



2365 Camino Vida Roble
Carlsbad, CA 92011
United States

Date: 17-March-2017

Reference: SO-406, Adult Nasal Oxygen Cannula with 3-channel tubing.

Data Sheet

Part Description	Material
Facepiece (Adult)	Polyvinylchloride
Tubing, 19"	Polyvinylchloride
Bolo	Low Density Polyethylene
Connector, "Y"	Polyvinylchloride
Tubing, 3-channel	Polyvinylchloride
Connector, End Piece	Polyvinylchloride

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)

I certify that the above information is accurate to the best of my abilities.

Please do not hesitate to contact me if I can be of any further assistance. My email address is mcollins@salterlabs.com and my phone number is 760-795-7102.

Peggy Collins
Regulatory Affairs
Salter Labs

SALTER LABS DE MEXICO, S.A. DE C.V.

REVISION: D
C.O. #: DCR-02159
EFFECTIVE DATE: 12/22/2015

DEVICE SPECIFICATIONS
ADULT NASAL CANNULA
WITH 7' 3-CHANNEL TUBE

PRODUCT # SO-406

PAGE 1 OF 1

1. NAME OF PRODUCT

Salter-Style Adult cannula

2. PERFORMANCE CHARACTERISTICS

Over-the-ear style cannula with 3 channel 7' oxygen supply tubing. Intended to deliver an oxygen flow to a patient nasally that will range from 0 to 6 liters per minute. Inlet connector - standard push on.

3. CLASSIFICATION

Class I Medical Device U.S. F.D.A
Class IIa EC Directive 93/42/EEC Annex IX
Class II Canadian Medical Device Regulations

4. PHYSICAL CHARACTERISTICS

Clear, lightweight. Large 7' supply tubing has 3 channels to resist kinking. The facepiece is formed by dipping and has curved nasal prongs, .640" apart center line to center line.

Facepiece (part #205023) - PVC, Platisol - Redish tint

Bolo (part #105020) - Low density Polyethylene, Natural

Over-the-ear tubing (part # 205100) - PVC, Clear 19" smooth bore .130" O.D. x .075" I.D.

Connector, wye (part #205011) - PVC, clear.

Supply tubing (part #206007) - PVC, 7' 3-channel .240" O.D. x .030" wall, clear.

Connector, End piece, (part # 205012) PVC, clear.

5. PACKAGING

Product shall be coiled and placed in an 8" x 10" clear polyethylene bag with label and heat sealed. Information required for identification and directions for use shall be on one label.

6. ENVIRONMENTAL LIMITATIONS

Product should be stored in a clean dry place, and should be kept away from fire.

7. USER SAFETY AND PERFORMANCE CONSIDERATIONS

Disposable, single patient use. Supply tubing has 3 channels to resist kinking.

For best comfort and performance, tubing should lay or curve without twisting or folding.

8. MATERIALS

The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

The selected materials are not made with natural rubber latex.

The selected materials do not contain lead or mercury.

Biocompatible per device classification in ISO 10993.