-10E  
Classification for MDD: Class I(MDD Annex IX Rule 1)  
Product Category for RoHS: Category 8 (Medical devices)

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.

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

### **Directives and Harmonized Standards**

General applicable directives:	Relevant regulations and harmonized standards
93/42/EEC Medical Device Directive (MDD)	EN 980:2008 EN 1041:2008 EN 60601-1:2006+A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010+A1:2015 EN 60601-1-11:2010 EN 62366:2008+A1:2015 EN ISO 14971:2012
2011/65/EU Restriction of Hazardous Substances (RoHS)	EN50581:2012

Place / Date: Kyoto / November 10, 2017

Signature:



Name:

Takefumi Nakanishi

Position:

General Manager  
Regulatory Affairs Department