









## 1. PRODUCT DESCRIPTION:

A nebulizer machine is a medical device used to convert liquid medication into a fine aerosol mist, allowing the patient to inhale the medicine directly into the lungs. It helps deliver respiratory medication effectively for the treatment of asthma, bronchitis, COPD, allergies, and other respiratory conditions. The device typically includes a compressor unit, medication cup, air tubing, and a mouthpiece or mask. The compressor generates airflow that passes through the medication, creating a consistent mist output for efficient inhalation therapy. It is suitable for use in home care, clinics, and hospitals, and is designed for both children and adults.

## 2. DEVICE CLASSIFICATION AND RULE:

The device is classified as Class III/Rule 20, as Per Medical Device Rule 2017/745.

## 3. PRODUCT CHARACTERISTICS & INTENDED USE:

A Nebulizer machine is medical equipment that a person with asthma or another respiratory condition can use to administer medication directly and quickly to the lungs. A nebulizer turns liquid medicine into a very fine mist that a person can inhale through a face mask or mouthpiece. A nebulizer is a small machine that creates a mist out of liquid medication, allowing for quicker and easier absorption of medication into the lungs.

## INTENDED USE:

Nebulizers are machines that turn liquid medications into a fine mist, allowing for easy absorption into the lungs. They are used for a variety of health conditions, including COPD, asthma, and cystic fibrosis, and are sometimes used in conjunction with inhalers.

## 4. PRODUCT VARIANTS:

Following variants are available for the products:

| S.NO | Product | Type | GMDN Code | Classification / Rule |
|---|---|---|---|---|
| 1. | Nebulizer Machine | Handy, Puppy, Panda, | 66295 | Class-III, Rule-20 |

## 5. MATERIAL OF CONSTRUCTION:

| S.no. | Component name | Material of Construction |
|---|---|---|
| 1. | Cover(Top Bottom) | ABS |
| 2. | Tube Connector | PVC |
| 3. | Nebulizer Cup | PC |
| 4. | Nebulizer Cover | PP |
| 5. | Nebulizer Tube | PVC |
| 6. | Nebulizer Regulator | PP |
| 7. | Face Mask | PVC |
| 8. | Filter Cap | ABS |

## 6. PRODUCT SPECIFICATION:

| S. No. | Model Name | Material of Construction | Product Specification<br>Specifications | | Accessories |
|---|---|---|---|---|---|
| 1. | Puppy | ABS,<br>PVC<br>PC<br>PP<br>ABS (W) | Maximum compressor Pressure | 25-30 bar | Tubing<br>Nebulizer insert<br>Nebulizer Cup<br>Nebulizer Cap<br>Universal mask<br>Mouth Piece<br>Extra Filters |
| | | | Nebulization Rate | 0.3ml/min | |
| | | | Nebulizer cup capacity | 6 ml | |
| | | | Particle Size | 0.5µm to 5µm | |
| | | | Noise Level | 55dba | |
| | | | Electrical Requirement | 120v/60Hz<br>22v/50Hz | |
| 2. | Handy | ABS<br>PVC<br>PP | Maximum compressor Pressure | 25-30 bar | Tubing<br>Nebulizer insert<br>Nebulizer Cup<br>Nebulizer Cap<br>Universal mask<br>Mouth Piece<br>Extra Filters |
| | | | Nebulization Rate | 0.3ml/min | |
| | | | Nebulizer cup capacity | 6 ml | |
| | | | Particle Size | 0.5µm to 5µm | |
| | | | Noise Level | 55dba | |
| | | | Electrical Requirement | 120v/60Hz<br>22v/50Hz | |
| 3. | MINI | ABS<br>PVC<br>PC<br>PP | Maximum compressor Pressure | 25-30 bar | Tubing<br>Nebulizer insert<br>Nebulizer Cup<br>Nebulizer Cap<br>Universal mask<br>Mouth Piece<br>Extra Filters |
| | | | Nebulization Rate | 0.3ml/min | |
| | | | Nebulizer cup capacity | 6 ml | |
| | | | Particle Size | 0.5µm to 5µm | |

## 7. REFERENCE COMPLIANCE STANDARD:

| S No. | Name of Standard | Number |
|---|---|---|
| | **Nebulizers Machine** | |
| 1. | Respiratory therapy equipment – Nebulizing systems and components – Methods of measurement of aerosol output and particle size distribution | EN ISO 27427:2013 |
| 2. | Medical electrical equipment – General requirements for basic safety and essential performance. | IEC 60601-1:2005 / EN 60601-1 |
| 3. | Electromagnetic compatibility (EMC) requirements for medical devices | IEC 60601-1-2:2014 / EN 60601-1-2 |
| | **General** | |
| 4. | Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration | EN ISO 14644-1:2015 |
| 5. | Clean Rooms And Associated Controlled Environments : Monitoring to provide evidence of clean room performance related to air cleanliness by particle concentration | EN ISO 14644-2:2015 |
| 6. | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements | EN ISO 15223-1:2021 |
| 7. | Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices | EN ISO 11135:2014 |
| 8. | Sterilization of health care products - Biological indicators - Part 1: General requirements | EN ISO 11138-1:2017 |
| 9. | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products | EN ISO 11737-1:2018 |
| 10. | Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems | EN ISO 11607-1:2019 |
| 11. | Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes | EN ISO 11607-2:2019 |
| 12. | Biological evaluation of medical devices –part 1,<br>Evaluation and testing within a risk management process | EN ISO 10993-1: 2020 |
| 13. | Biological evaluation of medical devices — Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity | EN ISO 10993-3:2014 |
| 14. | Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood | EN ISO 10993-4:2009 |
| 15. | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity | EN ISO 10993-5:2009 |
| 16. | Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals | EN ISO 10993-7:2008 |
| 17. | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | EN ISO 10993-10:2021 |
| 18. | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity | EN ISO 10993-11:2018 |

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|---|---|---|
| 19. | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials | EN ISO 10993-12:2021 |
| 20. | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances | EN ISO 10993-17:2023 |
| 21. | Clean rooms and associated controlled environments- bio-contamination control- general principles and methods | EN ISO 14698-1:2003 |
| 22. | Clean rooms and associated controlled environments- bio-contamination control- evaluation and interpretation of bio-contamination | EN ISO 14698-2:2003 |
| 23. | Medical devices -- Quality management systems -- Requirements for regulatory purposes | ISO 13485:2016 |
| 24. | Medical devices – application of risk management to medical devices | EN ISO 14971:2019 |
| 25. | European council directive concerning medical devices | MDR 2017/745 |

## 8. PACKAGING DETAILS:

| Packaging specifications | | |
|---|---|---|
| 1. | Blister Pack ( PVC film) | 01 Nos. |
| 2. | Inner (Duplex) Box | 10 Nos. |
| 3. | Outer / Master Carton (Corrugated box) | 40 Nos. |

## 9. COMPLIANCE INFORMATION:

**Manufacturer Information:** Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Phase-II, Sec-59, Ballabgarh, Faridabad-121004, Haryana (INDIA)
**Drug Manufacturing License No.:** MFG/MD/2019/000106
**QMS Certification:** EN ISO 13485:2016, TUV SUD Product Service GmbH CE Marking: **TUV SUD Product Service**: GmbH, EC Notified body No. 0123
**GMDN Code:** 34161

## 10. ABBREVIATIONS:

QMS – Quality Management System
GMDN – Global Medical Device Nomenclature
PP – Polypropylene
PC – Polycarbonate
A.B.S - Acrylonitrile Butadiene Styrene
PVC (Poly-vinyl Chloride)