AIR-Q®3 EXCHANGER

SINGLE-PATIENT | NON-STERILE | DEHP FREE | LATEX FREE | MR SAFE

DEVICE MANUFACTURING SPECIFICATIONS	
Reference Number	10-1004, 10-1005, 10-1006
Manufacturer (Legal)	SunMed, LLC (AirLife)
Manufacturer Address	2710 Northridge Drive NW, Suite A Grand Rapids, MI 49455 USA
Made In	China
Classification – US	Class I, Exempt
FDA Product Code	BSR - Stylet, Tracheal Tube
Classification – Australia	Class I, 217850
Classification – Brazil	Class II, 72852
Classification – Canada	Class II
Classification – Japan	Class II, BG3040242
Classification – European Union	Class IIa, Rule 5
CE Mark	CE 2797
EU Authorized Representative	MT Promedt Consulting GmbH
UK Authorized Representative	MT Promedt Consulting Ltd
EMDN Code	R01020199 - Laryngeal Mask, Other
GMDN Code	45036 - Laryngeal Mask Airway, Single-Use
UMDNS Code	R01020199 - Laryngeal Mask, Other
UNSPSC Code	42271730 - Laryngeal Mask Airway
Usage	Single-Use, Disposable, < 24 Hours
Patient Population	Neonatal, Infant, Pediatric, & Adult
Sterility	Non-Sterile
Packaging	10/Tube
Shelf Life	5 Years
Storage Conditions	Keep away from sunlight. Keep dry at a storage temperature of -20°C to 40°C.
Disposal Instructions	Dispose of device in accordance with local, state, and national regulations.

Description: The Air-Q®3 Exchanger is an accessory to the Air-Q3 Supraglottic Airways (SGA). It allows controlled removal of the Air-Q3 SGA without dislodging the oral endotracheal tube (OETT) from the trachea. The Air-Q3 Exchanger has a larger tapered endpiece connected to a rod. The tapered end has horizontal ridges and vertical grooves, which engage the OETT in a firm, secure grip, giving the user control of the OETT during the Air-Q3 SGA removal process. The Air-Q3 Exchanger is available in three sizes to accommodate multiple OETT sizes.

Intended Purpose: The Air-Q3 Exchanger is intended to help in the removal of the Air-Q3 SGA following oral-tracheal intubation through the SGA.

Area of Use: Hospitals, pre-hospital, and Surgical Centers.

Compatibility: The Air-Q Exchanger is for use with the Air-Q3 Supraglottic Airways.

Contraindications: No known contraindications.

DEVICE MATERIAL

Part Description	Material
Exchanger	Polypropylene Impact Copolymer Pellets

Biocompatibility Evaluation: Per EN ISO 18562-1:2020, the Air-Q3 Exchangers are not part of the gas pathway and do not have patient surface/mucosal contact. The devices do not contain DEHP, natural rubber latex or BPA. These devices are REACH compliant and do not contain 3TG conflict minerals. These devices do not contain blood derivatives or materials derived from animal or human tissue.

DEVICE SPECIFICATIONS

Size	Compatibility with Air-Q3	Maximum OETT	Patient Weight
00	0, 0.5, 1, 1.5	4.5 mm Uncuffed	< 17 kg
0	2, 3	6.0 mm	17 – 60 kg
1	4, 5	9.0 mm	> 60 kg

Part Number	Description	UOM	GTIN/UDI
10-1004	Air-Q3 Exchanger, Size 1	Each	10889483214107
		Case	20889483214104
10-1005	Air-Q3 Exchanger, Size 0	Each	10889483214114
		Case	20889483214111
10-1006	Air-Q3 Exchanger, Size 00	Each	10889483214121
		Case	20889483214128

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