



Controlled Environments
Product catalogue

Tyvek®
IsoClean®



CONTROLLED ENVIRONMENTS

Content overview



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Cleanroom clothing that gives you a peace of mind

DuPont understands your need to do everything possible to reduce contamination risks in your controlled environments.

One of the areas in which safety and health are of paramount importance is in cleanrooms and controlled environments. The DuPont cleanroom clothing portfolio offers a comprehensive selection of single-use cleanroom garments and accessories designed for use in pharmaceutical, medical device, biotech and electronic settings that require high standards for particle and microbiological contamination control.

Indeed, DuPont™ Tyvek® garments have a long history of use in cleanrooms due to their excellent barrier to particles, microorganisms and non-hazardous liquids. They offer an ideal balance of protection, durability, comfort and contamination control. They are available in many styles for different cleanroom and controlled environment applications and are packaged and

certified to meet local market requirements. With the DuPont Controlled Environments offering, you get the advantage of a wide range of proven, science-based solutions that help keep your cleanroom environment protected. In many industries that require high standards for particle and microbiological contamination control to ensure the highest quality of the finished products, there are strict quality-assurance procedures and protection must be assured throughout all processes. Operators represent the biggest source of contamination inside cleanrooms. They are responsible for 75% of all contaminants – both from the operators themselves and from their cleanroom garments.

Operator contamination can be reduced through training and impeccable hygiene, but it can't be eliminated. There is only one way to prevent particles generated by operators from contaminating the cleanroom: use cleanroom garments. They are the only barrier between the operator and the production environment. The 2020 draft of the Good Manufacturing Practice guidelines (GMP) Annex 1 states that '*cleanroom garments should retain particulates shed by the body*'. Sufficient cleanroom clothing is therefore required to prevent contamination and protect operators from hazardous substances.

For over 20 years Tyvek® IsoClean® garments have been an excellent choice for a variety of processes in cleanrooms and controlled environments because of the outstanding contamination control properties, fabric design and performance.

Why DuPont cleanroom clothing is right for you?

Tyvek[®]
IsoClean[®]





DuPont cleanroom clothing is made from DuPont™ Tyvek® fabric

DuPont™ Tyvek® fabric 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. When using cleanroom clothing made of Tyvek® you get an ideal balance of protection, durability, comfort and contamination control. The biggest advantage Tyvek® fabric offers to cleanrooms and controlled environments is keeping human contamination inside the garment and not allowing it to contaminate the cleanroom and the production.



Tyvek® is tough, yet lightweight and soft.



Keeps microbiological and particle contamination inside the garment



Sheds almost no particles



Resistant to abrasion and tearing



Repels aqueous liquids and liquid aerosols.



Breathable and comfortable to wear



Can be recycled when not in contact with hazardous substances



Available in many processing options, including clean-processed and sterile



Available in many styles – coveralls and accessories



DuPont cleanroom clothing is manufactured according to the highest quality standards

Sterilization

Dose audits

Dose audits are conducted quarterly to maintain dose validation.

Sterility Assurance

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.

ISO 13485 registered facilities

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.

Quality Assurance

Lot traceability

Lot traceability is maintained through garment manufacturing, processing and sterilization.

Quality documentation

Quality documents are readily available and accurate when requested to help meet customer requirements.

Customer audits

Customers are invited to audit our manufacturing and sterilization facilities.

Quality management system

The DuPont Controlled Environments quality management system is ISO 9001:2015 registered.

Packaging and folding

Aseptic folding

Clean-processed and sterile products are folded to aid aseptic donning procedures.

Validated cleanroom packaging

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.

Cleanliness

Garments are tested for particle shedding using the Helmke drum (IEST-RP-CC003.4) test and Body Box norms.

PPE

Type 5 and 6 PPE

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).

CE certification

All products are CE marked as Category III PPE in accordance with the PPE Regulation (EU) 2016/425 or Category I PPE. For sterile items the CE certification and corresponding certified property performance claims are made on the garment product after clean-processing and sterilization.



DuPont cleanroom clothing is single use and provides consistent performance, flexibility and cost control

Consistent performance

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 cleanroom clothing helps to minimize cross-contamination risk because clean-processing and packaging are done in a ISO 4 facility that only handles new garments. Control of the contamination risk linked to operators relies heavily on the barrier performance of cleanroom garments. Tyvek® IsoClean® sterile cleanroom garments make this control easier. If garments are only used once their Helmke drum,

particle filtration efficiency (PFE) and bacterial filtration efficiency (BFE) performances are constant. This is not the case for reusable cleanroom garments that are used, washed, dried and sterilized multiple times. 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](#).

