# Sterile AlphaSat®10

Sealed-border polyester wipers pre-wetted with 70% IPA in a small resealable package



# **Benefits**

# Sterility

- Pre-sterilized for aseptic and sterile environments
- Eliminates preparation, documentation and validation of in-house production of pre-wetted wipers

# Wipers

- Superior strength for rigorous wiping without snagging on equipment
- Wiper glides smoothly over surfaces with low abrasion
- Extremely low levels of releasable visible fibers consistent with requirements for sterile ISO Class 3-5

#### Pre-wetted with 70% IPA

- Optimizes IPA use for effective particulate removal
- Eliminates overspray of alcohol typical of the use with dry wipers
- Safer to store and handle than IPA bottles
- Eliminates IPA spills
- Reduces IPA waste and disposal

# **Packaging**

- Sized appropriately for limited isolator space
- Packaging permits alcohol wipedown of exterior bag before introduction of inner bag to isolator

# **Quality Assurance**

- Assures quality of each lot
- Lot-to-lot traceability

# **"T"** Texwipe

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# Description

Sterile AlphaSat® 10 features 9" x 9" SterileWipe™ LP 10 sealedborder wipers with 70% USP Isopropyl Alcohol (IPA) in a small resealable flexpack. SterileWipe LP 10 is a 100% continuousfilament polyester wiper with thermally sealed borders. It is engineered to have the lowest level of releasable particles and fibers for critical and sterile environments.

Sterile AlphaSat 10 wipers are designed to clean ISO Class 3-5 cleanroom environments including the interiors of Compounding Aseptic Isolators (CAIs), aseptic isolators in pharmaceutical manufacturing, and Biological Safety Cabinets (BSCs). The small footprint of the 7" x 13" flexpack optimizes the valuable space inside isolators.

Each case of Sterile AlphaSat 10 is gamma irradiated to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> in accordance with ANSI/AAMI/ISO 11137.

# **Features**

### **Wipers**

- Cleanroom-laundered 100% polyester knit with thermally sealed borders
- Pre-wetted with 0.2 µm filtered 70% IPA
- Gamma irradiated to a Sterility Assurance Level of 10-6

## **Packaging**

- Small resealable flexpack package
- Double-bagged for easy entry into aseptic and sterile isolators

#### **Quality Assurance**

- Lot-specific information on each case simplifies record
  - Certificate of Processing confirms radiation dosage
  - Certificate of Compliance
  - Expiration date marked on each package
- Independent quality control audits for sterility assurance

# **Applications**

- Clean interiors of sterile and aseptic isolators
  - Compounding Aseptic Isolators (CAIs)
  - Aseptic isolators in pharmaceutical manufacturing
  - Biological Safety Cabinets (BSCs)
- Contain spills inside isolators
- Wipe gloved hands prior to inserting hands in isolator sleeves and gloves

# **Products**

| TX Number | Description             | Packaging                  |
|-----------|-------------------------|----------------------------|
| TX3285    | Sterile AlphaSat® 10    | 20 folded wipers/flexpack; |
|           | 9" x 9" nominal         | 20 flexpacks/case,         |
|           | (23 cm x 23 cm)         | double-bagged              |
|           | polyester sealed-border |                            |
|           | wipers pre-wetted with  |                            |
|           | 70% IPA                 |                            |

# Sterile AlphaSat® 10

TX3285

| Product Specifications  |  |  |
|-------------------------|--|--|
| Property                | Description                                      |  |
| IPA Quality             | Meets the requirements of USP Isopropyl Alcohol  |  |
| Water Quality           | Meets the requirements of USP Purified Water     |  |
| Appearance              | Clear, colorless liquid                          |  |
| Odor                    | Characteristic alcohol                           |  |
| % IPA Content           | 68%–72%  |  |
| Specific Gravity (20°C) | 0.872–0.883                                      |  |
| Acidity                 | Not more than 1.0 mL of 0.020 N Sodium Hydroxide |  |
| Limit of NVR            | Does not exceed 5 mg (0.01%)                     |  |

ITW Texwipe is the only wiper company to be ISO 9001:2000, 13485:2003, 14001:2004 and OHSAS 18001:1999 registered.