

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 (VH₂O₂, 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.

Tyvek® is a registered trademark of Du Pont.

The information provided herein is based on laboratory evaluation and actual field experience and is to our knowledge true and accurate. However, it does not constitute part of any declared or implied product specification or guarantee, unless otherwise indicated, and we cannot accept liability for any recommendation or representation made. It is the responsibility of the end user to confirm suitability for their application. If in doubt about the feasibility of a particular end use, please seek technical assistance from Westfield Medical Limited.

Westfield Medical Limited

Second Avenue, Westfield Trading Estate,
Midsomer Norton, Radstock BA3 4DP

Registered in England No. 2769324

T +44 (0) 1761 408800 **E** sales@westmed.co.uk

F +44 (0) 1761 413714 **W** www.westmed.co.uk



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Sterile Barrier Association