

MEDIUM CONCENTRATION OXYGEN MASK

NON-STERILE | DISPOSABLE | SINGLE PATIENT MULTIPLE USE | LATEX FREE | DEHP FREE | BPA FREE | MR SAFE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Oxygen Masks
Basic UDI	006074TF1001_MasksTM
Manufacturer	AirLife
Manufacturer Address	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 - Oxygen Mask
Classification - Canada	Class II
Classification - EU	Class IIa Rule 2
CE Mark/Notification Body	CE 2797/BSI Group
EU Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	R03010201 - Air/Oxygen Masks
GMDN Code	35171 - Rebreathing Oxygen Face Mask
UMDNS Code	12448 - Masks, Air-Oxygen
UNSPSC Code	42271708 - Medical Oxygen Masks
Usage	Disposable, Single Patient Use
Patient Population	Infant, Pediatric, Adult
Area of Use	Hospitals, Pre-Hospital, Home, Surgical Centers, Skilled Nursing Facilities, Medical Clinics
Sterility	Non-Sterile
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years
Disposal Instruction	The product and package should be disposed of according to local environmental and waste disposal regulations

Description: A clear molded mask to place over a patient's nose and mouth to administer oxygen with an elastic fixation device. Available with a standard ribbed or female thread grip end connector.

Intended Purpose: To provide supplemental oxygen to a spontaneously breathing patient.

Contraindications: No known contraindications.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Flow Rate (Infant)	4 LPM to 10 LPM
Flow Rate (Pediatric, Adult)	5 LPM to 15 LPM
% FDO ₂	Variable 35% to 50%
Operating Temperature	+5° C to +40° C
Storage Temperature	-20° C to +50° C
Tubing	3-Channel Safety
Tubing Length	7' (2.1 m)
End Connector	Ribbed, Push-On or Female Thread Grip (TG)



DEVICE MATERIAL

COMPONENT	MATERIAL
Tubing	Polyvinyl Chloride
End Connector	Polyvinyl Chloride
Mask	Polyvinyl Chloride
Grommet	Polyvinyl Chloride
Nose Bar	Aluminum
Strap	Green, Braided Polyester Elastic/Polyisoprene

Biocompatibility: All materials are biocompatible, meeting skin irritation and sensitization requirements. The Oxygen Masks not contain DEHP, natural rubber latex or BPA. This device does not incorporate medicinal products. This device does not contain blood derivatives or materials derived from animals or human tissue.

PART NUMBER	SIZE	UOM	GTIN
1114-7	Infant	Each	00607411801037
1114-7-50	Infant	Case	20607411801031
1122-7	Pediatric	Each	00607411800726
1122-7-50	Pediatric	Case	10607411800723
8110-7	Adult	Each	00607411800306
8110-7-50	Adult	Case	10607411800303
8110TG-7	Adult	Each	00607411800313
8110TG-7-50	Adult	Case	10607411800310