I-GUARD AEROSOL MASK

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

DEVICE MANUFACTURING SPECIFICATIONS	
Reference Number	1107, 8107, 8107V
Manufacturer	AirLife
Legal Manufacturer	Salter Labs 30 Supur Drive El Paso, TX 79906 USA
Classification – US	Class I Exempt, Medical Device
FDA Product Code	BYG - Oxygen Mask
Classification – EU	Class IIa
CE Mark/Notified Body	CE2797/BSI Group
Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	R030103 - Aerosol Masks and Systems
GMDN Code	35172 - Aerosol Face Mask, Non-Rebreathing
UMDNS Code	12449 - Masks, Air-Oxygen, Aerosol Administration
Made In	Mexico
Usage	Disposable, Single Patient Use
Sterile	Non-Sterile
Patient Population	Pediatric, Adult
Packaging	Individually Packaged, 10/Case or 50/Case
Shelf Life	5 Years

Description: A clear molded aerosol mask without aerosol tubing. The mask has micro-vented exhalations ports with directional flow valves and a tapered 22 mm OD connector. Mask 8107 does not have directional flow valves.

Intended Use: Intended for the administration of aerosols to the patient's nose and mouth. When connected to nebulizers, aids in medication delivery to the patient's nose and mouth simultaneously while diminishing incidence of aerosol medication getting into the eyes.

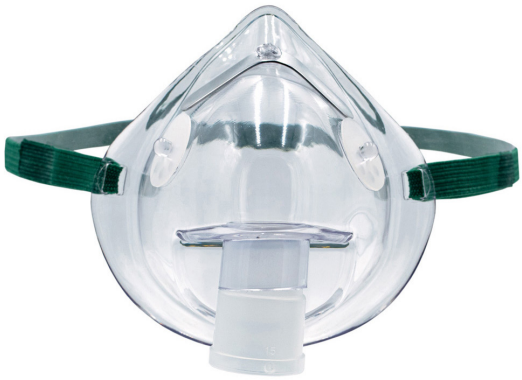
Area of Use: Hospitals, pre-hospital, home, surgical centers, skilled nursing facilities, medical clinics.

Contraindications: No known contraindications.

DEVICE SPECIFICATIONS

Description	Specification
Flow Rate	≥ 5 LPM
Operating Temperature	5^0 C to 40^0 C
Storage Temperature	-20^0C to 50^0C
Mask Connector	22 mm OD, 18 mm ID

Size	Part Number	UOM	GTIN/UDI
Pediatric	1107-0	Each	00607411800870
Pediatric	1107-0-10	Case	10607411800877
Pediatric	1107-0-50	Case	20607411800874
Adult	8107-0	Each	00607411800887
Adult	8107-0-50	Case	10607411800884
Adult	8107V-0	Each	00607411102035
Adult	8107V-0-50	Case	20607411102039



DEVICE MATERIAL

Component	Material
Mask	Polyvinyl Chloride
Grommet	Polypropylene
Nose Bar	Aluminum
Elastic Strap	Green, Braided Polyester Elastic/ Polyisoprene
Valve (1107 and 8107V)	Silicone

Latex: AirLife® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

Mercury-Lead: The selected materials do not contain lead or mercury.

Biocompatible per device classification in ISO 10993. AirLife manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMPs) as listed in 21 C.F.R. (U.S. code of Federal Regulations).

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