

| Manufacturers Specifications | | |
|------------------------------|-----------------------------------------------------------------|------|
| Reference Number | 2017 | 2018 |
| Manufacturer | SunMed LLC/ Salter Labs | |
| Classification- FDA | Class I | |
| Product Code | KGX Medical Adhesive Tapes and Bandages | |
| Classifications-EU | Class I | |
| Classification Canada | Class I | |
| CE Mark/Notified Body | CE /BSI Group | |
| EU Representative | MT Promedt Consulting Group GmbH | |
| EMDN Code | M030302, Protection System | |
| GMDN Code | 44990, Skin-cover adhesive strip | |
| UMDNS Code | 10028, Adhesive strips, hypoallergenic | |
| Made In | Mexico | |
| Usage | Disposable, single-patient multiple use | |
| Sterile | No | |
| Patient population | Pediatric, adult | |
| Packaging | Individually packaged 50 pairs/case (#2016) and 25/case (#2017) | |
| Shelf Life | 5 Years | |

Description. Soft, light gray, closed cell foam tubes designed to cover the cannula headset tubing (1016) or the mask’s elastic strap (1017) that fits around the ears.

Intended use: Soft, closed-cell foam tube accessories designed to prevent ear chafing when used with cannulas and masks

Compatibility (1016) Compatible with oxygen cannula with standard headset tubing. Do not use with soft headset tubing

Compatibility (1017) Compatible with Salter Labs oxygen and aerosol masks with a flat elastic strap.

Area of use: Hospitals, sub-acute, medical clinics, pre-hospital, home, surgical centers, skilled nursing facilities

Contraindications: No known.

Device Specifications

| Description | Specification |
|--------------------------|---------------|
| Cannula Ear Wraps (2016) | 3 inches |
| Mask Ear Wraps (2017) | 3 inches |
| Operating temperature | 5°C to 40°C |
| Storage temperature | -20°C to 50°C |

Product Material

| Part Description | Material |
|------------------|-------------------------------------|
| E-Z Wrap | Low density polyethylene foam, Gray |

Latex: Salter Labs does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex do not meet components or finished good during the manufacturing process.

Phthalates: The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

BPA: Salter Labs does not intentionally add or use material with bisphenol A (BPA) to manufacture bubble humidifiers.

Mercury-Lead: The selected materials do not contain lead or mercury

Biocompatible per device classification in ISO 10993.

Part Number and GTIN Code

| Unit | Part Number | GTIN |
|-------------|--------------------|----------------|
| Each | 1016-0 | 00607411001048 |
| Case | 1016-0-50 | 10607411001045 |
| Each | 1017-0 | 0060741891717 |
| Case | 1017-0-25 | 10607411891714 |