

TECHNICAL DATA SHEET

SOFT CREPE (Green, Blue, White)

PRODUCT CODE	:	SWP
RELATED STANDARDS	:	PMSSteripack branded Soft Crepes are produced in comply with EN 868-2 and ISO 11607-1 Standards. Soft Crepe meets the requirements of the Council Directive 94/62/EC on Packaging and packaging waste and (EU) 2017/745 Medical Device Regulation.
INTENDED USE	:	Sterility assurance is a critical concern of effective patient care. Therefore, the medical device wrapping is very important step of the sterilization process. Suitable wrapping techniques and proper wrapping material use provide sterile barrier during and after the sterilization process. PMSSteripack Soft Creepe sheet is used to wrap materials to be sterilized like the trays, surgical kit. Sof Crepe is preferred instead of the fabric due to the smaller pore structures.
OPERATION CONDITIONS	:	PMSSteripack soft crepes are used for steam, ethylene oxide, formaldehyde and gamma irradiation sterilization methods. The sterilization conditons should be determined by the end user regarding to material to be sterilized.
SPECIFICATIONS	:	

In accordance with EN 868- part2 : 2017

REQUIREMENTS AND TEST METHODS

SOFT CREPE PAPER	Characteristics	Test method	Unit	Requirement Average	Value/ Conformity
	General	Visual Observation		No tears, creases or localised thickening sufficient to impair its functioning	Conform
	Colour	Visual Observation		Visual examination of a hot extract method ISO 6588	No leaching
	Toxicity	National Regulation		No health hazard	Conform
	Average Mass of 1 m ²	ISO 536	g/m ²	The average mass shall be within $\pm 5\%$ of the nominal value stated by the manufacturer	60
	pH	ISO 6588		$5 \leq \text{pH} \leq 8$ (hot extraction method)	6,7
	Chloride	ISO 9197-1	%	$\leq 0,05\%$ (NaCl, hot extraction method)	0,03
	Sulphate	ISO 9198	%	$\leq 0,25\%$ (Na ₂ SO ₄ , (Hot extraction method)	0,055
	Fluorescence	4.2.1.7	%	No increase in brightness due to the optical brightener of more than 1 % and number of spots ≤ 5 ; spots axis $> 1\text{mm}/0,01\text{ m}^2$	0
	Bendtsen Porosity (2 sheets)	ISO 5636-3	ml/min	2.640-3.250	2.900



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	Air Permeance (2 sheets)	ISO 5636-3	µm/(Pa.s)	29,94-36,85	32,80
	Elongation	EN ISO 1924-2	%	≥10 in machine direction ≥ 2 in cross direction	14,0 5,0
	Water Repellency	ANNEX C	s	≥20 for penetration time	24
	Pore Size Diameter	ANNEX D	µm	≤50 (maximum equivalent pore size diameter)	35
	Thickness	ISO 12625-3	µm	240-260	250
	Tear Resistance	ISO 1974	mm	≥710 in machine direction ≥880 in cross direction	900 1000
	Tensile Strength	EN ISO 1924-2	kN/m	≥1,33 in machine direction ≥0,67 in cross direction	2,10 1,30
	Wet Tensile	ISO 3781	kN/m	≥0,33 in machine direction ≥0,27 in cross direction	0,70 0,40

PACKAGING

: Soft Crepes are packaged as below.

<u>Product Code</u>	<u>Pieces in Inner Packaging</u>	<u>Pieces in carton</u>
SWP3030	500	2000
SWP4040	500	1500
SWP4545	500	1000
SWP5050	500	1000
SWP6060	250	500
SWP7575	250	250
SWP9090	250	250
SWP100100	250	250
SWP120120	100	100



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