

1600 Adult Nasal Cannula with Ribbed Connector, 50/case

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Salter-Style® 1600 Adult Nasal Cannula				
Reference Number	1600-1-50	1600-3-50	1600-4-50	1600-7-50
	1600-9-50	1600-10-50	1600-12-50	1600-14-50
	1600-15-50	1600-16-50		
Manufacturer	SunMed LLC/Salter Labs			
FDA Classification	Class I Medical Device			
FDA Product Code	CAT – Nasal Oxygen Cannula			
Canadian MDR	Class II, Conformity Assessment Route: Medical Device License			
Classifications – EU	Class IIa, Rule 2, MDR 2017/745, Annex VIII			
CE Mark/Notified Body	CE2797 / BSI Group			
EMDN Code	R03010203, Air/Oxygen Nasal Cannula			
GMDN Code	35201 Nasal Cannulas			
UMDNS Code	12799, Cannulae, Nasal Oxygen			
Usage	Disposable, Single Patient Multiple Use			
Sterile	No			
Patient Population	Adult			
Packaging	Individually Packaged, 50/Case			

Intended use: Over-the-ear style nasal cannula for delivery of supplemental oxygen to nares of a spontaneously breathing patient.

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

Duration of use: Discard and replace nasal cannula every 14 days or sooner if the cannula becomes soiled or damaged.

Contraindications: No known.

Caution: Keep tubing straight and free of kinks. Do not sterilize.

Warning:

- If patient develops infection, skin irritation or material sensitization consult physician.
- Patient may become hypoxic if oxygen flow is interrupted.
- Position tubing to avoid strangulation or tripping hazard.
- Do not place anything on oxygen tubing that may obstruct flow.
- Use oxygen product as prescribed.
- When using oxygen, do use open flame or heat source.

Device Specifications	
Description	Specification
Oxygen Tubing Length	1' (0.3 m), 3' (0.9 m), 4' (1.2 m), 7' (2.1 m), 9' (2.7 m), 10' (3.0 m), 12' (3.7 m), 14' (4.3 m), 15' (4.6 m), 16' (4.9 m)
Oxygen Supply Tubing	Clear, 3-Channel Safety Tubing
Oxygen Flow Rate	0 LPM to 6 LPM
Tubing End Connector	Universal Ribbed
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

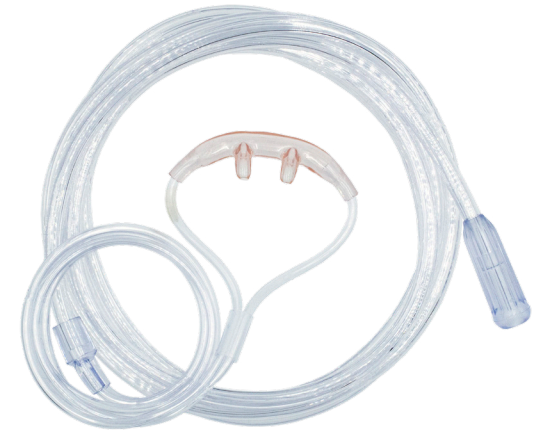
Product Material	
Part Description	Material
Nasal Face Piece	Plastisol, Reddish Tint
Oxygen Tubing	Polyvinyl Chloride, 3-Channel
Headset Tubing	Polyvinyl Chloride, Smooth Bore
Tubing End Connector	Polyvinyl Chloride
Bolo	Low Density Polyethylene

Latex: Salter Labs® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge, latex does not come in contact with components or finished good 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. Salter Labs 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).



Part Number	UOM	GTIN/UDI
1600-1	Each	00607411100000
1600-1-50	Case	10607411100007
1600-3	Each	00607411100161
1600-3-50	Case	10607411100168
1600-4	Each	00607411100192
1600-4-50	Case	10607411100199
1600-7	Each	00607411100253
1600-7-50	Case	10607411100253
1600-9	Each	00607411100277
1600-9-50	Case	10607411100274
1600-10	Each	00607411100017
1600-10-50	Case	10607411100014
1600-12	Each	00607411100031
1600-12-50	Case	10607411100052
1600-14	Each	00607411100055
1600-14-50	Case	10607411100052
1600-15	Each	00607411100062
1600-15-50	Case	10607411100069
1600-16	Each	00607411100079
1600-16-50	Case	10607411100076

TDS-10134 Rev 1

