

DISPOSAFE BRAND NAME	BRAND NAME
Oxygen Mask	Safe- Mask

1. PRODUCT DESCRIPTION

Oxygen mask is a single use sterile medical device sterilized by Ethylene oxide gas. The oxygen mask is designed to deliver oxygen to the patient during surgeries or critical care. An oxygen mask is made up of soft plastic attached with elastic and a plastic connector for connecting oxygen tube. Material of Composition: PVC, Aluminium, PP, PC, elastic.

2. DEVICE CLASSIFICATION AND RULE

The device is classified as Class IIa/Rule 2, medical device (classification as per ANNEX – VIII of EU MDR 2017/745).

3. PRODUCT CHARACTERISTICS & INTENDED USE

The oxygen mask is a single use, disposable device intended for delivering supplemental oxygen and monitoring exhaled carbon dioxide in non-intubated spontaneously breathing patients.

Intended Use: An oxygen mask provides a method to transfer breathing oxygen gas from a storage tank to the lungs.

- Swivel Connector for patient comfort.
- Made from food grade odour less PVC material.
- Elastic strap provided to position the mask properly.
- Long star lumen Kink resistant tube.
- Soft connector of funnel shape provided for easy connection to oxygen source.
- Sterile/Non-sterile, individually packed.

The product does not compromise with the clinical condition or the safety of patients.
This device to be used in ambient conditions and use of the device is restricted to a qualified doctor or paramedic.

4. PRODUCT VARIANTS

Following variants are available for the products

S. No.	Product	Size	Tube Length	GMDN Code	Classification/Rule
1.	**Oxygen Mask**	Small/Medium/Large	200cm	35171	Class-IIa, Rule-2

5. MATERIAL OF CONSTRUCTION

S. No.	Component Description	Material used
1.	Face Mask	PVC Soft (Poly Vinyl Chloride)
2.	Elastic Strap	Rubber
3.	Nose Clip	Aluminium
4.	Oxygen mask connector	PVC
5.	Oxygen Tube	PVC (Poly Vinyl Chloride)
6.	Tube Connector	PVC (Poly Vinyl Chloride)

6. PRODUCT SPECIFICATION

Size	Tube Length	Packing Inner/ Outer Unit
Small	200 CM	1/120
Medium	200 CM	1/120
Large	200 CM	1/120

7. REFERENCE COMPLIANCE STANDARD

S. No.	Standards	Standard Number
1)	Medical devices for conserving oxygen and oxygen mixtures	ISO 18779:2005
2)	Anaesthetic and respiratory equipment	ISO 23368:2022
3)	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	ISO 2859-1:1999
4)	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
5)	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
6)	Sterilization of health care products - Biological indicators - Part 1: General requirements	EN ISO 11138-1:2017
7)	Sterilization of health care products - Microbiological methods- Part 1: Determination of a population of microorganisms on products	EN ISO 11737-1:2018
8)	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2019
9)	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2019
10)	Biological evaluation of medical devices –part 1, Evaluation and testing within a risk management process	EN ISO 10993-1: 2018
11)	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008
12)	Medical devices – application of risk management to medical devices	ISO 14971:2019
13)	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	ASTM-F1980
14)	Medical devices - Quality management systems - Requirements for regulatory purposes	EN ISO 13485:2016
15)	Clean Rooms And Associated Controlled Environments: Classification of air cleanliness by particle concentration	EN ISO 14644-1:2015
16)	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

8. PACKAGING DETAILS and SPECIFICATIONS

ITEM	MATERIAL
Primary Packing	Pouch Packaging
Inner Carton	Kraft Pulp Paper
Master Carton	Kraft Pulp Paper

9. OTHER DETAILS

- **Intended Use:** refer the instruction for use before the application.
- **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 (Tube length, Seal strength test, packaging integrity, air leakage test, transparency of mask, fitting of connector, etc.) 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.

10. COMPLIANCE INFORMATION

Manufacturing Site Information: Disposafe Health and Life Care Ltd., Plot No. 1 & 2, Sec-59, Phase-II, Ballabgarh, 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: 35171