

INFU-SURG® Pressure Infusion Bag 1000 mL

LATEX FREE | DISPOSABLE | SINGLE PATIENT USE | NON-STERILE

| INFU-SURG Pressure Infusion Bag 1000 mL | |
|---|--|
| Reference Number | 4010H |
| Manufacturer | Ethox Medical/SunMed LLC |
| FDA Classification | Class I |
| FDA Product Code | KZD – Infusor, Pressure, for IV Bags |
| Registration Number | 880.5420 |
| Canada MDR Rule | Class 1 |
| Classifications – EU | Class I Council Directive 93/42/EEC Article 1; Rule 2 Annex IX |
| CE Mark/Notified Body | 01659 /BSI Group |
| CND | A0599 – Disposable Infusion Mechanical Systems – Accessories |
| GMDN Code | 13100 Infusion, Regulator, Pressure |
| UMDNS Code | 13100, Pressure Infusor |
| Usage | Single Patient Use |
| Sterile | Non-Sterile |
| Patient Population | Newborns, Infants, Pediatric and Adult Patients |
| Packaging | 5/Box 25/Case |

Description: A medical device with an inflatable bladder, a pressure gauge, and an inflation bulb. For rapid infusion of fluids to the patient, an intravenous fluid bag is placed between the sleeve and bladder, and the device is manually pressurized. The steady pressure on the bag pushes the liquid into a drip chamber to allow the fluids to flow into the patient.

Intended use: The device is intended to pressurize the IV bag, which in turn deliver a variety of fluids/medications to the human body. Device intended to be used with 1000 mL IV bags.

Area of use: For use by trained medical professionals. The product is often used in emergency rooms, trauma units, surgical suites, post-anesthesia care, intensive care units and emergency medical services.

Contraindications: None known.

| Device Specifications | |
|------------------------|------------------------------|
| Description | Specification |
| Pressure Gauge Display | 150 mm Hg to 300 mm Hg ± 15% |
| Bladder Size | 1000 mL |



| Product Material | |
|-----------------------|--|
| Part Description | Material |
| Bladder | Urethane Coated Nylon |
| Mesh Sleeve | Nylon/Polyester |
| Tubing | Polyvinyl Chloride |
| Stopcock | Polycarbonate/ High-Density Polyethylene |
| Inflation Bulb | Polyvinyl Chloride |
| Body Gauge & Cylinder | Acrylonitrile Butadiene Styrene |
| Gauge Spring | Carbon Steel |
| Gauge Seal | Elastomeric |
| Hanging Hook | High-Density Polyethylene |

Latex: SunMed® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge, latex does not contact components or finished goods during the manufacturing process.

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

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

Biocompatible: Per device classification in ISO 10993-1:2018. The INFU-SURG® device is manufactured from standard materials used in medical, transportation and aerospace industries. The materials were chosen based on performance in a non-patient contact environment.

The device does not contain human blood derivatives or animal tissue.

| Part Number | Ethox Part Number | UOM | GTIN/UDI | UOM | GTIN/UDI |
|-------------|-------------------|-----|----------------|------|----------------|
| 4010H | 950194310 | Box | 20889483151867 | Case | 30889483151864 |

