

TECHNICAL DATA SHEET

STERILIZATION REEL

- PRODUCT CODE** : smartfol 111349 / 111350 / 111351
- RELATED STANDARDS** : smartfol flat reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Type 1 indicator according to the ISO 11140-1 standard. smartfol reels meet the requirements of MDR (EU) 2017/745 Medical Device Regulation.
- INTENDED USE** : smartfol reels are designed to provide excellent barrier for sterile medical device packaging purposes. Reels meet the Medical Industry's requirement for high quality, hygiene and safety levels. smartfol reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. smartfol Reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.
- OPERATION CONDITIONS** : smartfol reels are used for steam and ethylene oxide sterilization methods. The sterilization conditions should be determined by the end user regarding to material to be sterilized.

SPECIFICATIONS :

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
MEDICAL PAPER	SUBSTANCE	g/m ²	ISO 536	60	
	THICKNESS	µm	ISO 534	83	
	BENDTSEN POROSITY	ml/min	ISO 5636-3	1000	
	AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4	
	BENDTSEN ROUGHNESS FS	ml/min	ISO 8791-2	375	
	BENDTSEN ROUGHNESS WS	ml/min	ISO 8791-2	375	
	TENSILE STRENGTH /MD	kN/m	EN ISO 1924-2	6,4	
	TENSILE STRENGTH /CD	kN/m	EN ISO 1924-2	3,4	
	WET TENSILE STRENGTH /MD	kN/m	ISO 3781	2,1	
	WET TENSILE STRENGTH /CD	kN/m	ISO 3781	1,1	
	BURST STRENGTH	kPa	ISO 2758	350	
	TEARING STRENGTH /MD	mN	ISO 1974	600	
	TEARING STRENGTH /CD	mN	ISO 1974	650	
	WET BURST	kPa	ISO 3689	150	
	WATER REPELLENCY	s	EN 868-2 (app.D)	35	
	PORE SIZE	µm	EN 868-2 (app.E)	21	
	COBB TEST (60 s)	g/m ²	ISO 535	15	
	FLUORESCENCE	pts/dm ²	EN 868-2 (app.B)	0	
	pH: between 5.0 and 8.0 (ISO6588-2)		Chloride content < 0,05% (ISO 9197) Sulphate Content < 0,25% (ISO9198)		
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				



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LAMINATED FILM	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE		
	THICKNESS	μm	ISO 534	LAM.FILM	53 \pm 5	
				PP	40 \pm 5	
				PET	12 \pm 2	
	THERMAL SEAL	$^{\circ}\text{C}$	ASTM F 88	180 \pm 5 (1.3 bar- 14 m/min)		
	TENSILE	N/15 mm	MD CD	ASTM D 882-12	min. 28	
					min. 30	
	TEAR	mN	MD CD	ASTM D 1922-09	min. 70	
min. 70						
HAZE	%	ASTM D 1003	max. 9			
FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS						

PRODUCT SPECIFICATIONS

REEL	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE		
	SEAL STRENGTH	cm	ASTM F 88	< 25	\geq 25	
		Edge Seal (N/15 mm)		3,0 \pm 0,5	4,0 \pm 0,75	
	BUBBLE TEST		ASTM F 2096-04	None		
	PINHOLE DETERMINATION		EN 868-5 Annex C	None		
	DIMENSION CONTROL	cm or mm	ASTM F 2203-13	Required dimensions		
	LEAKAGE TEST		ASTM F 1929-15	None		
	PEEL DIRECTION		EN 868-5 Annex E	Must not break the particle		
INDICATOR CONTROL		ISO 11140-1	Must return to the specified color			

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	Pink	Brown / Black
	EO	Blue	Yellow / Orange

PACKAGING : smartfol reels are packaged as below.

<u>Product Code</u>	<u>Dimension</u>	<u>Pieces in carton</u>
smartfol 111349	50 mm x 200 m	12
smartfol 111350	75 mm x 200 m	8
smartfol 111351	100 mm x 200 m	6



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