

# TECHNICAL DATA SHEET

## CREPE (Green, White, Blue)

<b>PRODUCT CODE</b>	:	<b>WP</b>
<b>RELATED STANDARDS</b>	:	PMSSteripack branded crepes are produced in comply with EN 868-2 and ISO 11607-1 Standards. Crepe meets the requirements of the Council Directive 94/62/EC on Packaging and packaging waste and (EU) 2017/745 Medical Device Regulation.
<b>INTENDED USE</b>	:	Sterility assurance is a critical cornerstone 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 Crepe sheet is used to wrap materials to be sterilized like the trays, surgical kit. Crepe is preferred instead of the fabric due to the smaller pore structures.
<b>OPERATION CONDITIONS</b>	:	PMSSteripack 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.
<b>SPECIFICATIONS</b>	:	

In accordance with EN 868- part2: 2017

### REQUIREMENTS AND TEST METHODS

CREPE PAPER	Characteristics	Test method	Unit	Requirement Average	Value
	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 <sup>2</sup>	ISO 536	g/m <sup>2</sup>	The average mass shall be within $\pm 5\%$ of the nominal value stated by the manufacturer	60
	pH	ISO 6588		5 ≤ pH ≤ 8 (hot extraction method)	6,7
	Chloride	ISO 9197-1	%	<0,05% (NaCl, hot extraction method)	0,04



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	Sulphate	ISO 9198	%	<0,25% (Na <sub>2</sub> SO <sub>4</sub> , Hot Extract 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> 1mm/0,01 m <sup>2</sup>	0
	Elongation	EN ISO 1924-2	%	≥ 10 in machine direction ≥ 2 in cross direction	11,3 5,1
	Water Repellency	ANNEX C	s	≥ 20 in penetration time	25
	Pore Size Diameter	ANNEX D	µm	≤ 35 ( maximum equivalent pore size diameter )	25
	Drape of the wrap	ANNEX B	mm	≤ 125 in machine direction ≤ 160 in cross direction	110 135
	Tensile Strength	EN ISO 1924-2	kN/m	≥ 1,33 in machine direction ≥ 0,67 in cross direction	2,10 1,60
	Wet Tensile	ISO 3781	kN/m	≥ 0,33 in machine direction ≥ 0,27 in cross direction	0,80 0,50

**PACKAGING** : Crepes are packaged as below.

<u>Product Code</u>	<u>Pieces in Inner Packaging</u>	<u>Pieces in carton</u>
WP3030	500	2000
WP3535	500	1500
WP4040	500	1500
WP4545	500	1000
WP5050	500	1000
WP6060	250	500
WP7575	250	250
WP9090	250	250
WP100100	250	250
WP120120	100	100
WP130150	100	100
WP150150	100	100



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