KEYSTONE
CLEANROOM PRODUCTS

PureClean™ Self-Sealing 1421B Tyvek® Autoclave Bag with Clear Film Side and Steam Indicator

- Designed for conformance to EU GMP Annex 1
- Clear film side for visual inspection to verify dryness
- PureClean™ 1421B Tyvek® is essentially the same as the original 1422A Tyvek® but without the antistat agent. *No anti-stat coating = no residues left behind*
- Specifically intended for pharmaceutical applications

A Solution to Annex 1 Compliance in the Steam Sterilization of Pharmaceutical Change Parts

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KEYSTONE CLEANROOM PRODUCTS

Designed with Annex 1 in Mind

PureClean™ 1421B Tyvek®

Keystone is proud to partner with DuPont™ to offer the new PureClean™ 1421B Tyvek® material as a potential replacement for the legacy 1422A type. PureClean™ Tyvek® is essentially the same as the original but without the antistat agent. This advanced material is designed for pharmaceutical manufacturing customers seeking the benefits of the next generation of Tyvek®.

Hermetically Sealed

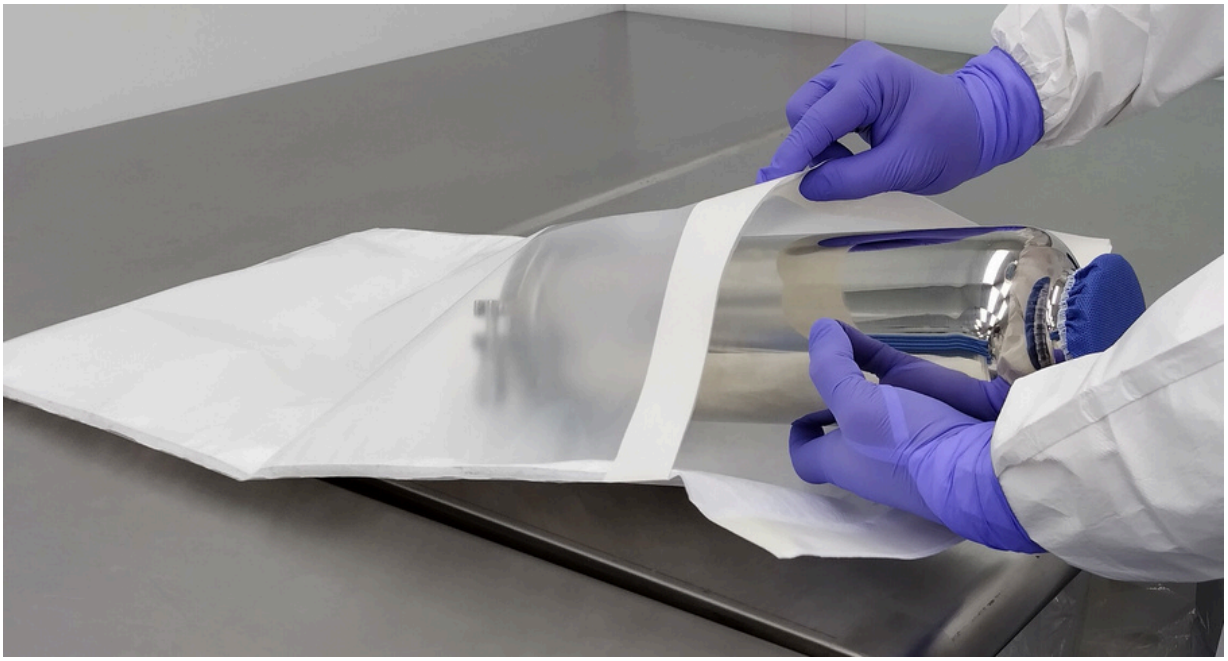
Keystone Cleanroom Products provides autoclave bags with both heat-seal and self-seal closures, eliminating the challenges posed by the drawstring closures found in larger Tyvek bags. These drawstring closures often make it difficult to fully dry the folds and creases of the twisted "gooseneck" design.

"Right-Sizing" Bags for Production

Using the correct size bag instead of an oversized drawstring bag by eliminating excess hydrophobic material removes the chance of any trace residue being left behind, prompting an investigation.

Clear Film Side for Visual Inspection

The clear film side allows for easy visual inspection without breaking the sterile barrier, as required by Annex 1.



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Property	Comparable standard test method	Units	Nominal value (range) Tyvek® 1421B
Preliminary product specifications (English units)			
Basis weight	ASTM D3776[1]	oz/yd²	1.22 [1.16–1.26]
Delamination	ASTM D2724[2]	lb_f	0.08 [>0.03]
Gurley Hill porosity	TAPPI T460[3]	sec/100 cc	20 [8–36]
Preliminary product specifications (metric units)			
Basis weight	ASTM D3776[1]	g/m²	41 [39–43]
Delamination	ASTM D2724[2]	N	0.36 [>0.13]
Gurley Hill porosity	TAPPI T460[3]	sec/100 cc	20 [8–36]
Preliminary miscellaneous properties (metric units)			
Thickness	EN ISO 534[1]	µm	152
Tensile strength, MD	EN ISO 1924-2[2]	N	34
Tensile strength, CD	EN ISO 1924-2[2]	N	28
Elmendorf tear, MD	ASTM D1424	N	10.6
Elmendorf tear, CD	ASTM D1424	N	8.5
Hydrostatic head	AATCC TM 127[3]	cm H_2O	112
Elongation, MD	EN ISO 1924-2[2]	%	10
Elongation, CD	EN ISO 1924-2[2]	%	15
Puncture resistance	EN 863[4]	N	12
Mullen burst	ISO 2758	kPa	365
Bendsten air permeability	ISO 5636-3[5]	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm², pressure 50 kPa.
2. Modified for speed, sample width 2.54 cm (1 inch).
3. Rate of use: 60 cm H_2O/min.
4. Modified for conditioning.
5. Electronic device.

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