

## TECHNICAL DATA SHEET

### STERILIZATION FLAT/GUSSET POUCH, 70gsm

	<b>PRODUCT CODE</b>	:	<b>4AFP (Flat Pouch) - 4AGP (Gusset Pouch)</b>		
<b>TECHNICAL DATA SHEET</b>	<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 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. 4A Medical pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. 4A Medical Pouches 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.		
	<b>FILLING VOLUME</b>	:	According to DIN 58953-7 (German national standard): Sealeable paper bags and sealeable pouches and reals shall be filled up to 3/4 max of their volume. This limits avoids too high stress / burdon to the seals. Below the bottom seal there must be space of minimum 30 mm between load and sealing area. There is no known limit bu standarts for weight and it is based on experience. However, it is suggested to follow the 3/4 rule. In terms of solid, heavy load (metal instruments), it is the weight itself, in case of any sharp objects which could damage the material, and the volume of condensate (directly related to mass=weight) which is created during the steam sterilization.		
	<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>	:			
<b>MEDICAL PAPER</b>	<b>PROPERTIES</b>		<b>UNITS</b>	<b>STANDARD</b>	<b>TYPICAL VALUE</b>
	SUBSTANCE		g/m <sup>2</sup>	ISO 536	70,0
	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
	PORE SIZE		µm	EN 868-2 (app.D)	20
	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 STRENGHT		kPa	ISO 2758	400
	WET BURST		kPa	ISO 3689	150
	TEARING STRENGHT MD		mN	ISO 1974	700
	TEARING STRENGHT CD		mN	ISO 1974	750
	COBB TEST (60s)		g/m <sup>2</sup>	ISO 535	16,0
	WATER REPELLENCY		s	EN 868-2 (app.E)	40,0
	FLOUORESCENCE		pts/dm <sup>2</sup>	EN 868-2 (app.B)	0,0
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

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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 STRENGHT	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 Flat/Gusset pouches are packaged laminated film and then in cartons boxes. Quantity in packing depend on size of pouches.	

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