

Achieving Annex 1 compliance with DuPont™ Tyvek® IsoClean®



What is required to be compliant with EU GMP Annex 1?

Manufacturers of sterile medicinal products need to establish a Contamination Control Strategy (CCS) to proactively identify, monitor, measure, scientifically evaluate and mitigate potential risks of microbial and particulate contamination to product safety, quality and efficacy.

The Contamination Control Strategy includes early detection, prevention, remediation and verification of all critical control points (design, personnel, equipment, operations, supplies, raw materials, containers, cleaning/disinfection, procedures) throughout facilities to manage and maintain the highest standards of safety, quality and compliance.

How to remain compliant

If you are operating in GMP Grade A/B cleanrooms, consider these questions related to your cleanroom garment systems in order to help ensure you remain compliant.

Advantages of Tyvek® IsoClean® single-use garments versus reusable garments:



Validated sterilization process

Are my cleanroom garments sterilized according to a validated sterilization process?
If so, according to what standard and what is the sterility assurance level (SAL)?

Sterility of Tyvek® IsoClean® garments is achieved by gamma irradiation. Radiation dosage is validated in accordance with ISO 11137 for an SAL of 10^{-6} for a five-year shelf life. A Certificate of Sterility comes with every shipment of Tyvek® IsoClean® sterile garments.

Reusable garments often only come with a certificate of irradiation, which does not guarantee sterility, only that garments were exposed to a certain radiation dose. Thus, most reusable garments only have a six-month shelf life.

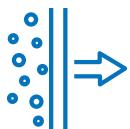


Cleanliness of cleanroom garments

For single-use cleanroom garments, are they clean processed?
How do I evaluate the cleanliness of my garments?
Do I have a Certificate of Compliance showing the Helmke Drum performance category for each box of garments?

Tyvek® IsoClean® garments are inherently low-linting.
Clean-processed Tyvek® IsoClean® garments are specially processed to help minimize particle shedding and are tested for particle shedding using the Helmke Drum (IEST-RP-CC003.5) test.

Reusable garments are washed and sterilized many times over their lifetime, increasing the risk of contamination. The frequent washing and sterilization of reusable garments leads to damaged fabric and larger pores, thereby increasing the release of particles and fibers into the environment.



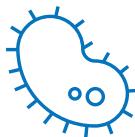
Particle filtration efficiency

How effective are my cleanroom garments at retaining the particles (skin flakes) shed by the operators?

What is the particle filtration efficiency of my cleanroom garments?

Tyvek® IsoClean® garments provide a consistent barrier against dry particles and microorganisms and because **Tyvek® IsoClean®** garments are only used once, particle filtration efficiency (PFE) and bacterial filtration efficiency (BFE) performances are constant.

This is not the case for **reusable cleanroom garments**. DuPont has demonstrated in a study that the performance of reusable garments is significantly reduced by repeated laundering and sterilization cycles. The study can be accessed [here](#).



Bacterial filtration efficiency

The EU GMP Annex 1 becomes more demanding on microbial contamination. What is the bacterial filtration efficiency of my cleanroom garments?

The average bacterial filtration efficiency of **Tyvek® IsoClean®** single-use clean and sterile garments is 98.4% with a standard deviation of 0.9% for 3.0 micron particles.

The average bacterial filtration efficiency range of new **reusable garment** fabric is 64% to 73%. This only degrades with repeated laundering and sterilization cycles.



Frequency of replacing cleanroom garments

For reusable cleanroom garments, how often are my garments being replaced?

Do I have test reports to confirm this frequency?

Tyvek® IsoClean® single-use garments are not subjected to multiple cycles of wearing, laundering and sterilization, so fabric barrier and strength are consistent and predictable.

A visual inspection of **reusable garments** will no longer suffice. You must have a technical solution to check whether the reusable garments are physically intact, or a set replacement frequency determined during qualification studies.



Packaging and folding

Are my cleanroom garments folded and packaged to minimize the risk of contamination?

Tyvek® IsoClean® sterile garments are folded to aid in aseptic donning and individually packaged in a pouch with a five-year shelf life. The case quantity is packaged in two polyethylene liners in a cardboard case. Additionally, clean-processing and packaging are done in an ISO 4 cleanroom that only handles new garments. All of these measures significantly reduce the risk of contamination.

Most **reusable garments** are packed in a bag with a six-month shelf life and then in a reusable crate.



Quality assurance and traceability

Do I have the necessary documentation to scientifically check if my cleanroom garments are meeting the new requirements set in the EU GMP Annex 1?

Do I have traceability of the garments' manufacturing process?

For **Tyvek® IsoClean®**, the production of raw materials is well controlled by DuPont as the sole manufacturer. **Tyvek® IsoClean®** sterile garments have lot traceability, from fabric manufacturing to garment conversion and sterilization. Quality documents are readily available and accurate when requested to help meet customer requirements.

For **reusable garments**, the risk of garment failure varies considerably across multiple manufacturers within that supply chain.

DuPont™ Tyvek® IsoClean®

Sterile single-use garment & accessory options*

Coveralls



Tyvek® IsoClean® coverall IC253

- Coverall with dolman sleeve design for comfort and ease of movement
- Bound seams and neck for lower particle shedding
- Covered elastic wrists and ankles for tighter fit

Reference: IC253BWHXX0025CS

Color: White

Size: SM-7X

Tyvek® IsoClean® coverall IC105

- Hooded coverall with elastic wrists and ankles for tighter fit
- Attached thumb loops to minimize bunching of sleeves
- Attached boots with PVC soles for enhanced skid resistance and durability

Reference: IC105BWHXX0025CS

Color: White

Size: MD-5X

Boot covers



Tyvek® IsoClean® boot cover IC458

- 18"-high boot cover offers extended protection higher up the calf
- Ties at ankles for secure fit
- Gripper™ sole for enhanced skid resistance and durability

Reference: IC458BWHXX0100CS

Color: White

Size: SM-XL

Tyvek® IsoClean® boot cover IC457

- 18"-high boot cover offers extended protection higher up the calf
- Ties at ankles for secure fit
- PVC sole for enhanced skid resistance and durability

Reference: IC457BWHXX01000S

Color: White

Size: SM-XL

Sleeves



Tyvek® IsoClean® sleeves IC501

- 18" sleeve with covered elastic at wrists and biceps
- Bound seams for lower particle shedding

Reference: IC501BWH000100CS

Color: White

Size: Universal sizing (00)

Tyvek® IsoClean® sleeves IC502

- 21" sleeve offers extended protection higher up the arm
- Incorporated thumb loop ensures the sleeve stays in place during use

Reference: IC502BWH000100CS

Color: White

Size: Universal sizing (00)

Hoods



Tyvek® IsoClean® hood/mask IC669

- Integrated one-piece hood and mask ensemble minimizes risk of exposed skin and simplifies SKU management
- Ties with loops help ensure a secure fit

Reference: IC669BWH0001000S

Color: White & Blue

Size: Universal sizing (00)

Tyvek® IsoClean® hood IC668

- Hood with bound full-face opening and bound seams for lower particle shedding
- Ties with loops help ensure a secure fit

Reference: IC668BWH000100CS

Color: White

Size: Universal sizing (00)

For more information on the life cycle assessment of reusable garment properties, please [read our case study](#) and [watch our video](#).

*More styles available. Visit DuPont™ SafeSPEC™ for the full portfolio and detailed product information.

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