

# Sterile AlphaSat® 10 with WFI

SterileWipe™ LP 10 wipers pre-wetted with 70% IPA and 30% WFI



## Applications

- Developed to clean sterile environments without compromising the sterile nature of those environments
- Designed for cleaning production equipment and environmental surfaces in a sterile environment during and following the production flow
- Ideal for wiping gloved hands

## Description

Sterile AlphaSat® 10 with WFI incorporates SterileWipe™ LP 10 sealed-border wipers pre-wetted with 70% USP Isopropyl Alcohol (IPA) and 30% Water for Injection (WFI) in a resealable flatpack package. SterileWipe™ LP 10 is a 100% continuous-filament polyester wiper with thermally sealed borders that have been designed to control particle and fiber contamination. Each case of wipers is triple-bagged and gamma irradiated to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> in accordance with ANSI/AAMI/ISO 11137-1994.

Sterile AlphaSat® 10 with WFI is used to clean critical sterile environments in pharmaceutical aseptic processing areas, biotechnology manufacturing facilities, microbiological laboratories, and prep rooms.

## Features

- Lot-specific information on each case simplifies record keeping:
  - Certificate of Processing confirms radiation dosage
  - Certificate of Compliance
  - Certificate of Analysis
  - Expiration date marked on each package
- Pre-wetted with 0.2 µm filtered 70% IPA /30% WFI by volume
- Cleanroom-laundered 100% polyester knit with thermally sealed borders
- Triple-bagged for easy entry into sterile environments
- Independent quality control audits for sterility assurance

## Benefits

- Eliminates blending, filtration, processing and QC expense of in-house production of IPA solutions
- Optimizes solution usage and eliminates overspray of alcohol
- Reduces IPA spill potential and eliminates the storage and disposal of excess solvents
- Superior wiper strength allows for rigorous wiping with minimal release of fibers and particles
- Wiper glides smoothly over surfaces
- Extremely low levels of releasable visible fibers consistent with requirements for sterile ISO Class 4 (Class 10) and higher cleanroom environments
- Packaging permits alcohol wipedown of exterior bag before introduction of inner bag to sterile suites
- Assures quality of individual lots and lot-to-lot traceability

## Products

TX Number	Description	Packaging
<b>TX3280</b>	Sterile AlphaSat® 10 with WFI 12" x 12" nominal (31 cm x 31 cm) polyester sealed-border wipers pre-wetted with 70% IPA/30% WFI	50 wipers/flatpack; 5 flatpacks/case, triple-bagged

**ITW Texwipe®**

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TX3280

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## Product Specifications

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Property	Description
IPA Quality	Meets the requirements of USP Isopropyl Alcohol
Water Quality	Meets the requirements of USP Water for Injection
Appearance	Clear, colorless liquid
Odor	Characteristic alcohol
% IPA Content	68%–72%
Endotoxin levels	<0.25 EU/mL
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%)

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**Certificates of Analysis provided with every lot.**

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