

TECHNICAL DATA SHEET

HEADER BAG

- PRODUCT CODE** : **HB**
- RELATED STANDARDS** : PMSSteripack Header Bag products are manufactured according to EN 868-5 and ISO 11607 standards. PMSSteripack Header Bag products meet the requirements of (EU) 2017/745 Medical Device Regulation.
- INTENDED USE** : Header Bag products are used to sterilize Temperature-sensitive medical devices. It is preferred at Low Temperature Sterilization regarding to its porous structure. Header Bags meet the Medical Industry's requirement for high quality, hygiene and safety levels. PMSSteripack Header Bags are used to enclose another medical devices to be sterilized.
- OPERATION CONDITIONS** : PMSSteripack Header Bag products are used for ethylene oxide, gas plazma (VH₂O₂) and Gamma sterilizations. The sterilization conditons should be determined by the end user regarding to material to be sterilized.
- SPECIFICATIONS** :

	PROPERTIES	UNIT	TYPICAL VALUE
TYVEK® COMPONENT (COATED)	DELAMINATION	N/2.54 cm	2.2
	BASIC WEIGHT	g/m ²	64.4
	POROSITY	sec/100 cc	22
	OPACITY	%	91
	THICKNESS	µm	165
	SPENCER PUNCTURE	J/m ²	6195
	MULLEN BURST	kPa	1055
	HYDROSTATIC HEAD	cm H ₂ O	145
	ELMENDORF TEAR, CD	mN	3203
	ELMENDORF TEAR, MD	mN	2980
	TENSILE STRENGTH,CD	N/2.54 cm	174
	TENSILE STRENGTH,MD	N/2.54 cm	163
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS		



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FILM COMPONENT	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
	THICKNESS	µm	ISO 534	100 ± 10	
	THERMAL SEAL	°C	ASTM F 88	117 ± 3	
	TENSILE	N/15 mm	MD	ASTM D 882-12	min. 20
			CD		min. 20
	ELONGATION AT BREAK	%	MD	ASTM D 882-12	min. 250
			CD		min. 250
	TEAR	mN	MD	ASTM D 1922	min. 2000
			CD		min. 2000
	HAZE	%	ASTM D 1003	max. 12	
LIGHT TRANSMITTANCE	%	ASTM D 1003	min. 80		
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS					

PRODUCT SPECIFICATIONS

HEADER BAG	PROPERTIES	UNIT	STANDARD OR TEST METHOD	TYPICAL VALUE	
	SEAL STRENGTH	Tyvek-Film Seal (N/15 mm)		ASTM F 88	3,0 ± 0,5
		Film Film (N/15 mm)			5,0 ± 0,5
	BUBBLE TEST		ASTM F 2096-04	None occurred	
	PINHOLE DETERMINATION		EN 868-5 Annex C	None occurred	
	DIMENSION CONTROL	cm or mm	ASTM F 2203-13	Required dimensions	
	LEAKAGE TEST		ASTM F 1929-15	No leakage	



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