No: OHQ(CS)-DoC(MDD)-9520535H

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 (code):	NE-C900 (NE-C900-E)
Classification for MDD:	Class IIa (MDD Article 9 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 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 1041:2008+A1:2013	EN ISO 10993-1:2009/AC:2010
	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 13485:2016
	EN 60601-1-6:2010+A1:2015	EN ISO 14971:2019
	EN 62366-1:2015	EN ISO 15223-1:2016
		EN ISO 17664:2017
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 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 / September 30, 2021

Signature:

T. Nakanishi

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department