



TECHNICAL DATA SHEET

TYVEK REELS

- PRODUCT CODE** : 4ATR
- RELATED STANDARDS** : 4A Medical Tyvek Reels are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices. It is compatible with ISO 11607.
- 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. One side is 40micron PE + 12 micron PET film material and other side is 60 gsm tyvek paper. Edges are sealed as triple welding. Sealing Temperature is between 120 - 140 degrees. 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. Sterilized material in sterilization package is storable for up to 6 month after the sterilization in a clean room conditions.
- 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. Process indicators are on printed on edge of pouches. All related informations are printed on edge of pouches such us Standard, dimension, Lot no and so on. Standard length is 70m but it can be produced as 100m.

SPECIFICATIONS :

		PROPERTIES	UNITS	TYPICAL VALUE
TYVEK		DELAMINATION	N/2.54 cm	2,7
		BASIC WEIGHT	g/m ²	60
		POROSITY	sec	22
		OPACITY	%	94
		THICKNESS	mils	155
		SPENCER PUNCTURE	J/m	5254
		MULLEN BURST	kPa	925
		HYDROSTATIC HEAD	cm H2O	145
		ELMENDORF TEAR, XD	mN	3694
		ELMENDORF TEAR, MD	mN	2803
		TENSILE STRENGTH,XD	N/2.54 cm	157
		TENSILE STRENGTH,MD	N/2.54 cm	156
	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		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:																						
		<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;"><u>Product dimensions</u></th> <th style="text-align: center;"><u>Pieces in carton</u></th> </tr> </thead> <tbody> <tr><td style="text-align: center;">75mm X 70m</td><td style="text-align: center;">8</td></tr> <tr><td style="text-align: center;">100mm X 70m</td><td style="text-align: center;">8</td></tr> <tr><td style="text-align: center;">150mm X 70m</td><td style="text-align: center;">4</td></tr> <tr><td style="text-align: center;">200mm X 70m</td><td style="text-align: center;">4</td></tr> <tr><td style="text-align: center;">250mm X 70m</td><td style="text-align: center;">2</td></tr> <tr><td style="text-align: center;">300mm X 70m</td><td style="text-align: center;">2</td></tr> <tr><td style="text-align: center;">350mm X 70m</td><td style="text-align: center;">2</td></tr> <tr><td style="text-align: center;">400mm X 70m</td><td style="text-align: center;">2</td></tr> <tr><td style="text-align: center;">450mm X 70m</td><td style="text-align: center;">2</td></tr> <tr><td style="text-align: center;">500mm X 70m</td><td style="text-align: center;">2</td></tr> </tbody> </table>	<u>Product dimensions</u>	<u>Pieces in carton</u>	75mm X 70m	8	100mm X 70m	8	150mm X 70m	4	200mm X 70m	4	250mm X 70m	2	300mm X 70m	2	350mm X 70m	2	400mm X 70m	2	450mm X 70m	2	500mm X 70m	2
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MANUFACTURER	:	DORT-A TIP MALZEMELERİ SAN. İTH. İHR. TIC. LTD. STİ. Balıkhisar Mahallesi, Köyiçi Serpmeleri, No:795 Akyurt, Ankara, Turkey Tel: +90 312 363 50 52 / 53 Fax: +90 312 363 52 10 Web: http://www.4amedical.com E-mail: export@4amedical.com																						