



Tyvek. IsoClean.

DUPONT CONTROLLED ENVIRONMENTS

Product Catalogue

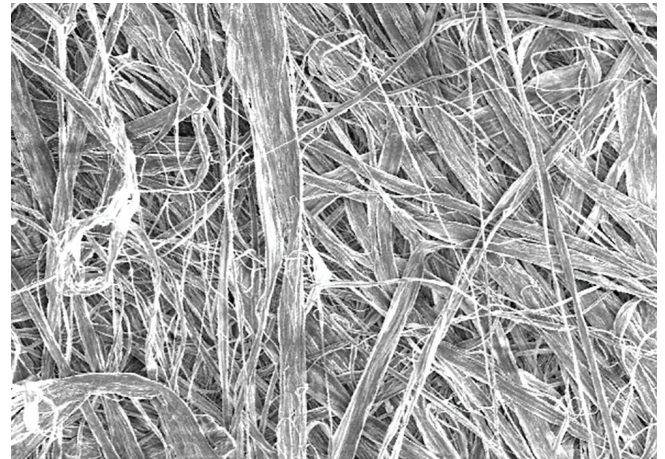
INTRODUCTION

DUPONT™ TYVEK® GARMENT MATERIAL

The highest performing garments in our product line are made from DuPont™ Tyvek®, which has been used to make high-quality cleanroom garments for more than 20 years. Tyvek® is made by DuPont with a proprietary flash-spinning process that creates continuous fibers of high-density polyethylene that are randomly distributed and non-directional.

- Tyvek® is tough, yet lightweight and soft.
- Tyvek® offers an ideal balance of protection, durability, comfort and contamination control.
- Tyvek® acts as a breathable barrier against particles and bacteria.
- Tyvek® repels aqueous liquids and liquid aerosols.
- Tyvek® is inherently low linting and abrasion resistant.

Picture 1: DuPont™ Tyvek® structure.



200x magnification Source: DuPont

DUPONT QUALITY SYSTEMS FOR CLEANROOM GARMENTS

DuPont single-use garments for controlled environments offer the following standards of quality:

- ✓ The DuPont Controlled Environments quality management system is ISO 9001:2008 registered.
- ✓ DuPont™ Tyvek® IsoClean® sterile garments have a sterility assurance level (SAL) of 10^{-6} . Radiation doses are validated in accordance with ANSI/AAMI/ISO 11137 through bio burden and dose verification testing.
- ✓ DuPont™ Tyvek® IsoClean® sterile garments are gamma irradiated in a facility that is registered by ISO 13485 quality standard and adheres to the requirements of ANSI/AAMI/ISO 11137.
- ✓ A Certificate of Sterility and a Certificate of Compliance come with every shipment of sterile Tyvek® IsoClean® single-use garments.
- ✓ Dose audits are conducted quarterly to maintain dose validation.
- ✓ Customers are invited to audit our manufacturing and sterilization facilities.
- ✓ Quality documentation is readily available and accurate when requested to help meet customer requirements.
- ✓ Lot traceability is maintained through garment manufacturing, processing and sterilization.
- ✓ All DuPont™ Tyvek® IsoClean® sterile products are packed in validated cleanroom sealed bags. Certain models are available packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The system serves both as an additional sterility risk management component and is a key element for contamination risk reduction when transferring apparel into clean areas.

INTRODUCTION

CE-CERTIFIED SINGLE-USE GARMENTS FROM DUPONT

DuPont clean-processed and sterile cleanroom garments, designed for single use, offer meaningful advantages in today's challenging cleanroom environments, including:

- ✓ **Quality** – single-use garments are not subjected to multiple cycles of wearing, laundering and sterilization, so fabric barrier and strength are consistent and predictable. Also, DuPont Controlled Environments garments help minimize cross-contamination risk because clean-processing and packaging are done in a facility that only handles new garments.
- ✓ **Flexibility** – the DuPont single-use apparel program allows you to order only the quantities that you plan to use, which offers flexibility as your needs change.
- ✓ **Cost Control** – single-use garments help eliminate budget uncertainties associated with garment repair, damage and loss, helping you to better predict expenditures.

