

EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Single Registration Number: JP-MF-000007213
Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN
European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.
Single Registration Number: NL-AR-000002683
Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category: Nebulizers
Model: NE-C28
Basic UDI-DI: 497547949401PE
MDR Classification: Class IIa (MDR Annex VIII Rule 12)

We herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer and the European Authorized Representative.

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

General applicable regulations:	Medical Device Regulation (EU) 2017/745
Standards:	EN 1041:2008+A1:2013 EN ISO 10993-1:2020 EN 13544-1:2007+A1:2009 EN ISO 10993-5:2009 EN 60601-1:2006+A1:2013 EN ISO 10993-10:2013 EN 60601-1-2:2015 EN ISO 10993-11:2018 EN 60601-1-6:2010+A1:2015 EN ISO 10993-18:2020 EN 60601-1-11:2010 EN ISO 13485:2016 EN 62366-1:2015 EN ISO 14971:2019 EN ISO 15223-1:2016 EN ISO 17664:2017 EN ISO 18562-1:2020 EN ISO 18562-2:2020 EN ISO 18562-3:2020 EN ISO 27427:2019

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 IX: HZ 2102042-1

General applicable directives:	RoHS Directive 2011/65/EU, (EU)2015/863 and (EU)2017/2102
Product Category for RoHS:	Category 8 (Medical devices)
Standards:	EN IEC 63000:2018

Place / Date: Kyoto / April 28, 2023

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department



Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9956290B

Intended purpose of the model:

This product is intended to be used for inhaling medication for respiratory disorders. The compressor is intended to be multiple patient multiple use. The nebulizer kit and its attachments are single patient multiple use.