

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.
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	:	Shelf life is 5 years

TECHNICAL DATA SHEET

PROPERTIES	UNITS	TYPICAL VALUE
DELAMINATION	N/2.54 cm	2,7
BASIC WEIGHT	g/m²	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:	
		Product dimensions	Pieces in carton
		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
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	