TECHNICAL DATA SHEET

STERILIZATION REEL

TECHNICAL DATA SHEET

PRODUCT CODE : **MELAfol 502 / 752 / 1002 / 1502 / 2002 / 2502**

RELATED STANDARDS : MELAfol flat reels are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. MELAfol reels meet the requirements of (EU) 2017/745 Medical Device Regulation.

INTENDED USE : MELAfol 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.MELAfol reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. MELAfol Reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.

OPERATION CONDITIONS : MELAfol reels are used for steam, ethylene oxide, formaldehyde 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/dm²	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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	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
LAMINATED FILM	THICKNESS	µm	ISO 534	LAM.FILM	53 ± 5
				PP	40 ± 5
				PET	12 ± 2
	THERMAL SEAL	ºC	ASTM F 88	180 ± 5 (1.3 bar- 14 m/min)	
	TENSILE	N/15 mm MD	ASTM D 882-12	min. 28	
		N/15 mm CD		min. 30	
	TEAR	mN MD	ASTM D 1922-09	min. 70	
		mN CD		min. 70	
	HAZE	%	ASTM D 1003	max. 9	
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS				

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
REEL	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 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	

	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
INDICATOR	STEAM	Pink	Brown / Black
	EO	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

PACKAGING : MELAfol reels are packaged as below.

Product Code		Pieces in carton
MELAfol 502	5 cm	1
MELAfol 752	7,5 cm	1
MELAfol 1002	10 cm	1
MELAfol 1502	15 cm	1
MELAfol 2002	20 cm	1
MELAfol 2502	25 cm	1

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TECHNICAL DATA SHEET

STERILIZATION POUCH

TECHNICAL DATA SHEET

PRODUCT CODE : **MELAfol 501 / 751 / 1001 / 2051**

RELATED STANDARDS : MELAfol flat sterilization pouches are manufactured according to EN 868-5 and ISO 11607 standards. The indicator used in the pouch production is classified as Class 1 Type Indicator according to the ISO 11140-1 standard. MELAfol Pouches meet the requirements of (EU) 2017/745 Medical Device Regulation.

INTENDED USE : MELAfol Pouches are designed to provide excellent barrier for sterile medical device packaging purposes. Pouches meet the Medical Industry's requirement for high quality, hygiene and safety levels. MELAfol pouches are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. MELAfol Pouches are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices.

OPERATION CONDITIONS : MELAfol pouches are used for steam, ethylene oxide and formaldehyde 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/dm²	EN 868-2 (app.B)	0
	pH: between 5.0 and 8.0 (ISO6588-2)	Chloride Content < 0,05% (ISO 9197) Sulfate Content < 0,25% (ISO9198)		
	FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS			

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

PRODUCT SPECIFICATIONS

	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
POUCH	SEAL STRENGTH	cm	ASTM F 88	< 25	≥ 25
		Edge Seal (N/15 mm)		3,0 ± 0,5	4,0 ± 0,75
		Top Seal (N/15 mm)		4,0 ± 0,5	5,0 ± 0,5
	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	Green	Yellow / Orange
	FORMALDEHYDE	Red	Green

PACKAGING : MELAfol flat pouches are packaged 250 pieces in a film package. Each 1000 pieces are packaged in a carton box.

MELAfol gusseted pouches are packaged 100 pieces in a film package. 100 pieces are packaged in a carton box.

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