

## 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: Medication Container  
Model: NEB-BTL-10E  
Classification: Class IIa (MDD Article 9 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 at 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 ISO 15223-1:2016  
EN 1041:2008  
EN 13544-1:2007+A1:2009  
EN 60601-1:2006+A1:2013  
EN 60601-1-6:2010+A1:2015  
EN 60601-1-11:2010  
EN 62366:2008+A1:2015  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
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 60100990 0001  
Place / Date: Kyoto / April 10, 2019  
Signature:



Name: Kazuhiko Shimose  
Position: Manager  
Regulatory Affairs Department

オムロンヘルスケア株式会社

〒617-0002 京都府向日市寺戸町九ノ坪53番地