

# TECHNICAL DATA SHEET

## STERILIZATION POUCH (FLAT / GUSSETED - 70 gr)

- PRODUCT CODE** : FP ( Flat ) - GP ( Gusseted )
- RELATED STANDARDS** : PMSSteripack flat and gusseted pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMSSteripack pouches meet the requirements of 93/42/EEC Medical Device Directive regulations with the amendment of 2007/47/EC.
- INTENDED USE** : PMSSteripack 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 pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. PMSSteripack pouches are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.
- OPERATION CONDITIONS** : PMSSteripack pouches are used for steam, ethylene oxide, formaldehyde 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	SUBSTANCE	g/m <sup>2</sup>	ISO 536	70	
	THICKNESS	µm	ISO 534	95	
	BENDTSEN POROSITY	ml/min	ISO 5636-3	1000	
	AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4	
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	350	
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	350	
	TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	7,2	
	TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,8	
	WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,4	
	WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,3	
	BURST STRENGTH	kPa	ISO 2758	400	
	TEARING STRENGTH /MD	mN	ISO 1974	700	
	TEARING STRENGTH /CD	mN	ISO 1974	750	
	WET BURST	kPa	ISO 3689	150	
	WATER REPELLENCY	s	EN 868-2 (app.D)	40	
	PORE SIZE	µm	EN 868-2 (app.E)	20	
	COBB TEST (60 s)	g/m <sup>2</sup>	ISO 535	16	
	FLUORESCENCE	pts/dm <sup>2</sup>	EN 868-2 (app.B)	0	
	pH: between 5.0 and 8.0 (ISO6588-2)		Chloride content < 0,05% ( ISO 9197 )		
			Sulphate Content < 0,25% (ISO9198)		
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS					



PMSSteripack®

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LAMINATED FILM	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE		
	THICKNESS	µm	ISO 534	LAM.FILM	53 ± 5	
				PP	40 ± 5	
				PET	12 ± 2	
	THERMAL SEAL	°C	ASTM F 88	180 ± 5		
	TENSILE	N/15 mm	MD CD	ASTM D 882-12	min. 28	
					min. 30	
	TEAR	mN	MD CD	ASTM D 1922	min. 70	
min. 70						
HAZE	%	ASTM D 1003	max. 9			
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	
	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25	
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 0,75	
	BUBBLE TEST		ASTM F2096-04	None		
	PINHOLE DETERMINATION		EN 868-5 Annex C	None		
	DIMENSION CONTROL	cm or mm	ASTM F 2203-02	Required dimension		
	LEAKAGE TEST		ASTM F 1929-12	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
	STEAM	Pink	Brown / Black
	EO	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

### PACKAGING :

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

PMSSteripack gusseted pouches are packaged 200 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.



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