

Getinge Pack

Tyvek Sterilization Pouch (1059B)

Getinge Pack Tyvek Sterilization Pouches 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 pouches are made from Tyvek grade material and heat sealed laminated multilayer PET/PE copolymer film that are heat sealed on 3 sides. The fourth side is left opened and heat sealed by the user with the help of a validated sealing process.



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 web of the each pouch. After exposure to Hydrogen Peroxide 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 devices and also maintain sterility of the enclosed devices until used.

Key Features

- Superior barrier with Tyvek 1059B
- 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 - Tyvek Web

Getinge uses highest quality uncoated Tyvek web for Getinge Pack branded Tyvek sterilization pouches. Tyvek complies 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 Pouches. The film web complies to European Standard EN 868-5 and all requirements listed in below table.

| Properties | Unit | Method | Typical Value | |
|--------------------|------|---------------------|----------------------|---------------------|
| | | | Before Sterilization | After Sterilization |
| Thickness | µm | ASTM F2251-03 | Lam. Film | min. 55 |
| 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) | | <25 or ≥25 | <25 or ≥25 |
| | Edge Seals (N/15mm) | ASTM F88/ F88M-09 | min. 1.5 | min. 1.5 |
| | Top 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 Pouch, 4 in. x 12 in. | 61301606737 |
| Tyvek Sterilization Pouch, 4 in. x 22 in. | 61301606738 |
| Tyvek Sterilization Pouch, 6 in. x 12 in. | 61301606739 |
| Tyvek Sterilization Pouch, 8 in. x 12 in. | 61301606740 |
| Tyvek Sterilization Pouch, 8 in. x 16 in. | 61301606741 |
| Tyvek Sterilization Pouch, 10 in. x 15 in. | 61301606742 |
| Tyvek Sterilization Pouch, 10 in. x 18 in. | 61301606743 |
| Tyvek Sterilization Pouch, 12 in. x 18 in. | 61301606744 |

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. MCV00044189 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 