

AIRLIFE™ UNDER-THE-CHIN AEROSOL MASKS

DISPOSABLE | SINGLE USE | NON-STERILE | LATEX FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Name	AirLife Aerosol 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, 510k Exempt
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	35172 – Aerosol Face Mask, Non-Rebreathing
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: Aerosol Masks are designed to cover the nose and face and are intended for the administration of aerosols (medication or oxygen) to the patient. The 22 mm tapered connector fits onto the nebulizer. The masks are light in weight and attached to patients using an elastic headband or over-the-ear loops.

Intended Purpose: Aerosol Masks are intended to provide the patient with the means of receiving aerosol.

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
Connector	Polyvinyl Chloride (PVC)

Biocompatibility: Per EN ISO 18562-1:2024, the masks are part of the gas pathway and have surface/mucosal contact. 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.

PART NUMBER	DESCRIPTION	UOM	GTIN
001206	AirLife Adult Aerosol Mask, Vinyl, Under-The-Chin Style	Each	10889483569276
		Case (50)	30889483569270
001207	AirLife Adult Aerosol Mask, Vinyl, Under-The-Chin Style, High Concentration	Each	10889483097311
		Case (50)	20889483097318
001263	AirLife Pediatric Aerosol Mask, Vinyl, Under-The-Chin Style	Each	10889483569641
		Case (50)	30889483569645