

# TECHNICAL DATA SHEET

## STERILIZATION REEL (FLAT / GUSSETED - 60 gr)

- PRODUCT CODE** : FL ( Flat ) - GS ( Gusseted )
- RELATED STANDARTS** : PMSSteripack flat and gusseted reels 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. PMS Steripack Pouches meet the requirements of 93/42/EEC Medical Device Directive regulations
- INTENDED USE** : PMSSteripack Reels are designed to provide excellent barrier for sterile medical device packaging purposes. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. PMSSteripack Reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices. Sterilized material in sterilization package is storable for up to 5 years after the sterilization in a clean room conditions.
- OPERATION CONDITIONS** : PMSSteripack reels 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	
<b>MEDICAL PAPER</b>		SUBSTANCE	g/m <sup>2</sup>	ISO 536	60	
		THICKNESS	µm	ISO 534	83	
		BENDTSEN POROSITY	ml/mn	ISO 5636-3	1000	
		AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4	
		BENDTSEN ROUGHNESS FS	ml/mn	ISO 8791-2	375	
		BENDTSEN ROUGHNESS WS	ml/mn	ISO 8791-2	375	
		TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	6,4	
		TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,4	
		WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,1	
		WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,1	
		BURST STRENGTH	kPa	ISO 2758	350	
		TEARING STRENGTH /MD	mN	ISO 1974	600	
		TEARING STRENGTH /CD	mN	ISO 1974	650	
		WET BURST	kPa	ISO 3689	150	
		WATER REPELLENCY	s	EN 868-2 (app.D)	35	
		PORE SIZE	µm	EN 868-2 (app.E)	21	
		COBB TEST (60 s)	g/m <sup>2</sup>	ISO 535	15	
		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						



**PMS Steripack®**

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LAMINATED FILM	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE		
	THICKNESS	Micron	ASTM D 374	LAM.FILM	53 ± 5	
				PP	40 ± 5	
				PET	12 ± 2	
	COF	F/M	ASTM F 1894	0,30-0,35		
		M/M		0,35-0,40		
	THERMAL SEAL	°C	ASTM F 88	150 ± 5		
	TEAR	G	MD TD	D1922	40 ± 5	
					50 ± 5	
	GLOSS	%	ASTMD 2457	150 ± 5		
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 ( gr / 15 mm)		250 ≤	300 ≤
	BUBBLE TEST		ASTM F2096-04	None	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None	
	DIMENSION CONTROL	cm or mm	ASTM F2203-02	Desired dimensions	
	LEAKAGE TEST		ASTM F1929-98	None	
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle	
	INDICATOR CONTROL		ISO 11140-1	Must return the specified color	

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	Pink	Brown / Black
	EO	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

## PACKAGING

: PMSSteripack reels are packaged as below.

<u>Product Code</u>	<u>Pieces in Inner Packaging</u>	<u>Pieces in carton</u>
05 cm	6	12
7,5 cm	4	8
10 cm	3	6
15 cm	2	4
20 cm	2	4
25 cm	1	2
30 cm	1	2
35 cm	1	2
40 cm	1	2



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