

# TECHNICAL DATA SHEET

## TYVEK STERILIZATION POUCH (1073B)

<b>PRODUCT CODE</b>	:	<b>TP</b>
<b>RELATED STANDARDS</b>	:	PMSSteripack Tyvek pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack Tyvek Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations
<b>INTENDED USE</b>	:	The Tyvek Pouches are used to sterilize temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.
<b>OPERATION CONDITIONS</b>	:	PMSSteripack Tyvek pouches are used for ethylene oxide, formaldehyde, gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.
<b>SPECIFICATIONS</b>	:	

	PROPERTIES	UNITS	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,31
	BASIC WEIGHT	g/m <sup>2</sup>	74,6
	POROSITY	sec	22
	OPACITY	%	92,4
	THICKNESS	µm	185
	SPENCER PUNCTURE	J/m	7355
	MULLEN BURST	kPa	1227
	HYDROSTATIC HEAD	cm H2O	150
	ELMENDORF TEAR, CD	mN	3514
	ELMENDORF TEAR, MD	mN	3425
	TENSILE STRENGTH,CD	N/2.54 cm	208
	TENSILE STRENGTH,MD	N/2.54 cm	193
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		



PMSSteripack®

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LAMINATED FILM	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE		
	THICKNESS	$\mu\text{m}$	ISO 534	LAM.FILM	65 $\pm$ 5	
				PE	50 $\pm$ 5	
				PET	12 $\pm$ 2	
	COF	F/M	ASTM F 1894	0,30-0,35		
		M/M		0,35-0,40		
	THERMAL SEAL	$^{\circ}\text{C}$	ASTM F 88	110 $\pm$ 5		
	TEAR	mN	MD CD	ASTM D 1922	90 min.	
					90 min.	
	GLOSS	%	ASTM D 2457	60 $\pm$ 5		
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS						

### PRODUCT SPECIFICATION :

POUCH	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE		
	SEAL STRENGTH	cm	ASTM F 88	< 25	$\geq$ 25	
		Edge Seal (N /15 mm)		3,0 $\pm$ 0,5	4,0 $\pm$ 0,75	
		Top Seal (N /15 mm)		4,0 $\pm$ 0,5	5,0 $\pm$ 0,5	
	BUBBLE TEST		ASTM F 2096-04	None		
	PINHOLE DETERMINATION		EN 868-5 Annex C	None		
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Desired dimensions		
	LEAKAGE TEST		ASTM F 1929-98	None		
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle		
	INDICATOR CONTROL		ISO 11140-1	Must return to the specified color		

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Blue

### PACKAGING :

PMSSteripack TYVEK pouches are packaged 250 pieces in each laminated film and each 1000 pouch are packaged in cartons.



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