



**Description:** SMS sterilization wrap

<b>Final dimensions:</b>	60 cm x60 cm
<b>Composition:</b>	SSMMS blue PP NW (5 layers).
<b>Construction:</b>	40 g/sqm
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>Sterilizable by:</b>	Moist heat or EO
<b>Colour:</b>	blue
<b>Shelf life:</b>	120 months
<b>CFU/g</b>	<10 <sup>2</sup>
<b>Bacterial filtration efficiency</b>	> 96 %
<b>Hydrostatic pressure</b>	>=40 mbar
<b>Weight/sqm</b>	40,0 ± 5% g/m <sup>2</sup>
<b>Fluorescence</b>	conform
<b>pH aqueous extract</b>	5,0 - 8,0
<b>Chloride content</b>	< 0,05 %
<b>Sulphate content</b>	< 0,25 %
<b>Dry Tensile Strength MD</b>	Approx. 1,9 (>1,0*) kN/m
<b>Dry Tensile Strength CD</b>	Approx. 1,0 (>0,65*) kN/m
<b>Tearing Resistance MD</b>	Approx. 4100 (>750*) mN
<b>Tearing Resistance CD</b>	Approx.5600 (>1000*) mN
<b>Elongation at break MD</b>	Approx. 70 (>5*) %
<b>Elongation at break CD</b>	<b>Approx. 80 (&gt;7*) %</b>
<b>Dry Bursting Strength</b>	Approx. 300 (>130*) kPa
<b>Also sterilizable by</b>	Plasma
<b>In accordance with</b>	EN 868-2:2017
<b>In accordance with</b>	EN ISO 11607-1:2017
<b>In accordance with</b>	ISO 2758
<b>Note:</b>	* EN 868-2 value
<b>In accordance with</b>	EN ISO1924-2;ISO3781
<b>Do not sterilize by</b>	Irradiation
<b>Length variation</b>	±20 mm
<b>Width variation</b>	±20 mm



<b>Nr and Revision Date:</b>	16 -- 2020/02/24
<b>CE Class:</b>	I
<b>Compliance with:</b>	MDD 93/42/ EEC amended by 2007/47/EC

<b>Applicable norms:</b>	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN ISO 11737-1:2006 ; EN 1041:2008 ; EN ISO 11737-1:2006/AC:2009 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ; EN 868-2:2017 ; EN ISO 11 607-1:2017 ;
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Level	Type	Dimension	Stamp	Labels
1	300 Plastic bag			labeled
2	300 Carton box	610x330x190mm		labeled

<b>Important Notes:</b>	Nr pcs/pack subjected to ± 3% variation DEHP free. With anti-static treatment. Without mechanical memory. Microbial barrier in double sheet: >=99,9%
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<b>Storage instructions</b>	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply
<b>Waste instructions</b>	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
<b>Intended use</b>	(When sterile) Intended for wrapping of medical devices producing a sterile barrier system under specified and controlled conditions.

**ISSUED BY: Quality Management Department, 2020/03/23**

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