CATEGORY III CHEMICAL PROTECTIVE CLOTHING

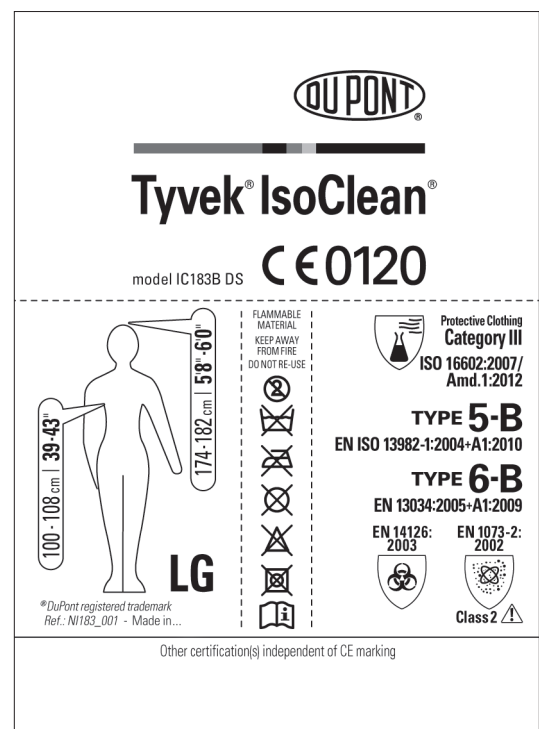
Selected DuPont™ Tyvek® IsoClean® garments are designed and manufactured to meet or exceed the European standards for Type 5 & 6 chemical protective clothing and are CE marked as Category III PPE in accordance with the PPE directive. Selected DuPont™ Tyvek® IsoClean® accessories (clean-processed and sterile, option code MS and a broad selection of the non-processed "bulk" items) are certified as Category I PPE and like garments carry the CE marking. The CE Certification and corresponding certified property performance claims are made on the garment after clean-processing and sterilization.

To carry the CE mark, chemical protective clothing must:

- ✓ Meet the minimum requirements of the corresponding product standard which includes requirements on:
 - Material and seam physical properties
 - Chemical and particulate barrier properties of the material and whole garment
 - Garment fit and labelling
- ✓ Hold a valid EC Type examination certificate (the "CE Certificate") from a 3rd party notified body
- ✓ Hold a valid Quality Surveillance contract / certificate with a 3rd party notified body

Tyvek® IsoClean® garments are certified as passing tests for compliance with both Type 5 (Protective clothing against airborne solid particulates) and Type 6 (Low level spray test). They have been additionally certified for protection against infective agents (EN 14126) and also meet the requirements of the ISO 16602 (Type 5 & 6) standard. See picture 2 for an example of the Tyvek® IsoClean® garment labelling

Picture 2: Tyvek® IsoClean® product labelling.



INTRODUCTION

CONTROLLED ENVIRONMENTS APPAREL SELECTION GUIDE

When it comes to working in a broad range of controlled environments, specifiers have many product options from which to select. The process to understand which option matches a given environment can be confusing. DuPont has tried to help reduce some of that burden by providing a complete line of products and information to help guide specifiers through their selection process.

To get the most out of your cleanroom apparel, it is necessary to understand where each product can be used. To provide a quicker overview of our products and where they are intended for use, we developed the simple guide below. Our goal is to provide the appropriate DuPont product that is suitable for a given environment or hazard.

Table 1. Fabric performance features.

Fabric	Available Sterile	Particle Barrier	Non-Hazardous Liquid Barrier	Comfort	Durability	Static Dissipation †	Particle Shedding and Cleanliness	Strengths
DuPont™ Tyvek® IsoClean® flashspun polyolefin, clean-processed and sterile	Yes, Option code CS,MS and DS	●	◐	◐	●		●	Ideal combination of protection, durability, comfort and cleanliness.
DuPont™ Tyvek® IsoClean® flashspun polyolefin, sterile	Yes, Sterile OS option	●	◐	◐	●	●	◐	
DuPont™ Tyvek® IsoClean® flashspun polyolefin, bulk	No, Option codes 00 and 0B	●	◐	◐	●	●	◐	

Table 2. Cleanroom garments and accessories selection guide.

	Environments/Hazards	DuPont™ Tyvek® IsoClean®			Considerations
		Clean-Processed and Sterile (Option codes CS, MS and DS)	Sterile (Option code OS)	Bulk Non-Sterile (Option codes 00 and 0B)	
Environments	GMP A&B, ISO 4/5, CLASS 10/100 controlled environments*	●	◐		Tyvek® IsoClean® sterile garments offer excellent cleanliness, barrier and sterility assurance level.
	GMP C&D, ISO 7/9, CLASS 10,000/100,000 controlled environments*			●	Tyvek® provides an inherent particle barrier and durability, and is low linting. Clean-processing and bound seams should be considered for more critical environments.
Hazards	Non-hazardous, dry particles	●	●	●	Tyvek® provides an inherent barrier against small particles. Bound seam garments offer a higher level of protection than serged seam garments.
	Hazardous powders Notice: DuPont Controlled Environments garments should not be used in potentially explosive or flammable environments.	●	●	●	Use bound seamed garments when working with hazardous powders.
	Hazardous liquid splash Examples: organic solvents, caustics				Please refer to our Tychem® product line for liquid and vapor chemical protection.
	Electric arc, industrial fire hazard, welding	Do Not Use			Please refer to Nomex® for flame-resistant apparel. Controlled Environment garments are not suitable for firefighting activities, nor for protection from hot liquids, steam, molten metals, welding, electric arc or thermal radiation.

