

PRODUCT CODE

SR (Flat) - KR (Gusseted)

RELATED STANDARTS

MEDSTER flat and gusseted 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. MEDSTER flat and gusseted reels meet the requirements of 93/42/EEC Medical Device Directive regulations

INTENDED USE

MEDSTER 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. MEDSTER reels are used for the packing of the Medical Devices before sterilization and it maintains the sterility of the products after sterilization. MEDSTER Reels are ease to package and indicator used for the sterilization provides information with the sterilization status of the medical devices. Sterilized material in sterilization package is storable for up to 5 years after the sterilization in a clean room conditions.

OPERATION CONDITIONS

MEDSTER 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
SUBSTANCE	g/m ²	ISO 536	60
THICKNESS	µm	ISO 534	83
BENDTSEN POROSITY	ml/mn	ISO 5636-3	1000
AIR PERMEANCE	µm/(Pa.s)	ISO 5636-3	11,4
BENDTSEN ROUGHNESS FS	ml/mn	ISO 8791-2	375
BENDTSEN ROUGHNESS WS	ml/mn	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 of water		ISO6588-2	5,8
Chloride content		ISO 9197	< 0,05%
Sulphate Content		ISO9198	< 0,25%
Bendsen Porosity			972

FREE FROM LEAD AND HEAVY METALS AND TOXIC MATERIALS

LAMINATED FILM	PROPERTIES	UNIT	STANDARD	TYPICAL VALUE	
	THICKNESS	Micron	ASTM D 374	LAM.FILM	53 ± 5
				PP	40 ± 5
				PET	12 ± 2
	COF	F/M	ASTM F 1894	0,30-0,35	
		M/M		0,35-0,40	
	THERMAL SEAL	oC	ASTM F 88	150 ± 5	
	TEAR	G	D1922	40 ± 5	
		MD TD		50 ± 5	
	GLOSS	%	ASTMD 2457	150 ± 5	
	GUSETTED REEL WIDTH	CM	EN 868-5	5-8	
	Minimum basic weight	g/cm2		65	
	Tensile Stregnht	N/mm		36,5N/15 mm	
	Fusion temperature of polyester	C		260	
Transparent plastic layer	65 g/m2		Min 65 g/m2, 12µm Polyester		

INDICATOR	STERILIZATION METHOD	BEFORE STERILIZATION	AFTER STERILIZATION
	STEAM	PINK	BROWN
	EO	ORANGE	YELLOW
Note:chemical indicators 10 by 10 cm on the side of the paper for the control of the packets exposure to steam or ethylene oxide sterilization processes.			

- Resistance to heat sealed seams (dry) minimum 4.6 N / 15mm
- Resistance to heat sealed seams (wet) minimum 3.2 N / 15mm
- CE marking

PACKAGING and ORDERING INFORMATION

MEDSTER reels are packaged as below

FLAT/GUSETTED STERILIZATION REELS

Product Code	Product Description	Product Size	Qty. / Box
SR05200	Flat Sterilization Reel	50 mm * 200 m	16 reels
SR75200	Flat Sterilization Reel	75 mm * 200 m	8 reels
SR10200	Flat Sterilization Reel	100 mm * 200 m	8 reels
SR15200	Flat Sterilization Reel	150 mm * 200 m	4 reels

SR20200	Flat Sterilization Reel	200 mm * 200 m	4 reels
SR25200	Flat Sterilization Reel	250 mm * 200 m	2 reels
SR30200	Flat Sterilization Reel	300 mm * 200 m	2 reels
SR35200	Flat Sterilization Reel	350 mm * 200 m	2 reels
SR40200	Flat Sterilization Reel	400 mm * 200 m	2 reels
KR05100	Gusseted Sterilization Reel	50 mm * 100 m	10 reels
KR75100	Gusseted Sterilization Reel	75 mm * 100 m	8 reels
KR10100	Gusseted Sterilization Reel	100 mm * 100 m	8 reels
KR15100	Gusseted Sterilization Reel	150 mm * 100 m	4 reels
KR20100	Gusseted Sterilization Reel	200 mm * 100 m	4 reels
KR25100	Gusseted Sterilization Reel	250 mm * 100 m	2 reels
KR30100	Gusseted Sterilization Reel	300 mm * 100 m	2 reels
KR35100	Gusseted Sterilization Reel	350 mm * 100 m	2 reels
KR40100	Gusseted Sterilization Reel	400 mm * 100 m	2 reels