Easier Quality Risk Management

Companies should have a Quality Risk Management system. As DuPont™ is the manufacturer of both the Tyvek® material and the finished clean and sterile Tyvek® IsoClean® cleanroom garments, the entire value-chain is under DuPont control and test data and certificates (such as lot-based certificates of sterility, irradiation and compliance) can be supplied any time. This makes qualification and subsequent quality audits easier than with reusable cleanroom garments involving several value-chain partners (PET filament manufacturer, textile weaver, garment manufacturer, laundry, etc.).

Flexibility

Single-use coveralls made from Tyvek® can offer more production flexibility and can speed up production as they do not require infrastructure or laundry processes. Inventories can be adjusted to meet production needs. DuPont single-use apparel allows you to order only the quantities that you plan to use, which offers flexibility as your needs change. Also, the stock management of a single Tyvek® IsoClean® garment is much easier than managing a reusable garment system (due to washing, disinfection and laundering cycles, garment replacement or repairs, complex invoice checking and others).

Recyclability

Additionally Tyvek® fabric be recycled at facilities that accept high-density polyethylene (HDPE) not in contact with hazardous substances. Please read more about recyclability of Tyvek® in medical packaging [here](#).

9 step guide to select & qualify cleanroom garments*

STEP 1
User Requirements
Specifications



STEP 2
Assessing barrier
properties



STEP 3
Assessing garment
linting



STEP 4
Sterility
assurance



STEP 5
Stability
testing



STEP 6
Checking the
packaging system



STEP 7
Checking
the folding



STEP 8
Updating
procedures



STEP 9
Integration in the
contamination
control strategy



*For details please refer to the Appendix "Selection and qualification of cleanroom garments" on page 27

Product Overview

Tyvek[®] IsoClean[®]



Tyvek® IsoClean® clean-processed and sterile, only sterile

Product name	Design	Seam type*	Processing	Cleanliness	Aseptic folding	Packaging	Norms	PPE Category		
Tyvek® IsoClean® Coverall IC 193 B WH DS	Coverall with hood and overboots	Bound	Clean-processed and sterile garments (option code MS, DS or CS): Garments are specially processed to minimize particle shedding. Sterility is achieved by gamma irradiation. Radiation dosage is validated in accordance with ISO 11137 for a Sterility Assurance Level (SAL) of 10 ⁻⁶ .	Particle Shedding (Helmke Drum) IEST-RP-CC003.4. Category I Bacterial Filtration Efficiency (3 µm) ASTM F2101 98.4 % ± 0.9 % STD DEV	Products are folded to aid in aseptic donning and packed in an ISO Class 4 cleanroom.	Validated cleanroom packaging. The box quantity is packed in a cardboard box with two polyethylene liners. Please refer to Appendix "Packaging options" on page 22 for detailed packaging options.	EN 14126 (barrier to infective agents), EN 1073-2 (protection against radioactive contamination) EN 14126 (barrier to infective agents), EN 1073-2 (protection against radioactive contamination)	Chemical protective clothing, Category III, Type 5-B and 6-B		
Tyvek® IsoClean® Coverall IC 183 B WH DS	Unhooded coverall with elastics	Bound					EN 14126 (barrier to infective agents)		Partial body chemical protective clothing, Category III, Type PB [6-B]	
Tyvek® IsoClean® Boot covers IC 458 B WH MS	Boot cover	Bound					N/A	Cat I		
Tyvek® IsoClean® Sleeve IC 501 B WH MS	Sleeve	Bound					N/A			Cat I
Tyvek® IsoClean® Hood IC 668 B WH MS	Hood	Bound					N/A			
Tyvek® IsoClean® Labcoat IC 270 B WH MS	Labcoat	Bound					N/A	Cat I		
Tyvek® IsoClean® Hood and Mask IC 982 B WH MS	Hood and Mask	Bound					N/A		Cat I	
Tyvek® IsoClean® Bouffant IC 729 S WH MS	Bouffant	Serged	N/A	Cat I						
Tyvek® IsoClean® Hood and Mask IC 689 B WH TS	Hood and Mask	Bound	Sterile (option code TS,OS): Sterility is achieved by gamma irradiation. Irradiation dosage is validated in accordance with ISO 11137 for a sterility assurance level (SAL) of 10 ⁻⁶ .		Cannot be clean-processed.	Items are folded and individually packaged in an ISO Class 4 cleanroom.	Validated cleanroom packaging. The box quantity is packed in a cardboard box with two polyethylene liners. Please refer to Appendix "Packaging options" on page 22 for detailed packaging options.	N/A	N/A	

