

AIRLIFE™ OXYGEN MASKS

DISPOSABLE | SINGLE USE | NON-STERILE | LATEX FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Name	AirLife Oxygen Masks
Company	AirLife
Manufacturer and Manufacturer Address	AirLife 2710 Northridge Dr NW, Suite A Grand Rapids, MI 49544
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I
FDA Product Code	BYG – Mask, Oxygen Mask
Classification – Canada	Class II
Classification – Australia	Class IIa
Classification – GHFT	Rule 2, According to the Principles of Medical Device Classification, GHFT/SG1/N15
GMDN Code	31285 – Mask, Air/Oxygen 35171 – Rebreathing Oxygen Face Mask 35173 – Non-Rebreathing Oxygen Face Mask 35175 – Venturi Masks
UMDNS Code	12449 – Masks, Air-Oxygen, Aerosol Administration
UNSPSC Code	42271708 – Medical Oxygen Masks or Parts
Usage	Maximum Use of 30 Days
Patient Population	Adults and Pediatrics
Sterility	Non-Sterile
Packaging	Individually Packaged in Clear Poly Bags (7.5" x 9.25"), 50/Case in Cardboard Boxes
Shelf Life	5 Years
Storage Conditions	Temperature: 0°C/32°F – 50°C/122°F
Disposal Instructions	Dispose of all materials in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Description: AirLife™ disposable oxygen masks are latex-free and made from soft, high-grade vinyl resins. The smooth, feathered edges are designed for patient comfort while reducing irritation points. The masks are designed for anatomical compatibility.

Intended Purpose: The Medium Concentration Oxygen Masks are intended for oxygen to be delivered to the patient at a prescribed concentration and/or flow rate. Oxygen tubing is connected to an oxygen source on one end and a mask on the other end to deliver oxygen to the patient.

The High Concentration, Non-rebreather Mask with Safety Vent and Without Safety Vent is intended for oxygen to be delivered to the patient at a prescribed concentration and/or flow rate. Oxygen tubing is connected to an oxygen source on one end and a mask on the other end to deliver oxygen to the patient.

The Venturi Mask is intended for oxygen to be delivered to the patient at a prescribed concentration and/or flow rate. Oxygen tubing is connected to an oxygen source on one end and a mask on the other end to deliver oxygen to the patient.

The 3-in-1 Mask is intended for oxygen to be delivered to the patient at a prescribed flow and/or flow rate. Oxygen tubing is connected to an oxygen source on one end and a mask on the other end to deliver oxygen to the patient. Non-rebreather, rebreather, medium concentration.

The Face Tent is intended as an oxygen delivery alternative for patient less tolerant of oxygen masks or cannulas.

Area of Use: Hospitals, surgical centers, pre-hospital.

Contraindications: None known.



DEVICE MATERIAL

COMPONENT	MATERIAL
Mask Body	Polyvinyl Chloride (PVC)
Head Strap	Elastic Polypropylene
Nose Clip	Aluminum, Polyethylene Coating
Tubing	Polyvinyl Chloride (PVC)
Flutter Valve	Silicone
Aerosol Connector	Polyvinyl Chloride (PVC)
Oxygen Connector	Polypropylene (PP)
U-Connector	Polyvinyl Chloride (PVC)
Jet Diluter	High-Density Polyethylene (HDPE)
Flex Tube	Ethylene Vinyl Acetate Copolymer

Biocompatibility: The masks have intact skin and indirect mucosal membrane contact and contact with patient airways. All materials utilized in these devices are biocompatible, meeting testing requirements per EN ISO 10993-1:2025. The devices have been assessed against EN ISO 18562-1:2024 and meet the gas pathway requirements per EN ISO 18562-2:2024 (particulate matter) and EN ISO 18562- 3:2024 (volatile organic substances).

They are intended for prolonged duration (> 24 hours and < 30 days).

The masks contain phthalates (DEHP).

The masks do not have natural rubber latex or BPA.

