

TECHNICAL DATA SHEET

STERILIZATION REEL (FLAT / GUSSETED - 70 gr)

- PRODUCT CODE** : FL (Flat) - GS (Gusseted)
- RELATED STANDARDS** : PMSSteripack flat and gusseted reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the reel production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. PMS Steripack Reels 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 :

MEDICAL PAPER	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE
	SUBSTANCE	g/m2	ISO 536	70
	THICKNESS	µm	ISO 534	95
	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	350
	BENDTSEN ROUGHNESS WS	ml/mn	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)	35
	PORE SIZE	µm	EN 868-2 (app.E)	20
	COBB TEST (60 s)	g/m2	ISO 535	16
	FLUORESCENCE	pts/dm²	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)		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 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.

Product Code	Pieces in Inner Packaging	Pieces in carton
5 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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