*For more information on seams construction please refer to Appendix "Seam construction overview" on page 28

Tyvek® IsoClean® non-sterile

Product name	Design	Seam type*	Processing	Cleanliness	Aseptic folding	Packaging	Norms	PPE category
Tyvek® IsoClean® Labcoat IC 270 B WH 0B	Labcoat	Bound	Non-sterile (option code 0B, 00)	Not clean- processed	Not aseptically folded	Box quantities are packed in a cardboard box with two polyethylene liners. Please refer to Appendix "Packaging options" on page 24 for detailed packaging options.	EN 14126 (barrier to infective agents)	Partial body chemical protective clothing, Category III, Type PB [6-B]
Tyvek® IsoClean® Gown IC 702 S WH 00	Gown	Serged						
Tyvek® IsoClean® Gown IC 703 S WH 00	Gown	Serged						
Tyvek® IsoClean® Hood IC 668 B WH 00	Hood	Bound						
Tyvek® IsoClean® Shoe cover IC 451 S WH 00	Shoe cover	Serged						
Tyvek® IsoClean® Boot cover IC 458 B WH 00	Boot cover	Bound						
Tyvek® IsoClean® Sleeve IC 501 B WH 00	Sleeve	Bound						
Tyvek® IsoClean® Bouffant IC 729 S WH 00	Bouffant	Serged						

*For more information on seams construction please refer to Appendix "Seam construction overview" on page 28

Clean-processed & sterile and only sterile range

- for GMP A&B, ISO 4/5 controlled environments

Tyvek[®]
IsoClean[®]

Tyvek® IsoClean®

CLEAN-PROCESSED AND STERILE COVERALL IC 193 B

New!

Coverall with attached hood and overboots

Sterility Assurance Level (SAL) of 10^{-6} (ISO 11137).

Helmke Drum Cat. 1 (IEST-RP-CC003.3).

Bacterial Filtration Efficiency (3 μm) $98.4\% \pm 0.9\%$ STD
DEV as per ASTM F2101

Dual barrier validated packaging system (option DS)
for contamination control and sterility risk management.

Packed in an ISO Class 4 Certified Cleanroom.

Internal bound seams covered with garment fabric
to reinforce seam protection and reduce potential
for liquid and particle penetration.

The hood fits a medical mask and goggles and has
attached ties.



Biotechnology



Pharmaceutical



Medical device
manufacturing



Integrated hood
with ties



Zipper closure
with storm flap



Integrated overboots
with Gripper™ sole



ISO 11137



Option DS



Category III



TYPE 5-B



TYPE 6-B



EN 1073-2
Class 2



EN 14126

Reference: IC 193 B WH DS

Colour: White

Size: XS to 7XL

*Does not protect from ionizing radiation

Tyvek® IsoClean®

CLEAN-PROCESSED AND STERILE COVERALL IC 183 B

Unhooded coverall

Sterility Assurance Level (SAL) of 10^{-6} (ISO 11137).

Helmke Drum Cat. 1 (IEST-RP-CC003.3).

Bacterial Filtration Efficiency (3 μ m) 98.4 % \pm 0.9 % STD DEV as per ASTM F2101

Dual barrier validated packaging system (option DS) for contamination control and sterility risk management.

Packed in an ISO Class 4 Certified Cleanroom.

Internal bound seams covered with garment fabric to reinforce seam protection and reduce potential for liquid and particle penetration.



Clean-processed and sterile



Medical device manufacturing



Pharmaceutical production



Bound neck



Waist elastication



Tyvek® covered thumb loops



ISO 11137



Option DS



Category III



TYPE 5-B



TYPE 6-B



EN 1073-2
Class 2



EN 14126

Reference: IC 183 B WH DS

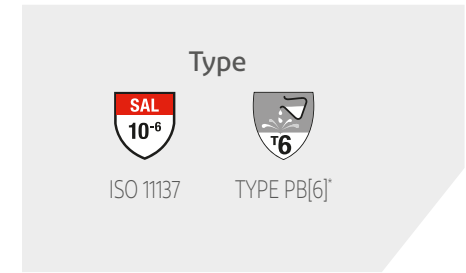
Colour: White

Size: SM to 7XL

* Does not protect from ionizing radiation.

