

Product Information Sheet – E-Z Wrap

November 2022

1016-0- E-Z Wrap for Nasal Cannula

| | |
|------------------------|--------------------------------------|
| Model/Product name | E-Z Wrap Ear Protector |
| Reference Number | 1016-0-50 |
| Manufacturer | SunMed/Salter Labs |
| Classification- FDA | Class I 510 K, Exempt |
| Classifications-EU | Class I |
| Classification -Canada | Class I |
| CE Mark | CE |
| GMDN Code | 35201, Basic nasal oxygen cannula. |
| UMDNS Code | 13858, Supports and Accessories |
| Usage | Disposable, single-patient use |
| Sterile | No |
| Patient population | Infant, pediatric, adult |
| Packaging | Individually packaged, 50 pairs/case |
| Shelf life | 5 years |

Description. Soft, light gray closed cell foam tubes designed to cover the headset tubing that sits around the ears wean wearing oxygen nasal cannulas.

Intended use: To improve comfort and help prevent chafing and soreness during oxygen therapy.

Compatibility: Compatible with oxygen cannula with standard headset tubing. Do not use ear wraps with soft headset tubing.

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

Contraindications: No known.

Device Specifications

Product Material

| Description | Specification | Part Description | Material |
|-----------------------|---------------|------------------|--------------------------|
| Length | 3 inches | Wrap | Low Density Polyethylene |
| Operating temperature | 5°C to 40°C | | |
| Storage temperature | -20°C to 50°C | | |

Latex: Salter Labs does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does 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 |