

| DISPOSAFE BRAND NAME | BRAND NAME |
|---|---|
| Nasal Oxygen Cannula | Nasal-safe |

## 1. PRODUCT DESCRIPTION

It is a low flow type of nasal cannula. The device has two prongs and sits below the nose. The two prongs deliver oxygen directly into your nostrils. The material used is soft PVC. Duration of Use: Short term.

## 2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 5, medical device (classification as per ANNEX – VIII of EU MDR 2017/745)

## 3. PRODUCT CHARACTERISTICS & INTENDED USE

**Intended Purpose:** The Nasal Oxygen Catheter/ Cannula is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help. The twin bore nasal oxygen set is intended use is to deliver oxygen to the patient nasally.

Nasal-safe cannula is a special cannula designed to give adult and pediatric users of dual port oxygen conservation delivery system all the comfort and convenience. Unique dual tubing delivers oxygen on demand through one tube while inspiratory/ expiratory effort is also sensed through other tube.

- Manufactured from soft and lightweight PVC material
- Equipped with curved, soft-tipped nasal prongs to enhance patient comfort
- Tubing length shall be a minimum of 150 cm
- Tubing shall have an internal diameter of 2.5 mm

- Designed with a funnel-shaped connector at the proximal end for easy and secure connection to the oxygen source
- Tubing shall be resistant to kinking and crushing
- Provided with fully adjustable harness and nasal prongs for proper fit
- Each unit shall be individually packed in a peelable pouch
- The product shall be latex-free
- Available in adult size

## 4. PRODUCT VARIANTS

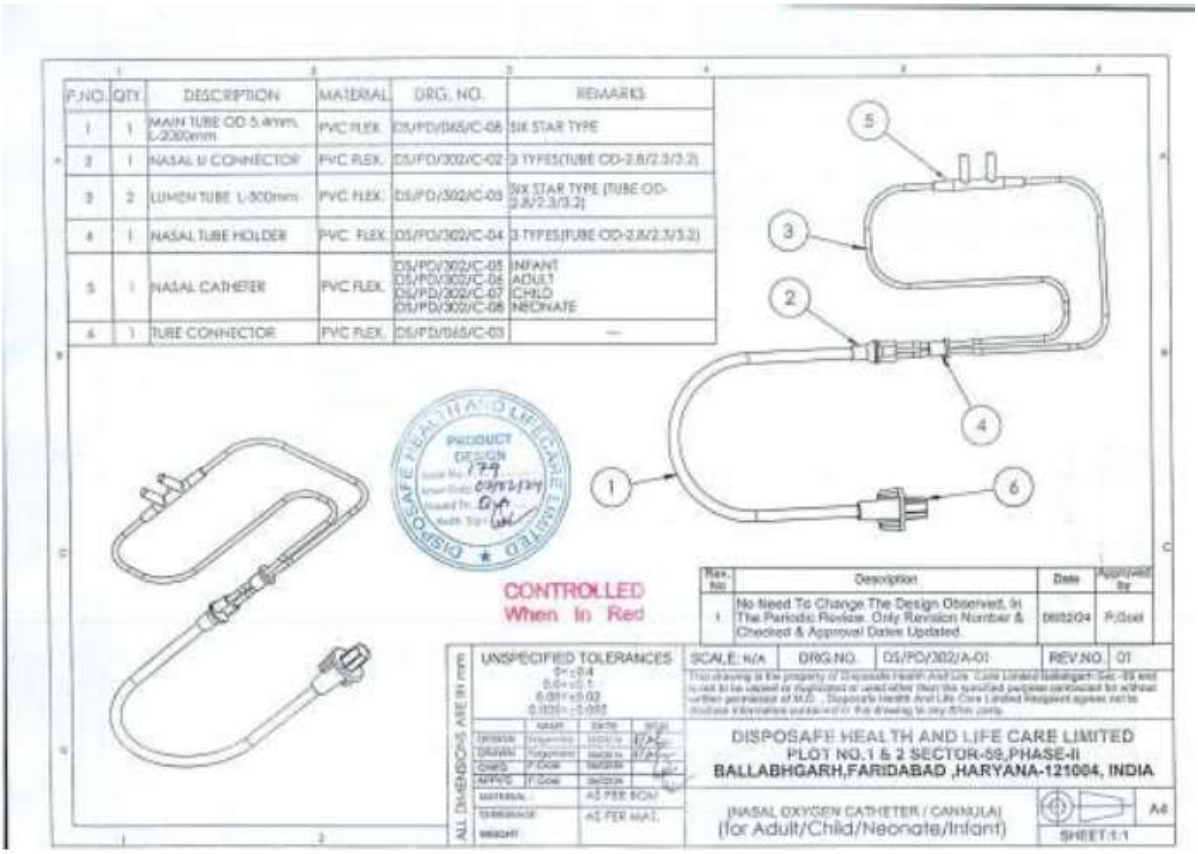
Following variants are available for the products

| S. No. | Product | Size | GMDN Code | Classification |
|---|---|---|---|---|
| 1. | **Twin bore nasal oxygen set** | 200 CM | 35201 | Rule-5, Class-IIa |