Tyvek® IsoClean®

CLEAN-PROCESSED AND STERILE ACCESSORIES*



Category I



CE Category III



CE Category III



CE Category III



Tyvek® IsoClean® Labcoat with bound neck - model IC 270 B option MS

Labcoat available in white in sizes SM to 3XL. Bound seams. Covered elastics at wrists. Front snap closure for easy donning and doffing. Packed in a dual barrier validated packaging system (double bagged).

Tyvek® IsoClean® Sleeve - model IC 501 B option MS

Sleeve available in white and in one size. Bound seams. Tunnelled elastics at wrist and bicep. Packed in a dual barrier validated packaging system (double bagged).

Tyvek® IsoClean® Boot cover - model IC 458 B option MS

Boot cover available in white, in sizes SM to XL. Bound seams. Covered elastics leg opening. Ankle ties. Slip-retardant Gripper™ sole. 18" (45.7 cm) high. Packed in a dual barrier validated packaging system (double bagged).

SM: 10" fits up to UK men's size 4.5/EU 37; 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; XL: 16" fits up to UK men's size 18 1/2/EU 53

Tyvek® IsoClean® Hood with ties - model IC 668 B option MS

Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit. Packed in a dual barrier validated packaging system (double bagged).

Reference: IC 270 B WH MS

Colour: White

Size: SM to 3XL

Reference: IC 501 B WH MS

Colour: White

Size: One size

Reference: IC 458 B WH MS

Colour: White

Size: SM to XL

Reference: IC 668 B WH MS

Colour: White

Size: One size

N/A = Not Applicable. *Partial body protection.

Tyvek® IsoClean®

CLEAN-PROCESSED AND STERILE ACCESSORIES*



CE Category I

Tyvek® IsoClean® Hood and mask - model IC 982 B option MS

HOOD: Bound internal seams. Bound head opening. Ties with loops for adjustable fit. MASK: Pleated polyethylene outer. 17.5 cm wide. Sterile. Blue. Items packed in a dual barrier validated packaging system (double bagged).



CE Category I

Tyvek® IsoClean® Bouffant - model IC 729 WH option MS

Bouffant available in white and in one size. Elastic headband. Packed in a dual barrier validated packaging system (double bagged).

Reference: IC 982 B WH MS

Colour: White

Size: One size

Reference: IC 729 S WH MS

Colour: White

Size: One size

N/A = Not Applicable.

Tyvek® IsoClean®

STERILE

New!

Tyvek® IsoClean® Hood with attached mask and ties IC 689 B TS

Hood with attached mask* and ties for adjustable fit in the chest area. Available in white and in one size. Gamma-sterilized and double bagged. Bound internal seams. Bound face opening for low particle shedding. Aseptically folded.

MASK: Pleated polyethylene outer. 17.5 cm wide. Sterile. Blue.



Reference: IC 689 B WH TS

Colour: White

Size: One size

*The attached mask is a blue sterile cleanroom mask made out of pleated polyethylene outer layer having a width of 17.5 cm. Please note that it is not a PPE (e.g. not an FFP1,2 or 3) mask.

Non-sterile accessories

- for GMP C&D ISO
6/9 controlled
environments

Tyvek[®]
IsoClean[®]

Tyvek® IsoClean®

NON-STERILE ACCESSORIES



CE Category III



Tyvek® IsoClean® Labcoat with bound neck - model IC 270 B option 0B

Labcoat available in white in sizes SM to 3XL. Bound seams. Covered elasticsation at wrists. Front snap closure for easy donning and doffing. White.



CE Category III



Tyvek® IsoClean® Gown - model IC 702 S option 00

Gown available in white and in sizes SM/MD and LG/2XL. Serged seams. Bound neck with ties. Knitted Cuffs. Bound ties originating at center front waist.



CE Category III



Tyvek® IsoClean® Sleeve - model IC 501 B option 00

Sleeve available in white and in one size. Bound seams. Covered elastic at both ends. 45 cm long.