These masks do not contain blood derivatives or materials derived from animal or human tissue.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Tubing Length	7' (2.1 m) Standard Supply Tubing or 7' Crush Resistant Tubing
Tubing Connector	Trumpet or U/Connect-It Adapter (Female, Threaded O ₂ DISS)
Mask Type	Medium Concentration, Open Mask, Venturi Mask, High Concentration Rebreather Mask, High Concentration Non-Rebreather Mask, 3-in-1 Mask
Flow Rate	Up to 15 LPM

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DEVICE MATERIAL

PART NUMBER	DESCRIPTION	UOM	GTIN
001201	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, Medium Concentration Mask, and Crush-Resistant Oxygen Tubing	Each Case	10889483569214 30889483569218
001205	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration Rebreather Mask (No Valves), and Crush-Resistant Oxygen Tubing	Each Case	10889483569252 30889483569256
001205U	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration Rebreather Mask (No Valves), and U/Connect-It Adapter	Each Case	10889483569269 30889483569263
001210	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask Without Safety Vent, Crush-Resistant Oxygen Tubing, and U/Connect-It Adapter	Each Case	10889483569320 30889483569324
001210U	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask Without Safety Vent, Crush-Resistant Oxygen Tubing, and U/Connect-It Adapter	Each Case	10889483569320 30889483569324
001211	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, and High Concentration Non-Rebreather Mask With Safety Vent	Each Case	10889483569344 30889483569348
001211U	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration Non-Rebreather Mask With Safety Vent, and U/Connect-It Adapter	Each Case	10889483569337 30889483569331
001212	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, and High Concentration Non-Rebreather Mask Without Safety Vent	Each Case	10889483569351 30889483569355
001212U	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration Non-Rebreather Mask Without Safety Vent, and U/Connect-It Adapter	Each Case	10889483569368 30889483569362
001221	AirLife Face Tent Mask, Vinyl, and 6' (1.8 m) Corrugated Tubing	Each Case	10889483569399 30889483569393
001250	Pediatric Venturi Style Mask, Vinyl, Under-The-Chin Style	Each Case	10889483569535 30889483569539
001260U	Pediatric Oxygen Mask, Vinyl, Short Style, Medium Concentration Mask with U/Connect-It Adapter	Each Case	10889483569603 30889483569607
001262	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, Medium Concentration Mask, and 7' (2.1 m) Crush-Resistant Oxygen Tubing	Each Case	10889483569627 30889483569621
001262U	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, Medium Concentration Mask, U/Connect-It Adapter, and Crush-Resistant Oxygen Tubing	Each Case	10889483569634 30889483569638
001265	Pediatric Oxygen Mask, Vinyl, Short Style, High Concentration, Rebreather Mask (No Valves), and Crush-Resistant Oxygen Tubing	Each Case	10889483569672 30889483569676
001265U	Pediatric Oxygen Mask, Vinyl, Short Style, High Concentration, Rebreather Mask (No Valves), U/Connect-It Adapter, and Crush-Resistant Oxygen Tubing	Each Case	10889483569689 30889483569683
001267	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration Rebreather Mask (No Valves), and Crush-Resistant Oxygen Tubing	Each Case	10889483569702 30889483569706
001267U	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration, Rebreather Mask (No Valves), Crush-Resistant Oxygen Tubing, and U/Connect-It Adapter	Each Case	10889483569719 30889483569713
001268	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask With Safety Vent, and Crush-Resistant Oxygen Tubing	Each Case	10889483569726 30889483569720
001268U	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask With Safety Vent, U/Connect-It Adapter, and Crush-Resistant Oxygen Tubing	Each Case	10889483569733 30889483569737
001269U	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, High Concentration, Non-Rebreather Mask With Safety Vent, Supply Oxygen Tubing, and U/Connect-It Adapter	Each Case	10889483569764 30889483569768
001269UC	Pediatric Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask With Safety Vent, and U/Connect-It Adapter	Each Case	10889483569764 30889483569768
001361	Adult Oxygen Mask, Vinyl, Under-The-Chin, Medium Concentration Mask, U/Connect-It Adapter, and 7' (2.1 m) Crush-Resistant Oxygen Tubing	Each Case	10889483570128 30889483570122
001362	Adult Oxygen Mask, Vinyl, Under-The-Chin Style, 3-in-1 Mask, 7' (2.1 m) Crush-Resistant Tubing, and U/Connect-It Adapter	Each Case	10889483570135 30889483570139
001363	Adult Venturi Style Mask, Vinyl, Under-The-Chin Style Mask, 6" (15 cm) Flex Tube, Six Diluter Jets, Nebulizer Hood, Oxygen Tubing, and U/Connect-It Adapter	Each Case	10889483570142 30889483570146