Comparison within the DuPont portfolio: ● Best ◐ Good (Blank) Not recommended

† Nuisance static.

Antistatic performance may be reduced for sterile products.

Barrier properties may be compromised through use.

* Tyvek® IsoClean® (Option Code CS, DS and MS) garments are most typically considered for use in GMP A-D, ISO Class 5-8. However, use in ISO Class 4 and 9 environments may also be considered depending on the needs of a particular application. In all cases, garment choice depends on evaluation of, among other attributes, garment design and processing, as well as the needs of specific applications. Clean-processed and bound seam garments offer the highest level of contamination control and should be used in more critical applications. Sterile garments are available if required. It is the end-user's responsibility to determine the appropriate garment for a given application.

INTRODUCTION

UNDERSTANDING CLEANROOM CLASSIFICATIONS

Over the past few years there has been an increasing trend to change from previous classification systems used to the ISO classification systems in ISO 14644-1 (see Table 3). However, many companies have continued to use the traditional Class 100, 10,000, 100,000 room classification system from Federal Standard 209-e. In Europe, the GMPs (Good Manufacturing Practice) utilize another system—Grades A through D (see Table 4).

EU GMP guidelines are more stringent than others, requiring cleanrooms to meet particle counts at operation (during manufacturing process) and at rest (when manufacturing process is not carried out, but room air handling unit is on). Many global companies, choose to use this classification system. All of these systems are acceptable for use.

Table 3. ISO 14644-1 Air cleanliness classes for cleanrooms and clean zones.

ISO Classification Number	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm	SI	English Former FED-STD-209E
ISO Class 1	10	2						
ISO Class 2	100	24	10	4	8			
ISO Class 3	1000	237	102	35	83		M 1.5	1
ISO Class 4	10000	2370	1020	352	832	29	M 2.5	10
ISO Class 5	100000	23700	10200	3520	8320	293	M 3.5	100
ISO Class 6	1000000	237000	102000	35200	83200	2930	M 4.5	1000
ISO Class 7				352000	832000	29300	M 5.5	10000
ISO Class 8				3520000	8320000	293000	M 6.5	100000
ISO Class 9				35200000	83200000	2930000		

Source: ISO 14644-1

Table 4. GMP grades - EU classification.

Class	Maximum particles/m³			
	At Rest	At Rest	In Operation	In Operation
	0.5 µm	5 µm	0.5 µm	5 µm
Grade A	3,520	20	3,520	20
Grade B	3,520	29	352,000	2,930
Grade C	352,000	2,930	3,500,000	29,300
Grade D	3,520,000	29,000	Not defined	Not defined

Source: EU GMPs Annex 1 - Recommended Limits for Particulate Contamination

DuPont™ TYVEK® ISOCLEAN® non-sterile (bulk) accessories

DuPont™ Tyvek® IsoClean® non sterile (bulk) single-use accessories offer an ideal balance of protection, durability and comfort for less demanding environments. Tyvek® IsoClean® (option codes 0B, 00) garments and accessories have not been clean-processed or gamma-irradiated but manufactured in an controlled

environment. In addition, they are exceptionally low linting with high particle barrier properties. Tyvek® IsoClean® non sterile accessories are available in a wide variety of styles, such as hoods, gowns, bouffants, shoe/boot covers and sleeves.