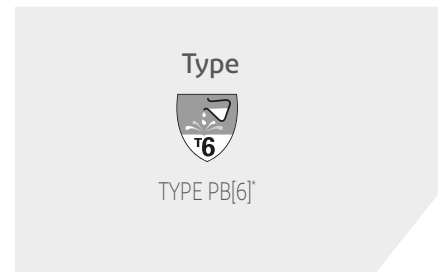


CE Category III



Tyvek® IsoClean® Shoe cover - model IC 451 S WH option 00

Shoe cover available in white and in sizes MD and LG. Fixation ties. Gripper™ sole. Serged 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



Reference: IC 270 B WH 0B

Colour: White

Size: SM to 3XL

Reference: IC 702 S WH 00

Colour: White

Size: SM/MD and LG/2XL

Reference: IC 501 B WH 00

Colour: White

Size: One size

Reference: IC 451 S WH 00

Colour: White

Size: MD and LG

N/A = Not Applicable. *Partial body protection

Tyvek® IsoClean®

NON-STERILE ACCESSORIES*



CE Category III



Tyvek® IsoClean Boot cover - model IC 458 B WH option 00

Boot cover available in white and in sizes MD and LG. Fixation ties. Gripper™ sole. Bound seams. MD: 12" fits up to UK men's size 6 ½/EU 39.5; LG: 14" fits up to UK men's size 13 ½/EU 48.5



CE Category III



Tyvek® IsoClean® Chemo gown model IC 703 S option 00

Collared gown with hook and loop closure in the neck. Increased skirt length ensures protection against frontal exposure. Openness in the back closure increases wearer comfort. Serged seams. Knit cuffs. Bound ties at waist originating from elasticated sides.



CE Category III



Tyvek® IsoClean® Hood with ties - model IC 668 B option 00

Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit.

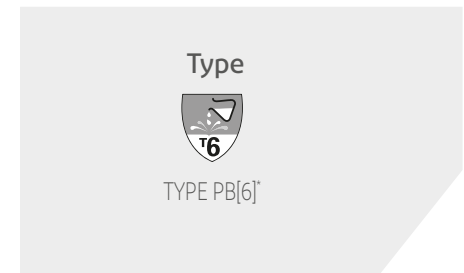


CE Category III



Tyvek® IsoClean® Bouffant - model IC 729 S option 00

Bouffant available in white and in one size. Serged seams. Elastic headband. 54 cm diameter.



Reference: IC 458 B WH 00

Colour: White

Size: MD and LG

Reference: IC 703 S WH 00

Colour: White

Size: XS – 3XL
FOR A BETTER FIT

Reference: IC 668 B WH 00

Colour: White

Size: One size

Reference: IC 729 S WH 00

Colour: White

Size: One size

N/A = Not Applicable. * Partial body protection.

Appendixes

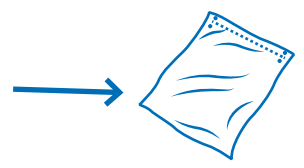
Tyvek[®]
IsoClean[®]



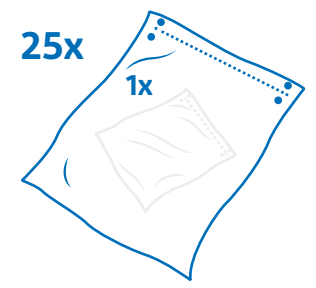
Packaging options

TYVEK® ISOCLEAN® CLEAN-PROCESSED AND STERILE

Example:
Tyvek® IsoClean®
Coverall IC 183 B WH DS



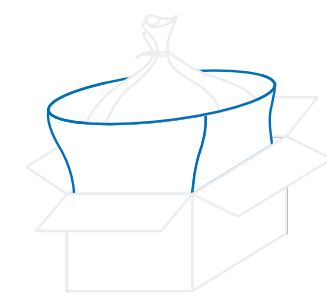
Primary sealed opaque bag (1 each)



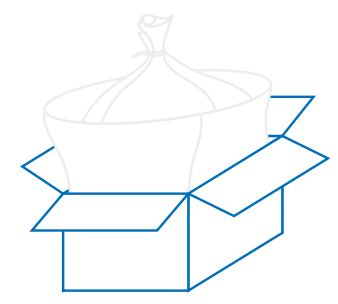
Secondary transparent sealed bag 25 x 1 coverall



