

4MSF3-L-7 O₂/EtCO₂ Nasal Sampling Cannula – Long Term Use

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

| O ₂ /EtCO ₂ Nasal Sampling Cannula | |
|--|---|
| Reference Number | 4MSF3-L-7-6-25 |
| Manufacturer | SunMed LLC/Salter Labs |
| U.S. FDA | Class II, K151421 & K133806 |
| Product Code | Code CCK – Carbon Dioxide Gas Analyzer |
| US Registration | 21 CFR 868.1400 |
| Canadian MDR | Class II, Conformity Assessment Route: Medical Device License |
| Made In | Mexico |
| CE Mark / Notified Body | CE 2797, BSI Group |
| Device Classification – EU | Class IIa, Rule 2, EU MDR 2017/745, Annex VIII |
| EMDN Code | R9099 Respiratory and Anesthesia Devices, other Z120306 Vital Signs Monitoring Consumables |
| GMDN Code | 36306, Carbon-Dioxide – Sampling Nasal Oxygen Cannula |
| UMDNS Code | 12700, Cannulae, Nasal Oxygen. |
| Oxygen Delivery | Yes |
| CO ₂ Sampling | Yes |
| Nafion | Yes |
| Patient Population | Adult |
| Usage | Disposable, Single Patient Multiple Use |
| Duration of Use | Prolonged Use |
| Sterile | No |
| Packaging | Individually Packaged (25/Case or 100/Case) |
| Shelf Life | 3 Years |

Intended use: The O₂/EtCO₂ Nasal Sampling Cannula is intended to be used to deliver low flow oxygen, and to monitor exhaled CO₂ in a spontaneously breathing patient.

Duration: Includes Nafion tubing for use in high humidity environment or long-term use.

Monitors: Reflective technology. For use with capnography monitors and modules that utilize Microstream technology.

Patient population: For use with non-intubated adult patients.

Area of use: Locations where procedures are performed where the patient requires monitoring of exhaled gases. Hospital, sub-acute, medical clinic, pre-hospital, surgical centers.

Contraindications: No known.

Caution: Keep tubing straight and free of kinks. Do not sterilize.

| Device Specifications | |
|---|--------------------|
| Description | Specification |
| CO ₂ Sampling Line Internal Diameter | 0.040" (1.02 mm) |
| CO ₂ Sampling Line Length | 6' (1.8 m) |
| CO ₂ Sampling | ≤0.065 lpm |
| CO ₂ Sampling Line End Connectors | Female Reflective |
| CO ₂ Sampling Line Filter | 0.22µm Filter |
| Oxygen Tubing Length | 7' (2.1 m) |
| Oxygen Tubing End Connector | Female Thread Grip |
| Oxygen Flow Rate – Adult | ≤4 lpm |
| Oxygen Flow Rate – Pediatric & Infant | ≤3 lpm |
| Operating Temperature | 5°C to 40°C |
| Storage Temperature | -20°C to 50°C |

| Product Material | |
|---------------------------|------------------------------------|
| Part Description | Material |
| Nasal Face Piece | Plastisol |
| CO ₂ Tubing | Polyvinyl Chloride |
| CO ₂ Connector | Acrylonitrile Butadiene Styrene |
| Moisture Management | Nafion |
| Bolo | Low Density Polyethylene |
| Filter Outer | Acrylonitrile Butadiene Styrene |
| Filter Media | Hydrophobic Polypropylene Membrane |

| Part Number | UOM | GTIN |
|--------------|------|----------------|
| 4MSF3-L-6 | Each | 0607411950933 |
| 4MSF3-L-6-25 | Case | 10607411950930 |



Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods 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 and ISO 18562. SunMed 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).

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