

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 IIa
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

Description: Over-the-ear style cannula with soft headset tubing and prongs. Includes oxygen supply tubing with a universal ribbed connector.

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

Component	Material
Nasal Face Piece	Plastisol, Reddish Tint
O ₂ Tubing	Polyvinyl Chloride, 3-Channel
Headset Tubing	Soft Durometer, Polyvinyl Chloride, 3-Channel
Tubing End Connector	Polyvinyl Chloride
Bolo	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