

Getinge Pack

Tyvek Sterilization Roll (1059B)

Getinge Pack Tyvek Sterilization Rolls are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in Vaporized Hydrogen Peroxide (VHP) sterilization method.

The Rolls are manufactured from Tyvek grade material and heat sealed laminated multilayer PET/PE copolymer film that are heat sealed on opposite two sides.



Performance Characteristics

The recommended (and validated) sterilization cycle is:

- For Vaporized Hydrogen Peroxide (VHP) Sterilization; Steris V-PRO 1 Lumen Cycle.

A process indicator is applied on the Tyvek surface of the each roll. After exposure to Hydrogen Peroxide Sterilization, the chemical indicator will provide an accurate visual confirmation by color changing, indicating the Getinge Pack was exposed to the sterilization process.

It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.

Key Features

- Made of transparent Tyvek 1059B
- Excellent microbial barrier properties
- Accurate & non toxic external color change process indicator from red to blue

Usage Information

Please consult IFU for detailed instructions

Physical Properties - Tyvek Web

Getinge uses highest quality uncoated Tyvek for Getinge Pack branded Tyvek sterilization rolls. Tyvek complies to compliance to European Standard EN 868-9 and all requirements listed in below table.

Properties	Unit	Related Standard	Value
Substance	g/m ²	EN ISO 536	64.5±4.5
Delamination	N	ASTM D2724	(1.8-3.6)
Gurley Hill Porosity	Sec/100 cc	ISO 5636-5	(8-36)
Thickness	µm	ASTM D645	min.150
Elmendorf Tear /MD	mN	DIN EN 21974 ISO 1974:2012	Min.1000
Elmendorf Tear /CD	mN	DIN EN 21974 ISO 1974:2012	Min.1000
Tensile Strength /MD	kN/m	DIN EN ISO 1924-2	min. 4.8
Tensile Strength /CD	kN/m	DIN EN ISO 1924-2	min. 5.0
Elongation /MD	%	DIN EN ISO 1924-2	19
Elongation /CD	%	DIN EN ISO 1924-2	23
Bendsten Air Permeability	ml/min	ISO 5636-3	557
Hydrostatic Head	cm H ₂ O	DIN EN 20811	157
Opacity	%	ISO 2471	92
Microbial Barrier	Log Reduction Value (LRV)	ASTM F1608	>4
Mullen Burst	kPa	ISO 2758	1034
Spencer Puncture	J/m ²	ASTM D3420	7746

Free from Lead, Heavy Metals and Toxic Materials

Physical Properties - Laminated Film (PET/PE)

Getinge uses highest quality vaporized hydrogen peroxide sterilizable PET/PE film webs for Getinge Pack branded Tyvek Sterilization Rolls. The film web complies to European Standard EN 868-5 and all requirements listed in below table.

Properties	Unit	Method	Typical Value	
Thickness	µm	ASTM F2251-03	Lam. Film	min. 55
			Before Sterilization	After Sterilization
Tensile	N	MD	min.26	min.26
		CD	min.26	min.26
Elongation	%	MD	min.28	min.28
		CD	min.30	min.30
Tear Resistance	mN	MD	min.90	min.90
		CD	min.90	min.90
Falling Dart	gr	ASTM D1709	max.325	max.325
Pinhole Control		TS EN 868-5 Annex C	None	None
Haze	%	ASTM D 1003	max.17	max.17
Light Transmission	%	ASTM D 1003	≥75	≥75

Free from Lead, Heavy Metals and Toxic Materials

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)	ASTM F88/ F88M-09	<25 or ≥25	<25 or ≥25
	Edge Seals (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	-	ASTM F1929-2012	No leakages	No leakages
Peel Direction	-	EN 868-5 Annex E	No particles	No particles
Indicator Control		ISO 11140-1	red	blue or (lighter)

Ordering Information

Getinge Pack

Order Number

Tyvek Sterilization Roll, 2 in. x 100 ft.	61301606732
Tyvek Sterilization Roll, 4 in. x 100 ft.	61301606733
Tyvek Sterilization Roll, 6 in. x 100 ft.	61301606734
Tyvek Sterilization Roll, 8 in. x 100 ft.	61301606735
Tyvek Sterilization Roll, 10 in. x 100 ft.	61301606736

Getinge is a registered trademark of Getinge AB, its subsidiaries, or affiliates in the United States or other countries • Copyright 2018 Getinge AB or its subsidiaries or affiliates • All rights reserved. MCV00044190 REVC

Manufactured for Getinge by PMS Tibbi Cihazlar Teknolojisi Sanayi ve Ticaret Anonim Şirketi
Karaduvar Mah. Serbest Bolge, 11.Cad. No.46, Mersin Serbest Bolgesi, Akdeniz | 33020 Mersin/TURKEY
Sales Office: Getinge USA, Inc. 1777 E. Henrietta Road Rochester, NY 14623 USA

www.getinge.com

GETINGE 