No: OHQ(CS)-DoC(MDR)-9956276

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
Product Description:	Child Mask
Model (code):	NEB-MSMP (NEB-MSMP-E)
Basic UDI-DI:	40156721023953
MDR Classification:	Class IIa (MDR Annex VIII Rule 2)

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 60601-1-6:2010+A1:2015	EN ISO 10993-10:2013
	EN 62366-1:2015	EN ISO 10993-11:2018
		EN ISO 10993-18:2020
		EN ISO 13485:2016
		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 / February 28, 2023

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9956276

Intended purpose of the model:

This product is child mask, which is accessory exclusively for OMRON nebulizer.

OMRON HEALTHCARE Co., Ltd.
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