

Medium Concentration Oxygen Mask – Adult

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Medium Concentration Oxygen Mask, Adult	
Reference Number	8110TG-7-50
Manufacturer	SunMed LLC/Salter Labs
FDA Classification	Class I Exempt, Medical Device
FDA Product Code	BYG-Oxygen Mask
Canadian Medical Device	Class II Conformity Assessment Route: MDL
Classifications – EU	Class IIa, Rule 2, EU MDR 2017/745, Annex VIII
CE Mark/ Notified Body	CE 2797, Global- BSI Group (Global)
EMDN Code	R03010201, Air/Oxygen Masks
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	Adult
Packaging	Individually Packaged, 50/case

Description: A clear molded mask to place over a patient’s nose and mouth to administer oxygen with an elastic fixation device.

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

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

Contraindications: No known contraindications.

Benefits: Provide supplemental oxygen to help treat hypoxia, relieve shortness of breath, and pre-oxygenate a patient.

Device Specifications	
Description	Specification
Flow Rate	5 LPM to 15 LPM
% FDO ₂	Variable 35% to 50%
Operating Temperature	6° C to 40° C
Storage Temperature	-40° C to 60° C
Tubing	3-Channel Safety
Tubing Length	7' (2.1 m)
End Connector	Thread Grip, DISS O ₂

Product Material	
Part Description	Material
Tubing	Polyvinyl Chloride
End Connector	Polyvinyl Chloride
Mask	Polyvinyl Chloride
Grommet	Polypropylene
Nose Bar	Aluminum
Strap	Elastic Cloth

Part Number	UOM	GTIN/UDI
8110TG-7	Each	607411800313
8110TG-7-50	Case	10607411800310

Latex: SunMed® 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. SunMed 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).



TDS-10165 Rev 1

