

TECHNICAL DATA SHEET

TYVEK POUCHES

- PRODUCT CODE** : 4ATP
- RELATED STANDARDS** : 4A Medical Tyvek Pouches are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices.
- INTENDED USE** : The 4A Medical 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. 4A Medical pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization.
- OPERATION CONDITIONS** : 4A Medical Tyvek Pouches are used for gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

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TYVEK	PROPERTIES	UNITS	TYPICAL VALUE
	DELAMINATION	N/2.54 cm	2,2
	BASIC WEIGHT	g/m ²	64
	POROSITY	sec	22
	OPACITY	%	91
	THICKNESS	mils	165
	SPENCER PUNCTURE	J/m	6195
	MULLEN BURST	kPa	1055
	HYDROSTATIC HEAD	cm H2O	145
	ELMENDORF TEAR, XD	mN	3203
	ELMENDORF TEAR, MD	mN	2980
	TENSILE STRENGTH,XD	N/2.54 cm	174
	TENSILE STRENGTH,MD	N/2.54 cm	163
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		

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LAMINATED FILM	PROPERTIES	UNIT	TYPICAL VALUE		
	THICKNESS	Micron	LAM.FILM	52 ± 5	
			PE	40 ± 5	
			PET	12 ± 2	
BREAKING FACTOR	N/15mm	35			
TEAR STRENGTH MD/CD	mN	300			
BOND STRENGHT	N/m	265			
ELONGATION	%	70			
TEMPERATURE DURABILITY	min/degrees	30 min/140C			
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS					

PRODUCT SPECIFICATION :

POUCH	PROPERTIES	UNIT	TYPICAL VALUE
	SEAL STRENGTH	N/15mm	2,5
	BUBBLE TEST		None
	PINHOLE DETERMINATION		None
	DIMENSION CONTROL	cm or mm	Desired dimensions
	LEAKAGE TEST		None
	PEEL DIRECTION		None
	INDICATOR CONTROL		Returns the specified color

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	VH2O2	Red	Yellow
PACKAGING :		4A Medical Tyvek pouches are packaged laminated film and then in cartons boxes. Quantity in packing depend on size of pouches.	

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