# EU Declaration of Conformity

according to the REGULATION (EU) 2017/745
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
Doc. No. WLYL-230728

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| **Manufacturer:** | Vapo Healthcare Co., Ltd |
| **Address:** | Southern unit of the floor building B No.99 Yudai West Rd,High tech district, Kunshan Suzhou,215301 Jiangsu P.R.China. |
| **European Representative (ER):** | Share Info GmbH |
| **Address:** | Heerdter Lohweg 83, 40549 Düsseldorf |
| **Single Registration Number (SRN) of ER:** | DE-AR-000005132 |

**We, the manufacturer, declare under our sole responsibility that the medical device(s):**

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| **Product Name:** | Electronic Nasal Aspirator |
| **Type/model:** | VP-X1,VP-X1A,VP-X1B,VP-X2,VP-X2A,VP-X2B |
| **Intended Purpose:** | The VAPO nasal aspirator is exclusively intended for the removaof nasal secretions from children.Do not use the nasal aspiratorfor other orifices or on animals.Children over the age of 8, disabled persons with reduced phy-sical or mental abilities, and people without experience or kno-wledge can operate the equipment in a safe environment if theyare supervised and understand the risks involved.Children shalnot play with the appliance. Cleaning and use shall not be madeby children without supervision.Operate the device according to the instructions outlined inthese instructions for use.Keep packaging material away from children(risk of suffocation).This nasal aspirator is suitable only for using in private homesand not for medical or commercial purposes.The nasal aspira-tor may only be used for the purpose for which it was designedand in the manner specified in the instructions for use.Any formof improper use can be dangerous.The manufacturer is notliable for damage resulting from improper or incorrect use.Donot use the nasal aspirator if one or several of the followingwarnings applies. |
| **Classification:(Annex VIII of the MDR)** | Class I medical device according to the rule 13 |

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| **Basic UDI-DI:** | Refer to the Appendix I for details. |
| **Conformity assessment procedure:** | EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III) |
| **Applied harmonized standards and Common Specification:** | Refer to the Appendix II for details. |
| **Notified Body:** | NA |
| **Address:** | NA |
| **Notified Body number:** | NA |
| **Registration No.:** | NA |

## Appendix I: Basic UDI-DI for product(s)

| Model/Specification | Basic UDI-DI |
|---|---|
| VP-X1,VP-X1A,VP-X1B,<br>VP-X2,VP-X2A,VP-X2B | 697097957VP-XWW |

## Appendix II: Applied harmonized standards and Common Specification

*is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.*

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| **Applied harmonized standards and Common Specification** | EN ISO 13485:2016<br>EN ISO 14971:2019<br>EN ISO 20417:2019<br>EN ISO 15223-1:2021<br>EN ISO 10993-1:2009/AC:2010 | MEDDEV 2.7/1 rev.4:2016<br>ISO/TR 24971: 2020<br>EN ISO 10993-5:2009<br>EN ISO 10993-10:2013<br>EN 62366:2015 |

This DoC is valid from 28 July, 2023.

Authorized by:

苏州雾联医疗科技有限公司
VAPO Healthcare Co.,Ltd.

Signature

Position: General Manager

Rev. 2.0

Signed on: 28 July, 2023.

Place: Kunshan, Jiangsu, China