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Tyvek®

# PROVEN SOLUTIONS FOR PHARMACEUTICAL PROTECTION

# We've got you covered

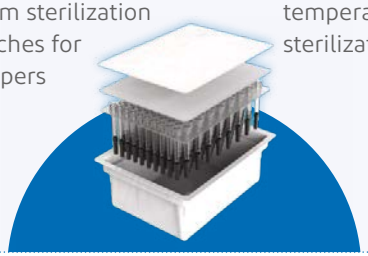
Tyvek® provides the highest level of protection for Pharmaceutical production, making it an ideal choice for pharmaceutical packaging and cleanroom garments and covers that requires high strength and superior microbial barrier.

## Garments

- Grade A/B Clean and Sterile garments
- Made of HDPE
- BFE 98-99%
- Helmke Drum Test Category I
- 5 years shelf life
- Excellent Body box test results
- Gamma irradiated to SAL $10^{-6}$, validated to ISO 11137

## Pharmaceutical packaging / autoclave

- Pharma Packaging: Tyvek® 1073B for aseptic processing and final product packaging
- Product Examples: Pre-filled syringe packaging and steam sterilization pouches for stoppers
- Made of HDPE
- Proven microbial barrier performance
- Compatibility with ethylene oxide, gamma and e-beam irradiation, steam and low-temperature sterilization



## Sterilization covers and bags

- Pharma Covers: Tyvek® 1421B for in-process steam sterilization applications
- Product Examples: Cleanroom equipment covers, stopper bowl covers, sterilization wrapping, autoclave component bags and covers
- Made of HDPE
- Proven microbial barrier performance
- Supports regulatory compliance of pharmaceutical processing (e.g., GMP Annex 1)

**Common features/arguments**

- **Low particle shedding**: continuous filament / high resistance to abrasion
- **Filtration efficiency**: Outstanding microbial barrier and particle filtration
- **Sterility assurance**: Compatibility with many sterilization processes
- **High mechanical resistance**: Air and water vapor permeability / Puncture resistance for optimal protection
- Supports regulatory compliance with **GMP Annex 1**
- **Stability**: extensive aging data available, 5, 7 or 10 years depending on styles

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# For wearer and aseptic process, DuPont™ Tyvek® garments provide trusted protection

Offering an ideal balance of protection, durability, comfort and contamination control, DuPont™ Tyvek® garments not only protect pharmaceutical products and processes from contamination, they also protect the operators working in cleanrooms and other controlled environments from potential exposure to hazardous substances.

Designed especially for use in cleanrooms and controlled environments demanding high levels of microbiological protection, sterile Tyvek® IsoClean® coveralls are suitable for cleanrooms up to GMP A&B, ISO 4/5 and CLASS 10/100 controlled environments. Tyvek® IsoClean® garments are available in a wide variety of styles, such as coveralls, hoods and boot covers, enabling protection from head to toe. Featuring the lowest linting and particle shedding of any garments in the DuPont portfolio, Tyvek® IsoClean® single-use garments offer consistent protection performance—every time—and help make both your inventory and cost more predictable.

Moreover, Tyvek® IsoClean® sterile garments:

- Feature typical bacterial filtration efficiency of 98.4% (for the CS option, as measured by ASTM F2101)
- Have a sterility assurance level (SAL) of $10^{-6}$; irradiation doses are validated in accordance with ANSI/AAMI/ISO 11137 through bioburden and dose verification testing
- Are gamma irradiated in a facility that is registered by ISO 13485 quality standard and adheres to the requirements of ANSI/AAMI/ISO 11137
- Come with a Certificate of Sterility and a Certificate of Compliance
- Are specially processed to minimize particle shedding, then folded for aseptic donning and individually packed

For the GMP A&B, ISO 4/5 controlled environments, Tyvek® portfolio is offering a clean-processed and sterile and only sterile range. **Tyvek® IsoClean® IC 193 B**, is ideal for biotechnology, pharmaceutical and medical device manufacturing, as it is a coverall with attached hood with ties, making it possible to fit a medical mask and goggles. In addition, there are integrated overboots with Gripper™ sole and has attached ties. It is available for Category III personal protective equipment (PPE), offers Option DS (double-bagged and sterile) for contamination control and sterility risk management, and is CE certified. Another option for the GMP A&B, ISO 4/5 controlled

environments is **Tyvek® IsoClean® IC 183 B**. This is an unhooded coverall that is available for Category III personal protective equipment (PPE) and also offers Option DS for contamination control and sterility risk management, and is CE certified. This garment is an excellent choice for clean-processed and sterile, medical device, manufacturing, and pharmaceutical production.

Lastly, DuPont offers numerous Tyvek® accessories, from labcoats and sleeves, to boot covers, hoods, masks and bouffants that are available for Category I and Category III personal protective equipment (PPE) and CE certified.

