

High Concentration, Non-Rebreather Oxygen Mask – Pediatric

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

High Concentration, Non-Rebreather Oxygen Mask with Safety Vent, Pediatric	
Reference Number	1180756
Manufacturer	SunMed LLC Sales Corp.
PDA Classification	O2 Concentration Medical Device
PDA Product Code	990 Oxygen Mask
Canadian Medical Device	Class II Conditionally Exempt Health - MDL
Classification - EU	Class IIa Rule 2. MDD 93/42/EEC Annex VI
CE Mark Number/Body	01 2187 (class II) class IIb class II
ENSO Code	920010001 Air Oxygen Mask
GMN Code	01 12, Animal Face Mask, Non-Respirating
SAMSR Code	12495 Mask, for Oxygen, Animal Administration
Made in	Mexico
UNSP	09400000 Single Patient Use
Style	Non-vented
Vendor Registration	Pediatric
Packaging	Technically Packaged 50/Case

Description: It does not contain a reservoir bag and oxygen supply tubing. The mask is attached over a patient's nose and mouth and held in place with an elastic headband. The non-rebreather mask has a one-way valve above the reservoir bag to prevent the patient from rebreathing previously exhaled gases and a one-way valve over the inlet for air flow into the mask.

Intended use: To provide supplemental oxygen to a patient with a breathing problem.
Area of use: Hospital, pre-hospital, home, surgical centers, skilled nursing facilities, medical clinics.
Contraindications: No known contraindications.
Warnings: Provide supplemental oxygen to help treat hypoxia, follow direction of health care provider and patient.

Device Specifications	
Flow Rate	± 10 LPM, Adjust flow to keep bag 2/3 full during inspiration
Flow Rate	Variable 5LPM to 15LPM
Operating Temperature	0°C to 40°C
Storage Temperature	40°C to 60°C
Tubing	4-Chamber Safety
Tubing Length	7.0 m (23')
End Connector	Standard, Universal Push-On

Product Material	
End Connector	Plastic
Tubing	Polyvinyl Chloride
End Connector	Polyvinyl Chloride
Mask	Polyvinyl Chloride
Headband	Polypropylene
Nose Pin	Stainless
Strap	Elastic Cloth
Valve	Silicone, Cloth
Reservoir Bag	Polyvinyl Chloride

Part Number	Unit	Quantity
1180756	Case	1000/21 (1000/21)
01497340	Case	1000/21 (1000/21)



Latex: SunMed® does not utilize latex or latex derivatives material in manufacturing products. To the best of our knowledge, latex does not contain components or finished goods during the manufacturing process.

Materials: If a selected material can be identified, SunMed was not intentionally utilized as part of the manufacturing process.

Mercury: SunMed The selected material does not contain lead or mercury.

Biocompatibility: Per device classification, SunMed SunMed manufactures product from medical grade material in compliance with Good Manufacturing Practices (GMP) as defined in 21 CFR, U.S. Code of Federal Regulations.



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