1611 Neonatal Nasal Cannulas with Trumpet Connector

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Salter-Style® 1600 Neonatal Nasal Cannula			
Reference Number	1611-7-50		
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	Neonatal		
Approximate Weight	1400 g to 2.5 kg		
Approximate Age	28 to 36 Weeks GA		
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, NICU.

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

Contraindications: No known.

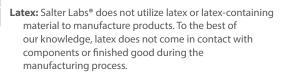
Caution: Keep tubing straight and free of kinks. Do not sterilize.

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	7' (2.1 m)	
Oxygen Flow Rate	0 LPM to 3 LPM	
Tubing End Connector	Universal, Trumpet Connector	
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	



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
1611-7	Each	607411100635
1611-7-50	Case	10607411201032

