

TECHNICAL DATA SHEET

TYVEK STERILIZATION REEL

- PRODUCT CODE** : 4ATR
- RELATED STANDARDS** : 4A Medical Tyvek Reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used on the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. 4A Medical Tyvek Reels meet the requirements of 93/42/EEC Medical Device Directive regulations.
- INTENDED USE** : The 4A Medical Tyvek Reels are used to sterilize temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. 4A Medical reels 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 Reels are used for gas plazma (VH2O2) sterilization. The sterilization conditons should be determined by the end user regarding to material to be sterilized.
- SPECIFICATIONS** :

TEHNICALDATA SHEET

	PROPERTIES	UNITS	TYPICAL VALUE		
TYVEK	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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L.AMINATED 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 reels are packaged in carton boxes as below:	

<u>Product dimensions</u>	<u>Pieces in carton</u>
50mm X 70m	10
75mm X 70m	8
100mm X 70m	8
120mm X 70m	4
150mm X 70m	4
200mm X 70m	4
250mm X 70m	2
300mm X 70m	2
350mm X 70m	2
400mm X 70m	2
420mm X 70m	2
450mm X 70m	2
500mm X 70m	2

MANUFACTURER

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