Sterilisation Barrier Solutions

Technical Datasheet (Product)

Uncoated Tyvek® Sterilisation Pouch / Reel

General Description

The product consists of an uncoated, non-woven polyolefin material, with a film front. The polyolefin material can be Tyvek® grade 1073B, 1059B or 2FS.

The product is suitable for sterilisation by Ethylene Oxide (EO), Irradiation and Vaporised Hydrogen Peroxide (VH_2O_2, with or without Plasma) processes. It can be printed with process indicators for both gaseous sterilisation processes, or with colour artwork to match customer requirements.

The pouch/reel is heat sealable, between 120°C and 140°C, achieving a minimum of 1.5N/15mm when tested in accordance with EN868-5.

Materials

Permeable Layer: Tyvek® 1073B, 1059B or 2FS, conforming to EN868-9.
Film: Polyester/PE laminated film, 12/38µm or 12/50µm.

Typical Properties

Property	Units	Test Method	Typical Value
Seal Strength	N/15mm	EN868-5	2.5 (Clean Peel)

Regulatory Compliance

The product conforms to ISO11607-1:2019 and EN868-5:2018.
Process indicators, when printed, are compliant with ISO 11140-1:2014 (Class 1).
The product is manufactured under a quality management system that conforms to ISO9001:2015 and ISO13485:2016 and the manufacturing process is validated to the requirements of ISO11607-2:2019.

This product has an Active Life of up to 5 years from the date of manufacture, dependant on storage conditions. For more information, please refer to Westfield Medical Advice Sheet 1: Active Life of Single-Use Sterilisation Packaging Materials, and Advice Sheet 20: Storage Conditions of Westfield Medical Packaging Products.

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