

TECHNICAL DATA SHEET

TYVEK STERILIZATION POUCH (2 FS)

- PRODUCT CODE** : **TP**
- RELATED STANDARDS** : 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 with the amendment of 2007/47/EC.
- INTENDED USE** : 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.
- OPERATION CONDITIONS** : PMSSteripack Tyvek Pouches are used for ethylene oxide, gas plazma (VH₂O₂) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.
- SPECIFICATIONS** :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK	DELAMINATION	N/2.54 cm	2,7
	BASIC WEIGHT	g/m ²	60
	POROSITY	sec/100 cc	22
	OPACITY	%	94
	THICKNESS	µm	155
	SPENCER PUNCTURE	J/m	5254
	MULLEN BURST	kPa	925
	HYDROSTATIC HEAD	cm H ₂ O	145
	ELMENDORF TEAR, CD	mN	3694
	ELMENDORF TEAR, MD	mN	2803
	TENSILE STRENGTH,CD	N/2.54 cm	157
	TENSILE STRENGTH,MD	N/2.54 cm	156
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		



PMSSteripack®

TYVEK STERILIZATION POUCH (2 FS)

LAMINATED FILM	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE		
	THICKNESS	µm	ISO 534	LAM.FILM	64 ± 5	
				PE	50 ± 5	
				PET	12 ± 2	
	THERMAL SEAL	°C	ASTM F 88	110 ± 5		
	TENSILE	N/15 mm	MD CD	ASTM D 882-12	min. 26	
					min. 26	
	TEAR	mN	MD CD	ASTM D 1922	min. 90	
min. 90						
HAZE	%	ASTM D 1003	max. 17			
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS						

PRODUCT SPECIFICATIONS

POUCH	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE		
	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25	
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 0,75	
		Top Seal (N/15 mm)		4,0 ± 0,5	5,0 ± 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	Required dimensions		
	LEAKAGE TEST		ASTM F 1929-12	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

PACKAGING

: PMSSteripack TYVEK reels are packaged as below.

<u>Product Code</u>	<u>Pieces in Inner Packaging</u>	<u>Pieces in carton</u>
05 cm	6	12
7,5 cm	4	8
10 cm	3	6
15 cm	2	4
20 cm	2	4
25 cm	1	2
30 cm	1	2
35 cm	1	2
40 cm	1	2



PMSSteripack®