

## TECHNICAL DATA SHEET

### STERILIZATION FLAT/GUSSET POUCH, 60gsm

<b>PRODUCT CODE</b>	:	<b>4AFP (Flat Pouch) - 4ASGP (Gusset Pouch)</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>	:	<p>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 easy 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.</p> <p>According to DIN 58953-7 (German national standard): Seleable paper bags and seleable pouches and reals shall be filled up to 3/4 max of their volume. This limits avoids too high stress / burdon to the seals. Belowe the buttom 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 experiance. 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.</p>
<b>FILLING VOLUME</b>	:	<p>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.</p>
<b>OPERATION CONDITIONS</b>	:	<p>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.</p>
<b>SPECIFICATIONS</b>	:	

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MEDICAL PAPER	PROPERTIES	UNITS	STANDARD	TYPICAL VALUE
	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			

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

**MANUFACTURER :**

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