

# TECHNICAL DATA SHEET

## ETO STERILIZATION POUCH (FLAT- 60 gr)

- PRODUCT CODE** : EFP
- RELATED STANDARDS** : PMSSteripack ETO flat pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Type 1 Indicator according to the ISO 11140-1 standard. PMSSteripack ETO Flat Pouches meet the requirements of (EU) 2017/745 Medical Device Regulation.
- INTENDED USE** : PMSSteripack ETO Flat Pouches are designed to provide excellent barrier for sterile medical device packaging purposes. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack ETO flat pouches are used for the packing of the Medical Devices before sterilization. PMSSteripack ETO flat pouches are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.
- OPERATION CONDITIONS** : PMSSteripack ETO flat pouches are used for ethylene oxide and gamma irradiation sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.

### SPECIFICATIONS :

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE
MEDICAL PAPER (ETHYPEL PREMIUM)	SUBSTANCE	g/m <sup>2</sup>	ISO 536	60
	THICKNESS	µm	ISO 534	73
	BENDTSEN POROSITY	ml/min	ISO 5636-3	150
	AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	1,7
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	300
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	180
	TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	6,7
	TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,0
	WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,7
	WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,3
	BURST STRENGTH	kPa	ISO 2758	350
	TEARING STRENGTH /MD	mN	ISO 1974	450
	TEARING STRENGTH /CD	mN	ISO 1974	530
	WET BURST	kPa	ISO 3689	170
	WATER REPELLENCY	s	EN 868-2 (app.D)	40
	PORE SIZE	µm	EN 868-2 (app.E)	12
	COBB TEST (60 s)	g/m <sup>2</sup>	ISO 535	15
FLUORESCENCE	pts/dm <sup>2</sup>	EN 868-2 (app.B)	0	
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				



PMSSteripack®

## STERILIZATION POUCH (FLAT - 60 gr)

LAMINATED FILM	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE		
	THICKNESS	µm	ISO 534	LAM.FILM	65 ± 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	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- 13	Required dimensions	
	LEAKAGE TEST	-	ASTM F 1929-15	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
	EO	Green	Yellow

**PACKAGING** : PMSSteripack flat pouches are packaged 250 pieces in a film package. Each 1000 pieces are packaged in a carton box.

PMSSteripack flat pouches are packaged 100 pieces in a film package. Products up to 20 cm width are packaged 1000 pieces in carton box and widers are packaged 500 pieces in carton box.



**PMS Steripack®**