For the GMP C&D, ISO 6/9 controlled environments, Tyvek® is offering a range of non-sterile accessories that are CE certified and available for Category III personal protective equipment (PPE). **Tyvek® 600 Plus** coverall offers the added benefit of protective design features and overtaped seams. It helps provide an effective barrier against many water-based inorganic chemicals in low concentration, small-sized hazardous particles and biological hazards. This coverall is ideal for applications within the pharmaceutical manufacturing sector that require effective whole suit protection offered by a Type 4 suit because it protects wearers from hazards such as liquid aerosols, liquid splashes or toxic airborne solid particulates. Specially designed for use in laboratories and in the pharmaceutical industry, **Tyvek® 500 Labo** coverall acts as a barrier that helps protect both the wearer - when exposed to water-based inorganic chemicals and fine particles - and the process, from contamination by the wearer. This makes it ideal for use during the production and handling of products such as pharmaceuticals, cosmetics and optical and electronic devices.

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## Benefits of Tyvek® garments
for pharmaceutical cleanrooms

- excellent cleanliness/low linting
- inherent particle barrier
- comfort plus durability
- lot traceability
- filtration efficiency
- microbial barrier

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# DuPont™ Tyvek® provides trusted protection for aseptic processing and final product packaging

**Packaging made with DuPont™ Tyvek® 1073B, a strong, low-linting material, enables sterilization and protection of parts for sterile pharmaceutical processing and helps protect final products, such as pre-filled syringes or combination products. Tyvek® 1073B is also an ideal material for use in product and processing concepts in cleanroom environments for aseptic processing.**

With its unmatched balance of properties, Tyvek® 1073B delivers trusted protection for a wide range of pharmaceutical packaging applications, helping pharmaceutical manufacturers around the world to:

- Enable sterilization and protection of parts for sterile pharmaceutical processing
- Ensure sterility maintenance of components such as closures, stoppers and pre-fillable containers prior to entering your sterile manufacturing area
- Provide a high degree of protection for packaged and sterilized drug and device combination products such as drug-coated stents
- Compatible with outside surface decontamination of a packaged (e.g., through low-temperature VHP sterilization, e-beam)
- Enhance the presentation and ease-of-use of sterile and non-sterile products in peel pouches, sterilization bags, port bags, header bags, nested container systems and flexible or rigid tray configurations
- Manufactured on multiple manufacturing lines with dual polymer sources for reliable interchangeable supply under rigorous change management.

# Benefits of Tyvek® 1073B

## for pharmaceutical packaging and aseptic processing applications

- clean environments thanks to low-linting features
- meeting requirements of rigorous international standards, including pharmacopeia monographs
- long-term sterility maintenance due to outstanding microbial barrier
- optimal protection due to excellent tear strength and puncture resistance
- sterilization compatibility

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# Tyvek® 1421B for in-process pharmaceutical applications

Tyvek® 1421B is specifically developed for in-process pharmaceutical applications to protect surfaces of cleanroom equipment, components and accessories from particle and microbial contamination. Made from HDPE using DuPont proprietary flash-spinning technology, Tyvek® 1421B is softer and more fabric-like compared to other healthcare packaging styles of Tyvek® used in sterile packaging. This makes Tyvek® 1421B ideal for pharmaceutical cleanroom and controlled environment covers and bags. Typical product examples include cleanroom equipment covers, stopper bowl covers, sterilization wrapping and autoclave component bags and covers.

Manufacturing processes for pharmaceutical products require strict quality practices. These requirements will further increase with the introduction of the revised European Good Manufacturing Practice (EU GMP) Annex 1 that describes principles applied for manufacture of sterile products. Special focus is on the systematic implementation of quality risk management (QRM) to ensure prevention of microbial and particulate contamination in the final product. Anticipating these GMP changes, the recently published ISO/DIS 13408-1 provides guidance on how to manage quality risks and on developing an adequate contamination control strategy for aseptic processing of healthcare products.

In-process pharmaceutical coverings made of Tyvek® 1421B support manufacturers in establishing efficient production and safe sterilization processes. When working in an aseptic processing environment, minimizing the risks of particle contamination is critical. Consisting of continuous and interconnected fine HDPE filaments, Tyvek® 1421B helps minimize the risk of particle or microbial contamination of the pharmaceutical products or materials being handled.

**The porous nature of Tyvek® 1421B makes it highly breathable, which is essential for effective steam sterilization cycles and to minimize the formation of condensation. Material durability and drapability facilitate various product designs while high tear and puncture resistance provide additional security against punctures from sharp edges.**

# Benefits of Tyvek® 1421B

## for in-process pharmaceutical applications

- Minimize the risk of particle contamination in cleanrooms and controlled environments
- Provides sterility assurance with trusted microbial barrier performance of Tyvek®
- Supports regulatory compliance of pharmaceutical processing (e.g., GMP Annex 1)
- Resists tears and punctures
- Fabric drapability supports various designs
- Breathability helps to minimize the formation of condensation in steam sterilization
- Tyvek® is made of HDPE and products made of 100% Tyvek® material can be recycled at facilities that recycle flexible HDPE materials. Please check recycling facilities in your area to ensure they can recycle Tyvek®

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For more information about how DuPont™ Tyvek® can help meet your pharmaceutical protection needs, visit **pharmaprotection.dupont.co.uk**

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