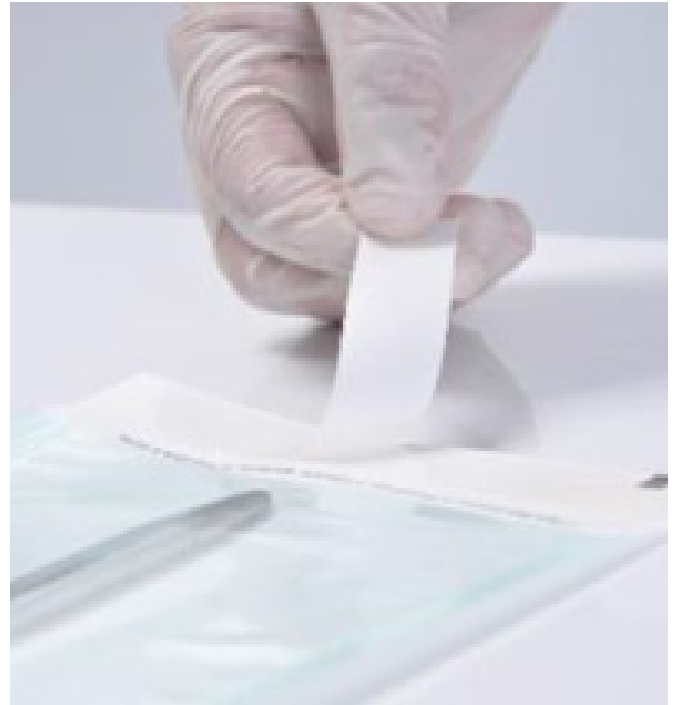


Getinge Pack

Self-Seal Sterilization Pouch (60gsm)

Getinge Pack Self-Seal Sterilization Pouches are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in steam or Ethylene Oxide (EO).

The pouches are constructed of multilayer PET/PP copolymer film and medical grade paper that is heat sealed on 3 sides. The fourth side has an adhesive strip that is used to seal the pouch without the need for a heat sealing machine. Release paper used in the pouch is a silicon coated paper. A strip covers the adhesive area and is released before sealing the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or Ethylene Oxide gas.



Performance Characteristics

The recommended (and validated) sterilization cycle is:

- 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. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 30 days.

Key Features

- Superior barrier with 60gsm 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 Self-Seal Sterilization Pouches. Medical grade paper is in compliance to European Standards EN 868-3 and all requirements listed in below table.

Properties	Unit	Related Standard	Value
Substance	g/m ²	ISO 536	60
Thickness	µm	ISO 534/ASTM D 645	83 ± 5
Bendsten Porosity	ml/min	ISO 5636-3	1000
Air Permeance	µm/(Pa.s)	ISO 5636-3	11.4
Bendsten Roughness FS	ml/min	ISO 8791-2	375
Bendsten Roughness WS	ml/min	ISO 8791-2	375
Tensile Strength /MD	kN/m	DIN EN ISO 1924-2 ASTM D882-12	6.4 ± 1.2
Tensile Strength /CD	kN/m	DIN EN ISO 1924-2 ASTM D882-12	3.4 ± 1.0
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 ± 150
Tearing Strength /CD	mN	ISO 1974	650 ± 200
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 (60s)	g/m ²	ISO 535	15
Fluorescence	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/PE)

Getinge uses highest quality steam sterilizable PET/PP film webs for Getinge Pack branded Self-Seal 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 Value			
			Lam. Film			
Thickness	µm	ISO 534/ ASTM F2251-03	Lam. Film	53 ± 5		
			PP	40 ± 5		
			PET	12 ± 2		
Tensile	N	MD CD	ASTM D882-12	Before Sterilization	After Steam Sterilization	After EO Sterilization
				min.28 min.30	min.32 min.36	min.28 min.30
Elongation	%	MD CD	ASTM D882-12	min.30 min.31	min.35 min.30	min.30 min.31
Tear Resistance	Mn	MD CD	ASTM D1922-09	min.70	min.70	min.70
Falling Dart	gr		ASTM D1709	max.350	max.350	max.350
Pinhole Control			TS EN 868-5 Annex C	None	None	None
Haze	%		ASTM D1003	max.9	max.12	max.9
Light Transmission	%		ASTM D1003	min.80	min.80	min.80

Physical Properties

Getinge's first priority is to meet customer's expectations by highest quality and standard conform 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			
			Before Sterilization		After Sterilization	
Seal Strength	Size (cm) Edge Seal (N/15mm) Top Seal (N/15mm)	ASTM F88/ F88M-09	<25	≥25	<25	≥25
			5.0 ± 1.0	6.0 ± 1.0	5.0 ± 1.0	6.0 ± 1.0
			4.0 ± 1.0	4.0 ± 1.0	4.0 ± 1.0	4.0 ± 1.0
Bubble Test	-	ASTM F2096-2011	No bubbles		No bubbles	
Dimension Control	mm	ASTM F2203-02	Correct dimensions		Correct dimensions	
Dye Penetration	-	ASTM F1929-2012	No leakages		No leakages	
Peel Direction	-	EN 868-5 Annex E	No particles		No particles	
Indicator Control		ISO 11140-1	Color change to reference color		Color change to reference color	

Quality Statement

Confidence in the Getinge Group is the most important quality criteria. This is the hallmark of all our external and internal commitments, activities and products. Products and services supplied by Getinge conform to the agreed terms and expectations. The achievement of these quality goals is the basis for continued competitive and successful enterprise.

Ordering Information

Getinge Pack

Order Number

Self-Seal Sterilization Pouch, 3.5 in. x 9 in. 61301606722

Self-Seal Sterilization Pouch, 4 in. x 11 in. 61301606723

Self-Seal Sterilization Pouch, 5 in. x 15 in. 61301606724

Self-Seal Sterilization Pouch, 6 in. x 12 in. 61301606726

Self-Seal Sterilization Pouch, 8 in. x 16 in. 61301606727

Self-Seal Sterilization Pouch, 10 in. x 15 in. 61301606728

Self-Seal Sterilization Pouch, 12 in. x 18 in. 61301606729

Self-Seal Sterilization Pouch, 13 in. x 18 in. 61301606730

Getinge is a registered trademark of Getinge AB or its subsidiaries or affiliates in the United States or other countries. • Copyright 2017 Getinge AB or its subsidiaries or affiliates. • All rights reserved. • MCV00042005 REV B

Manufactured for Getinge by PMS, Mersin, Turkey

Sales Office: Getinge USA, Inc. 1777 East Henrietta Road, Rochester, NY 14623 USA

www.getinge.com

GETINGE 