VITAL SIGNS® ANESTHESIA GAS SAMPLING LINE

NON-STERILE | LATEX FREE | DEHP FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	Vital Signs Gas Monitoring Products
Manufacturer	AirLife Finland Oy
Manufacturer Address	Kuortaneenkatu 2, FI-00510 Helsinki, Finland
Country of Origin/Made In	China – 73306, 73318-HEL, 733188, 73319-HEL, 733199, GSLCO31010 Estonia – 733170, 73325-HEL
Classification – US/510k #	Class II (GSLCO31010- K171678)
FDA Product Code	FDA – Analyzer, Gas, Oxygen, Gaseous-Phase
Classification – Australia	Class IIa
Classification – Brazil	Class II
Classification – Canada	Class II
Classification – EU	Class IIa, Rule 2
CE Mark/Notification Body	CE 2797 / BSI Group
EMDN Code	Z1203020485 – Gaseous Exchange Monitoring Instruments - Consumables
GMDN Code	45566 – Gas-Sampling/Monitoring Respiratory Tubing, Single-Use
UMDNS Code	11848 Gas Sampling Units
UNSPSC Code	42272218 – Ventilator Gas Sampling Ports or Lines
Duration of Use	Single Use. The device is intended for short term use for more than sixty minutes and less than thirty days.
Patient Population	Pediatric to Adult
Sterility	Non-Sterile. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
Packaging	Individually Packaged in Low-Density Polyethylene (LDPE) Pouches
Shelf Life	5 Years
Storage Conditions	-20°C/-4°F to +50°C/+122°F
Disposal Instruction	This product and package should be disposed of according to local environmental and waste disposal regulations.

Description: Gas sampling lines act as conduit for gas sample from breathing circuit to a monitoring device. The gas sampling line can be used for monitoring CO_2, O_2, N_2O and anesthetic agents. The gas sampling lines have standardized Luer connectors at both ends, enabling the connection to a suitable component in the breathing circuit and to the monitoring device. The gas sampling lines have indirect contact via gas passing through sampling site. These devices are indicated for use by healthcare professionals.

Intended Purpose: Gas Sampling Lines: Intended to deliver gas sample to a monitoring device for themeasurement of respiratory gases.
Exhaust Line: Intended for gas return of scavenging.

Contraindications: None Known.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Length	2 m (7'), 3 m (10'), 6 m (20')
Internal Diameter	1.2 mm (±0.07 mm)
Connectors	Male/Male Luer; Male/Female Luer
Sampling Line (733170, 73325-HEL)	Use with D-Lite or Pedi-Lite Sensors
Sampling (73306, 73318-HEL, 733188, 73319-HEL, 73199, GSLCO31010)	Use with GE Healthcare Compact Airway modules and CARESCAPE Respiratory modules for monitoring CO_2, O_2, N_2O and anesthetic agents and with E-miniC for monitoring CO_2



DEVICE MATERIAL

COMPONENT	MATERIAL
Luer Lock Connector	Acrylic
Sampling Line (73306, 73318-HEL, 733188, 73319-HEL, 73199)	Thermoplastic Elastomer (TPE)
Sampling Line (733170, 73325-HEL, GSLCO31010)	Co-Extruded Polyvinyl Chloride (PVC)/ Polyethylene (PE)

Biocompatibility: The gas sampling lines do not contain DEHP, or natural rubber latex or BPA. These devices, including their components, do not contain blood derivatives, and do not contain materials derived from animal or human tissue. The gas sampling lines are not considered to be a medicinal product.

PART	MATERIAL	UOM	UDI/GTIN
73306	Anesthesia Gas Sampling Line, Disposable, 6 m (20'), 5/Pkg	Each	10889483588628
		Pkg	20889483588625
73318-HEL	Anesthesia Gas Sampling Line, Disposable, 2.0 m (7'), 10/Pkg	Each	10889483588659
		Pkg	20889483588656
733188	Anesthesia Gas sampling line, Disposable, 2.0 m (7'), 10/Pkg, 100/Case	Each	10889483588659
		Pkg	20889483588656
		Case	30889483588646
73319-HEL	Anesthesia Gas Sampling Line, Disposable, 3.0 m (10'), 10/Pkg	Each	10889483588673
		Pkg	30889483588660
733199	Anesthesia Gas Sampling line, Disposable, 3.0 m (10'), 10/Pkg, 100/Case	Each	10889483588673
		Pkg	20889483588670
		Case	30889483588660
733170	Anesthesia Gas Sampling Line, Disposable with Male/Male Elbow Connector, 3 m (10') 10/Pkg	Each	10889483588635
		Pkg	20889483588632
73325-HEL	Gas Sampling Line, M/F Luer, Disposable, 3.0 m (10') 10/Pkg	Each	10889483588697
		Pkg	20889483588694
GSLC031010	Gas Sampling Line, Coextruded, Disposable, 3.0 m (10') 10/Pkg	Each	10889483600511
		Pkg	20889483600518

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