GOWNING FOR GMP C&D (ISO 7/8, CLASS 10,000/100,000) CONTROLLED ENVIRONMENTS



DuPont™ TYVEK® ISOCLEAN® non-sterile (bulk) accessories

	Product description	Category	Reference
	DuPont™ Tyvek® IsoClean® Frock with bound neck - model IC 270 B option 00 (Bulk packed) Frock available in white in sizes S to XXXL. Bound seams. Covered elastication at wrists. Front snap closure for easy donning and doffing. White.	Cat. I	IC 270 B WH 00
	DuPont™ Tyvek® IsoClean® Gown - model IC 701 S option 00 (Bulk Packed) Gown available in white and in one size. Serged seams. Bound neck with ties. Knitted Cuffs. Bound ties originating at center front waist.	Cat. I	IC 701 S WH 00
	DuPont™ Tyvek® IsoClean® Sleeve - model IC 501 B option 0B (Bulk Packed) Sleeve available in white and in one size. Bound seams. Covered elastic at both ends. 45 cm long.	Cat. I	IC 501 B WH 0B
	DuPont™ Tyvek® IsoClean® Shoe cover - model IC 451 S WH option 0B (Bulk Packed) Shoe cover available in white and in sizes M and L. Fixation ties. Gripper™ sole. Stitched seams. MD: 11.75" fits up to UK men's size 6 1/2/EU 39.5 LG: 14" fits up to UK men's size 12 1/2/EU 47	Cat. I	IC 451 S WH 0B
	DuPont™ Tyvek® IsoClean® Boot cover - model IC 458 B WH option 0B (Bulk Packed) Boot cover available in white and in sizes M and L. Fixation ties. Gripper™ sole. Bound seams. MD: 12" fits up to UK men's size 6 1/2/EU 39.5 LG: 14" fits up to UK men's size 13 1/2/EU 48.5	Cat. I	IC 458 B WH 0B
	DuPont™ Tyvek® IsoClean® Hood with ties - model IC 668 B option 0B (Bulk packed) Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit.	Cat. I	IC668 B WH 0B
	DuPont™ Tyvek® IsoClean® Bouffant - model IC 729 S option 0B (Bulk Packed) Bouffant available in white and in one size. Serged Seams. Elastic headband. 54 cm Diameter.	Cat. I	IC 729 S WH 0B
	DuPont™ Sierra™ Mask - model ML 7360 option BH Mask available in white and in one size. Bound Tyvek® Ties. Pleated Rayon Outer Facing. Metal Nose Piece.	N/A	ML 7360 WH BH

N/A - Not Applicable.

PROCESSING AND PACKAGING OPTIONS

PROCESSING OPTIONS

CLEAN-PROCESSED AND STERILE

Clean-processed and sterile garments (option code MS, DS or CS): Garments are specially processed to minimize particle shedding, then folded to aid in aseptic donning and packed in an ISO Class 4 cleanroom.

The box quantity is packed in a cardboard box with two polyethylene liners. Sterility is achieved by gamma irradiation. Radiation dosage is validated in accordance with ISO 11137 for a Sterility Assurance Level (SAL) of 10^{-6} .

STERILE

Sterile (option code OS): Garments are folded to aid aseptic donning and individually packaged. The box quantity is packaged in a cardboard box with two polyethylene

liners. Some sterile items are folded and individually packaged in an ISO Class 5 cleanroom. Sterility is achieved by gamma irradiation. Irradiation dosage is validated in accordance with ISO 11137 for a sterility assurance level (SAL) of 10^{-6} .

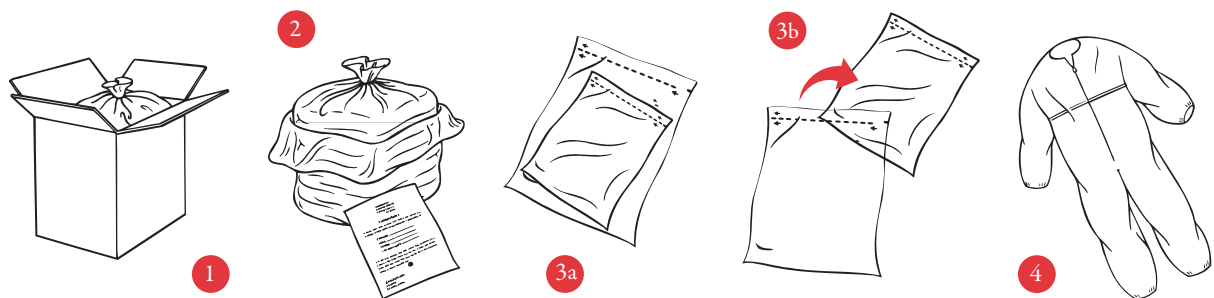
NON-STERILE

Bulk (option code 0B,00 or BH): Box quantities are packed in a cardboard box with two polyethylene liners. IsoClean® garments are individually packed, with one polyethylene liner in the cardboard box. Note: Individual packaging for sleeves, shoe and boot covers indicates that each pair has its own sealed bag. Masks may have subgroupings of individually packed items within the case.