## 5. MATERIAL OF CONSTRUCTION

| S. No. | Component Description | Material used |
|---|---|---|
| 1. | Main Tube | PVC |
| 2. | Tube Connector | PVC |
| 3. | Nasal Catheter | PVC |
| 4. | Nasal Tube Holder | LDPE |
| 5. | Lumen Tube | PVC |
| 6. | Nasal U Connector | PVC |

## 6. DRAWING:




| Prepared by: | Reviewed by: | Approved by: | Issued by: | |
|---|---|---|---|---|
| | | | | DISPOSAFE HEALTH AND LIFE CARE LTD. |

## 7. DESCRIPTION OF THECOMPONENTS:

| S. No. | Parts | Functionality |
|---|---|---|
| 1. | Tube Connector | Junction point where the oxygen tubing connects to the cannula. Ensures secure and airtight connection |
| 2. | Nasal Catheter | Ensures regular supply of oxygen |
| 3. | Nasal Tube Holder | Loops around the patient's ears and head to prevent the cannula from slipping |
| 4. | Lumen Tube | Multiple channels within the tube, allowing uninterrupted oxygen flow even if the tubing becomes kinked |
| 5. | Nasal U Connector | Connects the oxygen tubing to the nasal prongs |
| 6. | Main Tube | Transports oxygen flow efficiently and effectively |

## 8. PRODUCT SPECIFICATION

| Size | Tube Length | Packing Inner/ Outer Unit |
|---|---|---|
| Small | 200 CM | 200 |
| Medium | 200 CM | 200 |
| Large | 200 CM | 200 |

## 9. REFERENCE COMPLIANCE STANDARD

| S.No. | Harmonized standards | Standard Number |
|---|---|---|
| 1. | Anaesthetic and respiratory equipment Low-flow nasal cannulae for oxygen therapy. | ISO 23368:2022 |
| 2. | Sampling Procedure For Inspection By attributes | ISO 2859-1 : 1999 |
| 3. | Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration | EN ISO 14644-1:2015 |
| 4. | 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 |
| 5. | 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 |
| 6. | 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/ and 1:2018 |
| 7. | Sterilization of health care products-Biological indicators- Part 1: General Requirements | EN ISO 11138-1:2017 |
| 8. | Sterilization of health care products- Microbiological methods- Part 1: Determination of a population of microorganisms on products | EN ISO 11737-1:2018 |
| 9. | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems | EN ISO 11607-1:2019 |
| 10. | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes | EN ISO 11607-2:2019 |
| 11. | Sterilization of health care products- Biological indicators for ethylene oxide sterilization processes | EN ISO 11138-2:2017 |
| 12. | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process | EN ISO 10993-1:2018 |
| 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 | EN ISO 10993- |

| | | |
|---|---|---|
| | blood | 4:2017 |
| 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 6: Tests for local effects after implantation | EN ISO10993-6:2016 |
| 17. | Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization Residuals | EN ISO 10993-7:2008 |
| 18. | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | EN ISO 10993-10:2021 |
| 19. | Biological evaluation of medical devices - Part 11 : Tests for systemic toxicity | EN ISO 10993-11:2017 |
| 20. | Biological evaluation of medical devices - Part 12 : Sample preparation and reference materials | EN ISO 10933-12:2021 |
| 21. | Medical devices - Quality management systems - Requirements for regulatory Purposes | EN ISO 13485:2016 |
| 22. | Medical devices – application of risk management to medical devices | EN ISO 14971:2019 |
| 23. | The European Union Medical Device Regulations | MDR 2017/745 |
| 24. | Clean rooms and associated controlled environments- bio-contamination control-general principles and methods | EN ISO 14698-1:2003 |
| 25. | Clean rooms and associated controlled environments- bio-contamination control-evaluation and interpretation of bio-contamination data | EN ISO 14698-2:2003 |

## 10. PACKAGING DETAILS AND SPECIFICATIONS

| ITEM | MATERIAL |
|---|---|
| Individual Sterile Packing | Pouch Packaging |
| Master Carton | 5 Ply Corrugation Box |

## 11. OTHER DETAILS

- **Intended Use:** The Nasal Oxygen Catheter/ Cannula is a device used to deliver supplemental oxygen or increased airflow to a patient or person in need of respiratory help.
- **Storage:** store in a cool and dry place and keep away from direct sunlight and extreme heat.
- **Method of Sterilization:** sterilized using ethylene oxide.
- **Shelf life:** 05 years from the month / date of sterilization.
- **Testing and Analysis:** Testing for sterility, pyrogen content and physical characteristics is performed on each batch before release.
- **Biocompatibility:** the product is tested as per the international standard ISO 10993-1 and parts applicable, and evaluation results are found conform to the standard requirements. The report from the actual study is available with Quality Assurance and will be available for review on request.
- **Disposal:** Dispose of the used product in to biohazard container / clinical wastage bag or according to hospital and country specific protocol.

## 12. COMPLIANCE INFORMATION

**Manufacturing Site Information:** Disposafe Health and Life Care Ltd., Plot No. 1 & 2 ,Sec-59, Phase-II, Ballabhgarh, Faridabad-121004, Haryana (INDIA)

**Drug Manufacturing License No.:** MFG/MD/2019/000106

**QMS Certification:** EN ISO 13485:2016

**CE Marking:** TUV-SUD Product Services GmbH

**GMDN Code:** 35201