Getinge Pack

Sterilization Pouch (70gsm)

Getinge Pack Flat Sterilization Pouches are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in steam or ethylene oxide sterilization (EO).

The Flat Sterilization Pouches are constructed of multilayer PET/PP copolymer film and medical grade paper. Type I process indicators for steam and ethylene oxide is applied on the medical grade paper surface of the each pouch. After exposure to steam or ethylene oxide sterilization, the chemical indicator will provide an accurate visual confirmation by color changing, indicating that sterilization conditions were met.

Performance Characteristics

The recommended (and validated) sterilization cycle parameters are:

- For steam sterilization pre-vacuum cycle at 270°F/132°C for 4 minutes
- For EO sterilization, 100% ethylene oxide (EO) with a concentration of 725mg/l at 131°F/55°C and 50-80% relative humidity, for 60 minutes. Aeration time is 8 hours

A process indicator is applied on the paper surface of each pouch. After exposure to steam or Ethylene Oxide sterilization, the chemical indicator will provide an accurate visual confirmation by color changing, indicating that the Getinge Pack was exposed to the sterilization process. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Key Features

- Superior barrier with 70gsm medical grade paper
- Reinforced film to avoid tearing during opening
- Triple band seal for higher package integrity
- Accurate & non-toxic external process indicator

Usage Information

Please consult IFU for detailed instructions.

Physical Properties - Medical Grade Paper

Getinge uses highest quality medical grade paper for Getinge Pack branded sterilization pouches. Medical grade paper is in compliance to European Standard EN 868-3 and all requirements listed in below table.

Properties	Unit	Related Standard	Value
Substance	g/m^2	ISO 536	70±3
Thickness	µm	ASTM D 645	min.90
Bendsten Porosity	ml/min	ISO 5636-3	min. 700
Air Permeance	µm/(Pa.s)	ISO 5636-3	min. 7.9
Bendsten Roughness FS	ml/min	ISO 8791-2	min.250
Bendsten Roughness WS	ml/min	ISO 8791-2	min.250
Tensile Strength /MD	kN/m	EN ISO 1924-2/	min. 4.4
Tensile Strength /CD	kN/m	EN ISO 1924-2/	min. 2.2
Wet Tensile Strength /MD	kN/m	ISO 3781	min. 1.0
Wet Tensile Strength /CD	kN/m	ISO 3781	min. 0.6
Burst Strength	kPa	ISO 2758	min. 270
Tearing Strength /MD	mN	ISO 1974	min. 550
Tearing Strength /CD	mN	ISO 1974	min. 550
Wet Burst	kPa	ISO 3689	min. 80
Water Repellency	s	EN 868-2 (App. D)	min. 20
Pore Size	µm	EN 868-2 (App. E)	max. 35
COBB Test (60s)	g/m^2	ISO 535	max. 20
Fluorescense	pts/dm^2	EN 868-2 (App. B)	0
pH: between 5.0 and 8.0 (ISO 6588-2)			
Chloride Content <0.05% (ISO 9197)			
Sulfate Content: <0.25% (ISO 9198)			

Free from Lead, Heavy Metals and Toxic Materials

Physical Properties - Laminated Film (PET/PP)

Getinge uses highest quality steam sterilizable PET/PP film webs for Getinge Pack branded sterilization pouches. The film web is in compliance to European Standard EN 868-5 and all requirements listed in below table.

Properties	Unit	Method	Typical Values		
Thickness	µm	ASTM F2251-03	Lam. Film		Min.45
			Before Sterilization	After Steam Sterilization	After EO Sterilization
Tensile	N MD CD	ASTM D882-12	min.28 min.28	min.32 min.32	min.28 min.28
Elongation	% MD CD	ASTM D882-12	min.30 min.30	min.30 min.30	min.30 min.30
Tear Resistance	mN MD CD	ASTM D1922-09	min.70	min.70	min.70
Falling Dart	gr	ASTM D1709	max.280	max.280	max.280
Pinhole Control		TS EN 868-5 Annex C	None	None	None
Haze	%	ASTM D1003	<9	<12	<12
Light Transmission	%	ASTM D1003	≥75	≥75	≥75

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Physical Properties

Getinge first priority is to meet customer's expectations by highest quality and standard conformed products. Implemented and applied quality control stages and in-house and external laboratory tests help us to ensure high product quality and sustainable production outcome. All final products are tested for compliance with ISO 11607-1, ISO 11140-1 and EN 868-5.

Properties	Unit	Method	Typical Value	
	cm		**Before Sterilization** <25 or ≥ 25	**After Sterilization** <25 or ≥ 25
Seal Strength	Edge Seal (N/15mm)	ASTM F88/ F88M-09	min. 1.5	min. 1.5
	Top Seal (N/15mm)		min. 1.5	min. 1.5
Bubble Test	-	ASTM F2096-2011	No bubbles	No bubbles
Dimension Control	mm	ASTM F2203-02	Correct dimensions	Correct dimensions
Dye Penetration Test	-	ASTM F1929-2012	No leakages	No leakages
Peel Direction	-	EN 868-5 Annex E	No particles	No particles
Indicator Control (Steam)		ISO 11140-1	Pink	Brown
Indicator Control (EO)		ISO 11140-1	Turquoise	Yellow

Ordering Information

Getinge Pack	Order Number
Sterilization Pouch 3 in. x 8 in.	61301606751
Sterilization Pouch 4 in. x 8 in.	61301606752
Sterilization Pouch 4 in. x 12 in.	61301606753
Sterilization Pouch 4 in. x 22 in.	61301606754
Sterilization Pouch 5 in. x 15 in.	61301606755
Sterilization Pouch 6 in. x 10 in.	61301606756
Sterilization Pouch 7.5 in. x 13 in.	61301606757
Sterilization Pouch 8 in. x 10 in.	61301606758
Sterilization Pouch 8 in. x 16 in.	61301606759
Sterilization Pouch 10 in. x 15 in.	61301606760
Sterilization Pouch 12 in. x 12 in.	61301606761
Sterilization Pouch 12 in. x 18 in.	61301606762
Sterilization Pouch 16 in. x 16 in.	61301606763

Manufactured for Getinge by PMS Tibbi Cihazlar Teknolojisi Sanayi ve Ticaret Anonim Şirketi
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