KEYSTONE CLEAN ROOM PRODUCTS

PRODUCT DATA SHEET

PART #: BGT2A1624D

1422A Tyvek® Autoclavable Bag with Drawstring and Steam Indicator, 16" x 24"

Keystone Cleanroom Products 1422A Tyvek® Autoclave Bags with drawstring closures are made from 1422A DuPont™ Tyvek®. These are an efficient and consistent method of preparing difficult to wrap pharmaceutical production equipment, for steam sterilization. After sterilization, the covered critical surfaces are protected from particulate and microbial contamination during the aseptic installation and setup activities.

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

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	24.00	1”
Width	16.00	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 an ISO6 cleanroom where they are folded and sealed. The bags are then transferred into an ISO8 sewing cleanroom where the drawstring channels are sewn in with clean polyester thread and the drawstrings are inserted. The steam indicator is applied and they are packaged in heat sealed, labeled poly bags.

Packing: 50 per poly bag, 5 poly bags per case. Case quantity is 250 bags.

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