Closed internal liner bag

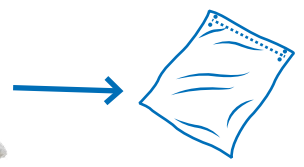


Open case liner bag

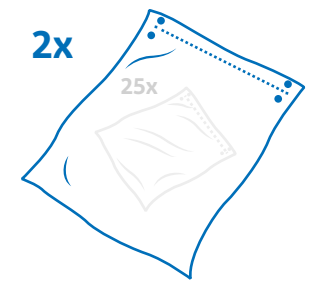


Box with 25 coveralls

Example:
Tyvek® IsoClean®
Boot cover IC 458 B WH MS



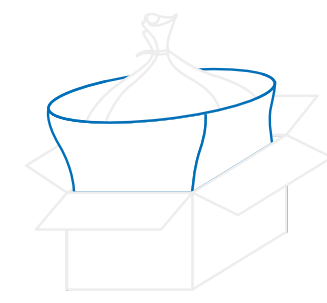
Primary sealed opaque bag (1 pair)



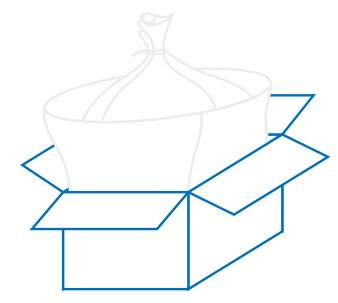
Secondary transparent sealed bag 2 x 25 pairs



Closed internal liner bag



Open case liner bag



Box with 100 boot covers (50 pairs)

Note: This is a visual representation of selected products from the Tyvek® IsoClean® clean-processed and sterile product range, for details on each product please refer to the table on the next page.

Packaging options

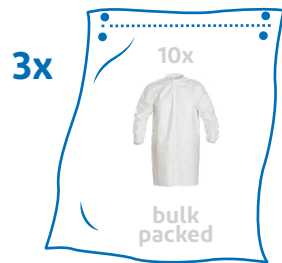
TYVEK® ISOCLEAN® CLEAN-PROCESSED AND STERILE, ONLY STERILE

Product name	Primary sealed white opaque bag <i>Quantity of products per bag</i>	Secondary transparent sealed bag <i>Quantity of primary opaque bags in secondary transparent sealed bag</i>	Closed internal liner bag <i>Quantity of closed internal liner bags in the box</i>	Open case liner bag <i>Quantity of open internal liner bags in the box</i>	Box quantity <i>Quantity of products per box</i>
Tyvek® IsoClean® Coverall IC 193 B WH DS	1 each	20 primary sealed white opaque bags, all individually packed in a secondary transparent bags	1	1	20 eaches
Tyvek® IsoClean® Coverall IC 183 B WH DS	1 each	25 primary sealed white opaque bags all individually packed in a secondary transparent bags	1	1	25 eaches
Tyvek® IsoClean® Labcoat IC 270 B WH MS	1 each	30 primary sealed white opaque bags all individually packed in a secondary transparent bags	1	1	30 eaches
Tyvek® IsoClean® Boot covers IC 458 B WH MS	2 eaches (pair)	50 primary sealed white opaque bags grouped by 25, in 2 secondary transparent bags	1	1	100 eaches
Tyvek® IsoClean® Sleeve IC 501 B WH MS	2 eaches (pair)	50 primary sealed white opaque bags grouped by 25, in 2 secondary transparent bags	1	1	100 eaches
Tyvek® IsoClean® Hood IC 668 B WH MS	1 each	100 primary sealed white opaque bags grouped by 20 eaches, in 5 secondary transparent bags	1	1	100 eaches
Tyvek® IsoClean® Hood and Mask IC 982 B WH MS	1 each	100 primary sealed white opaque bags grouped by 20 eaches, in 5 secondary transparent bags	1	1	100 eaches
Tyvek® IsoClean® Bouffant IC 729 S WH MS	1 each	250 primary sealed white opaque bags grouped by 25 eaches, in 10 secondary transparent bags	1	1	250 eaches
Tyvek® IsoClean® Hood and Mask IC 689 B WH TS	1 each	100 primary sealed white opaque bags, all individually packed in a secondary sealed transparent bags	1	1	100 eaches

