

1602 Cannulas with Ribbed Connector – Pediatric

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

Device Manufacturing Specifications	
Reference Number	1602
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	CE2797/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	Pediatric
Approximate Weight	≥ 12.5 kg
Approximate Age	≤ 6 Years of Age
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years

Description: Over-the-ear style headset tubing and nasal prongs. Includes oxygen supply tubing with a ribbed end connector.

Intended Purpose: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through both nostrils at flows from 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 Specifications	
Description	Specification
O ₂ Supply Tubing	Clear, 3-Channel Safety
O ₂ Tubing Length	1' (0.3 m), 4' (1.2 m), 7' (2.1 m), 9' (2.7 m), 14' (4.2 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

Device Material	
Component	Material
Nasal Face Piece	Plastisol, Reddish Tint
O ₂ 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
1602-1	Each	00607411100468
1602-1-50	Case	10607411100465
1602-4	Each	00607411101779
1602-4-50	Case	10607411101776
1602-7	Each	00607411100550
1602-7-50	Case	20607411100554
1602-9	Each	00607411100567
1602-9-50	Case	10607411100564
1602-14	Each	00607411100475
1602-14-50	Case	10607411100472

TDS-10140 Rev 2

