Bastos Viegas
4560-164 Guilhufe, Penafiel - Portugal

Ref:	4501-011

Technical Specifications

Brand:	

Description:	SMS sterilization wrap

Final dimensions:	1,3 m x130 cm
Composition:	SSMMS blue PP NW (5 layers).
Construction:	40 g/sqm
Latex:	Free
PVC:	Free
Re use:	No
Sterilizable by:	Moist heat or EO
Colour:	blue
Shelf life:	120 months
CFU/g	<10^2
Bacterial filtration eficienc	> 96 %
Hydrostatic pressure	>=40 mbar
Weigth/sqm	40,0 ± 5% g/m^2
Fluorescence	conform
pH aqueous extract	5,0 - 8,0
Chloride content	< 0,05 %
Sulphate content	< 0,25 %
Dry Tensile Strength MD	Approx. 1,9 (>1,0*) kN/m
Dry Tensile Strength CD	Approx. 1,0 (>0,65*) kN/m
Tearing Resistance MD	Approx. 4100 (>750*) mN
Tearing Resistance CD	Approx.5600 (>1000*) mN
Elongation at break MD	Approx. 70 (>5*) %
Elongation at break CD	**Approx. 80 (>7*) %**
Dry Bursting Strength	Approx. 300 (>130*) kPa
Also sterilizable by	Plasma
In accordance with	EN 868-2:2017
In accordance with	EN ISO 11607-1:2017
In accordance with	ISO 2758
Note:	* EN 868-2 value
In accordance with	EN ISO1924-2;ISO3781
Do not sterilize by	Irradiation
Width variation	±35 mm
Length variation	±35 mm

Nr and Revision Date:	13 -- 2020/02/24
CE Class:	I
Compliance with:	MDD 93/42/ EEC amended by 2007/47/EC
Applicable norms:	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN ISO 11737-1:2006 ; EN 1041:2008 ; ENISO11737-1:2006/AC:2009 ; ISO 16142-1:2016 ; EN ISO 15 223-1:2016 ; EN 868-2:2017 ; EN ISO 11 607-1:2017 ;

Level		Type	Dimension		Stamp	Labels
1	50	Plastic bag				labeled
2	150	Carton box	790x390x300mm			labeled

Important Notes:	Nr pcs/pack subjected to ± 3% variation
	DEHP free. With anti-static treatment. Without mechanical memory. Microbial barrier in double sheet: >=99,9%

Storage instructions	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
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	(When sterile) Intended for wrapping of medical devices producing a sterile barrier system under specified and controlled conditions.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	698

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