1600-1600Q Nasal Cannula with Ribbed Connector – Adult

Device Manufacturing Specifications

Reference Number	1600, & 1600Q
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	Adult
Packaging	Individually Packaged, 20/Case, 25/Case or 50/Case
Shelf Life	5 Years

Description: Over-the-ear style headset tubing with nasal prongs. Includes oxygen supply tubing with a ribbed end connector.1600Q has a larger face piece.

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 (1600 series and 0LPM-8LPM (1600Q series)

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

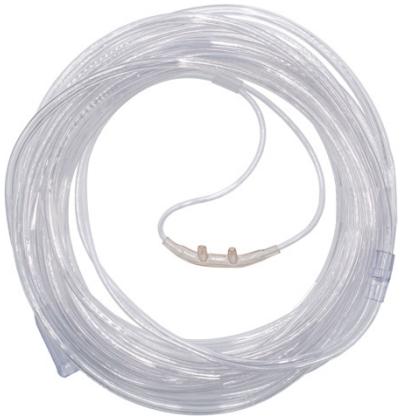
Duration of Use: Discard and replace nasal cannula every 30 days or sooner if the cannula becomes soiled or damaged.

Device Material

Component	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

Device Specifications

Description	Specification
O_2 Supply Tubing	Clear, 3-Channel Safety
O_2 Supply Length 50/Case	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)
O_2 Tubing Length 25/Case	20' (6.1 m), 21' (6.4 m), 24' (7 m), 25' (7.6 m)
O_2 Tubing Length 20/Case	30' (9.1 m), 35' (10.7 m), 40' (12.2 m), 50' (15.2 m)
O_2 Flow Rate	0 LPM to 6 LPM (1600); 0 LPM - 8 LPM (1600Q)
Tubing End Connector	Universal, Ribbed
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C



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.

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	Part Number	UOM	GTIN/UDI	Part Number	UOM	GTIN/UDI
1600-1	Each	00607411100000	1600-12-50	Case	10607411100038	1600-25	Each	00607411100154
1600-1-50	Case	10607411100007	1600-14	Each	00607411100055	1600-25-25	Case	10607411100151
1600-3	Each	00607411100161	1600-14-50	Case	10607411100052	1600-30	Each	00607411100178
1600-3-50	Case	10607411100168	1600-15	Each	00607411100062	1600-30-20	Case	10607411100175
1600-4	Each	00607411100192	1600-15-50	Case	10607411100069	1600-35	Each	00607411100185
1600-4-50	Case	10607411100199	1600-16	Each	00607411100079	1600-35-20	Case	10607411100182
1600-7	Each	00607411100253	1600-16-50	Case	10607411100076	1600-40	Each	00607411100208
1600-7-50	Case	10607411100250	1600-20	Each	00607411100116	1600-40-20	Case	10607411100205
1600-9	Each	00607411100277	1600-20-25	Case	10607411100113	1600-50	Each	00607411100239
1600-9-50	Case	10607411100274	1600-21	Each	00607411100123	1600-50-20	Case	10607411100236
1600-10	Each	00607411100017	1600-21-25	Case	10607411100120	1600Q-7	Each	00607411100369
1600-10-50	Case	10607411100014	1600-24	Each	00607411100147	1600Q-7-25	Case	10607411100366
1600-12	Each	00607411100031	1600-24-25	Case	10607411100144	1600Q-7-50	Each	20607411100363
1600Q-14	Each	00607411100376	1600Q-25	Each	00607411100321	1600Q-7-25	Case	10607411100236
1600Q-14-50	Case	10607411100373	1600Q-25-25	Case	10607411100328			

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