

## TECHNICAL DATA SHEET

### STERILIZATION SELF SEALING POUCHES, 60gsm

<b>PRODUCT CODE</b>	:	4ASSP	
<b>RELATED STANDARDS</b>	:	4A Medical flat and gusset pouches are in compliance with the provisions of the Medical Device Regulation 2017/745 for medical devices.	
<b>INTENDED USE</b>	:	4A Medical self seal pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical self seal pouches are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.	
<b>OPERATION CONDITIONS</b>	:	4A Medical 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.	
<b>SPECIFICATIONS</b>	:		

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	PROPERTIES	UNITS	STANDARD	TYPICAL VALUE	
<b>MEDICAL PAPER</b>	SUBSTANCE	g/m <sup>2</sup>	ISO 536	60,0	
	THICKNESS	µm	ISO 534	76	
	BENDTSEN POROSITY	ml/min	ISO 5636-3	650	
	AIR PERMEANCE	µm (Pa*s)	ISO 5636-3	7,4	
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	250	
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	250	
	PORE SIZE	µm	EN 868-2 (app.D)	17	
	TENSILE STRENGTH, MD	kN/m	EN ISO 1924-2	5,9	
	TENSILE STRENGTH, CD	kN/m	EN ISO 1924-2	2,9	
	WET TENSILE STRENGTH, MD	kN/m	ISO 3781	1,6	
	WET TENSILE STRENGTH, CD	kN/m	ISO 3781	0,9	
	BURST STRENGHT	kPa	ISO 2758	300	
	WET BURST	kPa	ISO 3689	100	
	TEARING STRENGHT MD	mN	ISO 1974	600	
	TEARING STRENGHT CD	mN	ISO 1974	650	
	COBB TEST (60s)	g/m <sup>2</sup>	ISO 535	15,0	
	WATER REPELLENCY	s	EN 868-2 (app.E)	30,0	
	FLOUORESCENCE	pts/dm <sup>2</sup>	EN 868-2 (app.B)	0,0	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

**STERILIZATION SELF SEALING POUCHES, 60gsm**

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 STRENGTH	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 DETERMINATION		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
	STEAM	BLUE	GREEN
	EO	PINK	ORANGE
	FORMALDEHYDE	PURPLE	GREEN
<b>PACKAGING:</b>		4A Medical self seal pouches are packaged laminated film and then in cartons boxes. Quantity in packing depend on size of pouches.	

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