KEYSTONE CLEAN ROOM PRODUCTS

PRODUCT DATA SHEET

PART #: BGT2A1418SS

Self-Sealing 1422A Tyvek® Autoclavable Bag with Steam Indicator, 14” x 18”

Keystone Cleanroom Products 1422A Tyvek® Autoclave Bags are made from 1422A DuPont™ Tyvek®. These are an efficient and consistent method of preparing difficult to wrap pharmaceutical production equipment, for steam sterilization. These bags feature a convenient self-sealing closure. Eliminates the need for autoclave tape or use of a heat sealer.

PHYSICAL PROPERTIES	
Material – DuPont™ Tyvek® Type 1422A	
Basis Weight	1.2 oz. sq. yd
Thickness	5.3 mils
Particulate Burden	< 5 Particles (50 µ or greater) per 10 cm^2 (Unprocessed Tyvek® raw material)

STRENGTH PROPERTIES – (MD machine direction; CD cross direction.)	
Seal Strength	> 4.5 lbs
Strip Tensile (MD | CD)	7.9 | 7.6 lbs. in.
Work to Break (MD | CD)	2.4 | 2.1 in. – lbs.
Tongue Tear (MD | CD)	2.2 | 2.4 lbs.
Mullen Burst	60 lbs. / sq. in.

THERMAL PROPERTIES
Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250˚F to 260°F [121°C to 127°C] at 30 psi for 30 minutes). Melting point is 135°C. For best results do not exceed steam sterilization temperatures of 257°F / 125°C.

BARRIER PROPERTIES	
Hydrostatic Head	120 cm. in H^2O
Microbial Barrier	4.5*

*Microbiological barrier testing of sterile barrier materials (ASTM F1608).

ASTM F1608, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method), measures the ability of porous sterile barrier materials to prevent bacterial spore penetration. A completely impermeable control sample (microbial penetration is zero) is challenged with one million or 106 colony forming units (cfu). The number of cfu 106 has a log10 value of 6. If a sample challenged in the same way as the control allows 10 cfu (log 10=1) to penetrate, then its log reduction value (LRV) is 5 (6–1=5). Therefore, the higher the LRV, the more resistant the packaging is to microorganisms.

BARRIER PROPERTIES (CONT)	
Water Vapor Permeability	580 gsm / 24 hours

ADHESIVE SELF-SEALING STRIP:

DESCRIPTION
9254M Medical-grade acrylic adhesive, double coated to PET film with 74# Polycoated Kraft liner, 1.5 inches wide.

STEAM STERILIZATION PROCESS INDICATOR: ETIGAM BV #4.01

THERMAL PROPERTIES
Steam sterilization process indicators undergo a significant color change from pink to dark brown when exposed to steam. Designed for use in steam autoclaves operating at 121°C / 1 bar or 134°C / 2 bar. The color change of the sterilization process indicators is dose dependent. 11140-1:2009 "Sterilization of health care products - Chemical indicators - Part 1: General requirements". Sterilization process indicators are not dosimeters. Color change of the sterilization process indicators indicates exposure to the process. The process itself needs to be validated in order to assure the sterility of the products.

KEY DIMENSIONS		
	Inches	Tolerance +/-
Length	18.00	1”
Width	14.00	1”

Construction: Keystone Cleanroom Product’s raw material is precision cut utilizing a sophisticated CAD cutting system within an ISO8 cleanroom. After cut, the raw material is transferred into ISO6 where they are folded and sealed to form a bag. The steam indicator and self-sealing tape is applied. All are packaged in heat sealed, labeled poly bags, within ISO6.

Packing: 25 per poly bag, 10 poly bags per case. Case quantity is 250 bags.

The information presented here is based on data which Keystone CRP believes to be reliable. It is presented to assist in product evaluation and verification. KEYSTONE CRP makes no guarantee of results and assumes no obligation or liability connected with this information. Since conditions of use are outside our control, we make no warranties, express or implied, including without limitation, no warranties of fitness for a particular use and assume no liability in connection with any of this information. This data is subject to revision as technical knowledge and experience advances. Revisions are not intended to indicate a process or product change.