

Medium Concentration Oxygen Mask

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Device Manufacturing Specifications	
Reference Number	SO-407
Manufacturer	SunMed LLC/Salter Labs
Classification – US	Class I
FDA Product Code	BYG-Oxygen Mask
Classification – EU	Class IIa
CE Mark/Notified Body	CE 2797/BSI Group
EU Authorized Representative	Mt Promedt Consulting GmbH
Classification – Canada	Class 2
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	Pediatric, Adult
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years

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

Intended Purpose: 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.

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).

Device Specifications	
Description	Specification
Flow Rate	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	Trumpet

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

Part Number	Size	UOM	GTIN/UDI
SO-407-0	Adult	Each	00607411800818
SO-407	Adult	Case	10607411800815



TDS