PACKAGING OPTIONS

STERILE PACKAGING PROCESS FOR OPTION DS

The garment is individually packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The box quantities are packed in a cardboard box with two polyethylene liners.

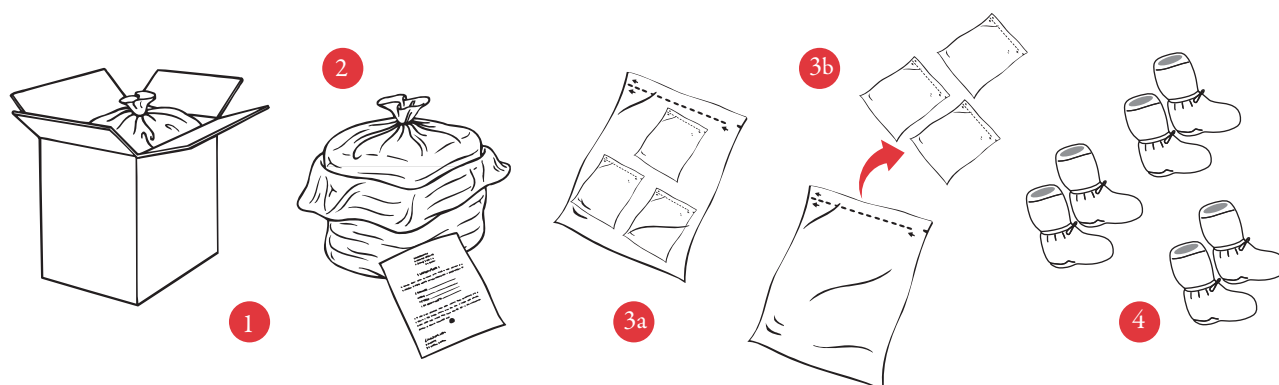


1. Outer shipping box is securely sealed. Carton displays product label, sterile dot indicator and fully traceable lot and the certificate of sterility.
2. Multilevel interior packaging features two polyethylene box liners. The outer liner provides protection from dust and contamination, particularly if outer box is discarded. A lot-specific Certificate of Compliance with sterile dot indicator is placed between the two liners. The inner liner is closed and allows transportation of product to a cleaner, more controlled environment.
3. (3a and 3b) Each garment is packed in a dual barrier packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The validated dual barrier packaging system serves both as an additional sterility risk management component and is a key element for contamination risk reduction when transferring apparel into clean areas.
4. Sterile garment consistently folded and packed to ease aseptic donning. Traceable lot numbers are stamped on each individual sterile garment.

GARMENT PROCESSING AND PACKAGING OPTIONS

STERILE PACKAGING PROCESS FOR OPTION MS

Items are packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The accessories are individually packed and sub-grouped together in an outer bag. The box quantities are packed in a cardboard box with two polyethylene liners. See safespeccleanroom.dupont.co.uk for the exact packaging configuration details.



1. Outer shipping box is securely sealed. Box displays product label, sterile dot indicator and fully traceable lot number and the certificate of sterility.
2. Multilevel interior packaging features two polyethylene box liners. The outer liner provides protection from dust and contamination, particularly if outer box is discarded. A lot-specific Certificate of Compliance with sterile dot indicator is placed between the two liners. The inner liner is closed allows transportation of product to a cleaner, more controlled environment.
3. (3a. and 3b.) Multiple items are packed in a dual barrier packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The validated dual barrier packaging system serves both as an additional sterility risk management component and is a key element for contamination risk reduction when transferring apparel into clean areas.
4. Sterile items are consistently folded and packed to ease aseptic donning. Traceable lot numbers are stamped on each Tyvek® IsoClean accessory.



DUPONT
Tyvek IsoClean®

DuPont™ SafeSPEC™ – CONTROLLED ENVIRONMENTS

Tyvek® IsoClean®
Coverall

Tyvek® IsoClean®
Hood

Tyvek® IsoClean®
Gown



DuPont™ SafeSPEC™



**Need help finding and selecting protective clothing for your cleanroom?
Try DuPont™ SafeSPEC™ – CONTROLLED ENVIRONMENTS**

Browse and compare products by brand, design or certification, with direct access to all relevant information including permeation data.

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DuPont Personal Protection

DuPont de Nemours (Luxembourg) S.a r.l.
Contern - L-2984 Luxembourg
Customer Service
Tel.: +352 3666 5111 Fax: +352 3666 5071
E-mail: garments.europe@dupont.com
www.ipp.dupont.com



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