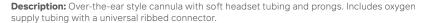


16SOFT™ NASAL CANNULA WITH RIBBED CONNECTOR - ADULT

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

DEVICE MANUFACTURING SPECIFICATIONS		
Reference Number	16SOFT	
Manufacturer	SunMed LLC/Salter Labs	
Classification – US	Class I Medical Device	
FDA Product Code	CAT – Nasal Oxygen Cannula	
Classification – EU	Class Ila	
CE Mark/Notified Body	CE 2797/BSI Group	
Authorized Representative	Mt Promedt Consulting GmbH	
Classification - Canada	Class 2	
EMDN Code	R03010203, Air/Oxygen Nasal Cannula	
GMDN Code	35201 Nasal Cannulas	
UMDNS Code	12799, Cannulae, Nasal Oxygen	
Made In	Mexico	
Usage	Disposable, Single Patient Multiple Use	
Sterile	No	
Patient Population	Adult	
Packaging	Individually Packaged, 50/Case	
Shelf Life	5 Years	



Intended Purpose: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils at flows 0 LPM to 6 LPM.

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

Duration of Use: Discard and replace nasal cannula every 30 days or sooner if the cannula becomes soiled or damaged.

Contraindications: No known.

DEVICE MATERIAL

Material	
Plastisol, Reddish Tint	
Polyvinyl Chloride, 3-Channel	
Soft Durometer, Polyvinyl Chloride, 3-Channel	
Polyvinyl Chloride	
Low Density Polyethylene	

Latex: AirLife® 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 (GMP's) as listed in 21 C.F.R. (U.S. code of Federal Regulations).



DEVICE SPECIFICATIONS

Description	Specification
O ₂ Supply Tubing	Clear, 3-Channel Safety
O ₂ Supply Length	2' (0.6 m), 4' (1.2 m), 7' (2.1 m), 14' (4.2 m), 25' (7.6 m)
O ₂ Flow Rate	0 LPM to 6 LPM
Tubing End Connector	Universal, Push-On, Ribbed
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C

Part Number	UOM	GTIN
16SOFT-4	Each	00607411915833
16SOFT-4-50	Case	10607411915830
16SOFT-7	Each	00607411915772
16SOFT-7-50	Case	10607411915779
16SOFT-14	Each	00607411915840
16SOFT-14-50	Case	10607411915847
16SOFT-25	Each	00607411915857
16SOFT-25-50	Case	10607411915854