## TDS-10101 Rev

## **4000F EtCO<sub>2</sub> Nasal Sampling Cannula – Adult**

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

EtCO <sub>2</sub> Nasal Sampling Cannula, Female Luer			
Reference Number	4000F-2-25 4000F-7-10 4000F-7-25		
Manufacturer	SunMed LLC/Salter Labs		
FDA	Class II K151421		
Product Code	CCK Analyzer, Gas Carbon-Dioxide, Gaseous-Phase		
CE Mark / Notified Body	2797/BSI Group		
Device Classification – EU	Class I, Rule 2 EU MDR 2017/745 Annex VIII		
EMDN Code	R9099, Respiratory and Anesthesia Devices, Other Z120306, Vital Signs Monitoring Instrument		
GMDN Code	36306, Carbon Dioxide Nasal Cannula		
UMDNS Code	11838, Gas Sampling Unit		
Made In	Mexico		
Oxygen Delivery	No		
CO <sub>2</sub> Sampling	Yes		
Patient Population	Adult		
Usage	Disposable, Single Patient Use		
Sterile	Non-Sterile		
Packaging	Individually packaged, 10/case (4000F-7-10) or 25/case		
Shelf Life	3 years		

**Description:** Over-the-ear style EtCO<sub>2</sub> nasal sampling cannula with a female luer style connector.

**Intended use:** The Nasal CO<sub>2</sub> Sample Line is intended to be used to sample exhaled gas in spontaneously breathing patients requiring expired gas monitoring.

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

Usage: Non-sterile, disposable, single-patient multiple use.

**Area of use:** Locations where procedures are performed where the patient requires monitoring of exhaled gases e.g. procedural sedation, lower GI procedures, EMS, or surgical cases. Used in hospital, sub-acute, and pre-hospital settings.

Contraindications: No known.

**Benefits:** Notifies clinicians of change in patient's ventilatory status.

Device Specifications			
Description	Specification		
CO <sub>2</sub> Sampling Line Internal Diameter	0.050" (1.27 mm)		
CO <sub>2</sub> Sampling Line Length	2'(0.6 m), 7'(2.1 m)		
CO <sub>2</sub> Line End Connectors	Female Luer Style		
CO₂ Sampling Rate	≤ 0.5 LPM		
Operating Temperature	5°C to 40°C		
Storage Temperature	-20°C to 50°C		

Product Material			
Part Description	Material		
Nasal Face Piece	Plastisol		
Headset Tubing	Polyvinyl Chloride		
CO <sub>2</sub> Tubing	Polyvinyl Chloride		
CO <sub>2</sub> Connector	Acrylonitrile Butadiene Styrene		
Bolo	Low Density Polyethylene		

Part Number	UOM	GTIN
4000F-2	Each	00607411401022
4000F-2-25	Case	10607411401029
4000F-7	Each	00607411400018
4000F-7-10	Case	10607411400015
4000F-7-25	Case	20607411400012



Latex: SunMed® does not utilize latex or latexcontaining 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. 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).

