VIXONE™ DISPOSABLE NEBULIZERS

NON-STERILE | DISPOSABLE | SINGLE PATIENT MULTIPLE USE | LATEX FREE | DEHP FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS	
Product Family	VixOne Disposable Nebulizer
Company	AirLife
Manufacturer Address	SunMed LLC 2710 Northridge Dr. NW, Suite A Grand Rapids, MI 49554 USA
Country of Origin/Made In	Mexico
Classification – US	Class II
FDA Product Code	CAF Nebulizer (Direct Patient Interface)
IMDRF (GHFT) Classification	Class B, According to GHTF/SG1/N77:2012
Classification – Canada	Class II
GMDN Code	31309 - Nebulizing System Delivery Set, Single Use
UMDNS Code	12712 - Nebulizers
UNSPSC Code	42271802 - Nebulizer or Accessories
Usage	Replace Every 7 Days or After 21 Cleaning Cycles
Patient Population	Pediatric, Adult
Area of Use	Hospital, Home
Sterility	Non-Sterile
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years
Disposal Instruction	Safely dispose of device in accordance with local, state, or national biohazard regulations.

Description: The nebulizer device is non-sterile, disposable, and for single patient use to deliver medicated aerosols to the patient. Available packaged with pediatric or adult aerosol masks.

Intended Purpose: Nebulizers are intended to be used under medical supervision to deliver diagnostic formulations and aerosolized medications that are prescribed for delivery to a patient's lungs.

Contraindications: None Known.

PART	DESCRIPTION	UOM	GTIN
0209	Disposable Nebulizer, Mouthpiece, Anti-Spill Tee, 7' Kink Resistant Tubing with Threaded Nut & Flex Hose	Each Case	10889483223932 20889483223939
0210	Disposable Nebulizer, Mouthpiece, Anti-Spill Tee, 7' Kink Resistant Tubing & Flex Hose	Each Case	10889483223932 20889483223946
0210-14	Nebulizer, Mouthpiece, Tee, 14' Tubing, 6" Flex Hose	Each Case	10889483227718 20889483227715
0214	Disposable Nebulizer, Unassembled, No Tubing	Each Case	10889483224113 20889483224110
0217	Disposable Nebulizer, Anti-Spill Tee, 7' Kink Resistant Tubing	Each Case	10889483224120 20889483224127
0218	Nebulizer, Mouthpiece, Tee	Each Case	10889483224137 20889483224134
0222	Disposable Nebulizer, Mouthpiece, Anti-Spill Tee, 7' Kink Resistant Tubing	Each Case	10889483224144 20889483224141
0310	Disposable Nebulizer, with 7' Kink Resistant Tubing and Adult Mask	Each Case	10889483229996 20889483229993
0311	Disposable Nebulizer, with 7' Kink Resistant Tubing and Pediatric Mask	Each Case	10889483220008 20889483220005
0312	Disposable Nebulizer, with 7' Kink Resistant Tubing and Super Spike Pediatric Mask	Each Case	10889483230015 20889483220012
0313	Disposable Nebulizer, with 7' Tubing, Threaded Nut and Super Spike Pediatric Mask	Each Case	10889483230022 20889483220029
0319	Disposable Nebulizer, with 7' Tubing, Threaded Nut and Pediatric Mask	Each Case	10889483220039 20889483230036



DEVICE MATERIAL

COMPONENT	MATERIAL
Supply Tubing, KROT Tubing, and Tubing Connectors	Polyvinyl Chloride (PVC)
Nebulizer Bowl	Polystyrene
Nebulizer Top and Nebulizer Universal Anti-Spill Tee	Polypropylene (PP)
Nebulizer Jet	Styrene-Butadiene Copolymer (SBC)
Nebulizer Mouthpiece	High-Density Polyethylene (HDPE)
Flex (10 mm x 12") Tubing, and Corrugated Tubing (22 mm)	Ethylene-Vinyl Acetate Low Density Polyethylene (EVA-LDPE)
Aerosol Mask	Polyvinyl Chloride (PVC)
Mask Strap	Spandex Fiber-Elastane Filament Yarn
Mask Swivel Adapter	Polypropylene (PP)
Super Spike Face Mask	Polyvinyl Chloride (PVC)
Packaging Material	Polybag, Cardboard Box

Material Statement: The subject devices are not composed of natural rubber latex, and the selected materials are not formulated with Di-2-ethylhexyl phthalate (DEHP) or bisphenol A (BPA). Additionally, the devices do not contain blood derivatives or materials of animal or human origin. The overall biocompatibility profile supports that the devices are safe for patient contact under their intended conditions of use.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Flow Rate	4–10 LPM
Supply Tubing	7', 14'
Medication Cup	10 mL
Connector	Trumpet, Female Threaded Nut

TDS-20782-C1 Rev 1