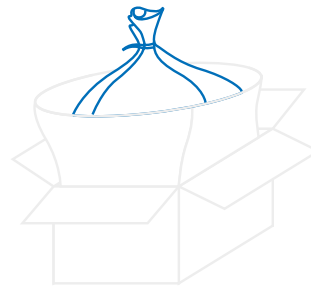
Packaging options

TYVEK® ISOCLEAN® NON-STERILE

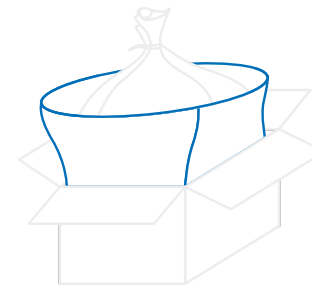
Example
Tyvek® IsoClean®
Labcoat IC 270 B WH OB



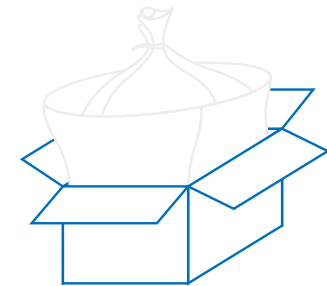
Transparent sealed bag
3 x 10 labcoats



Closed internal
liner bag



Open case
liner bag



Box

Note: This is a visual representation of selected products from the Tyvek® IsoClean® non-sterile product range, for details on each product please refer to the table on the next page.

Packaging options

TYVEK® ISOCLEAN® NON-STERILE

Product name	Transparent sealed bag <i>Quantity of products per transparent sealed bags in closed internal liner</i>	Closed internal liner bag <i>Quantity of closed internal liner bags in the box</i>	Open case liner bag <i>Quantity of open internal liner bags in the box</i>	Box quantity <i>Quantity of products per box</i>
Tyvek® IsoClean® Labcoat IC 270 B WH 0B	3 x 10 eaches bulk packed in a transparent sealed polybag	1	1	30 eaches
Tyvek® IsoClean® Gown IC 702 S WH 00	3 x 10 eaches bulk packed in a transparent sealed polybag	1	1	30 eaches
Tyvek® IsoClean® Gown IC 703 S WH 00	3 x 10 eaches bulk packed in a transparent sealed polybag	1	1	30 eaches
Tyvek® IsoClean® Hood IC 668 B WH 00	4 x 25 eaches bulk packed in a transparent sealed polybag	1	1	100 eaches
Tyvek® IsoClean® Shoe cover IC 451 S WH 00	5 x 20 eaches bulk packed in a transparent sealed polybag	1	1	100 eaches
Tyvek® IsoClean® Boot cover IC 458 B WH 00	5 x 20 eaches bulk packed in a transparent sealed polybag	1	1	100 eaches
Tyvek® IsoClean® Sleeve IC 501 B WH 00	5 x 20 eaches bulk packed in a transparent sealed polybag	1	1	100 eaches
Tyvek® IsoClean® Bouffant IC 729 S WH 00	10 x 25 eaches bulk packed in a transparent sealed polybag	1	1	250 eaches

Table 1

Understanding cleanroom classifications

Non pharmaceutical cleanrooms are using the ISO classification systems as per ISO 14644-1 (see Table 1) to classify their cleanrooms into classes ISO 1 to ISO 9. In Europe, pharmaceutical cleanrooms apply the GMPs (Good Manufacturing Practices), which use a different classification in Grades A through D (see Table 2). EU GMP guidelines require 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 since it is mandatory for importing pharmaceutical drugs into Europe. All of these systems are acceptable for use.

ISO 14644-1 Air cleanliness classes for cleanrooms and clean zones (maximum particles/m³ of air).

Source: ISO 14644-1

ISO Classification Number	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1.0 µm	5.0 µm
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1,000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2,930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

Table 2

GMP grades - EU classification.

Source: EU GMPs Annex 1 - Recommended limits for particulate contamination

Class	Maximum particles/m ³			
	At Rest	At Rest	In Operation	In Operation
	0.5 µm	5.0 µm	0.5 µm	5.0 µm
Grade A	3,520	20	3,520	20
Grade B	3,520	29	352,000	2,900
Grade C	352,000	2,900	3,520,000	29,000
Grade D	3,520,000	29,000	Not defined	Not defined



Selection and qualification of cleanroom garments

Step 1 - User Requirements Specifications:

It is important to define upfront the requirements on the cleanroom garments system from the users and the environment they work in. The User Requirements Specifications are dependent on the cleanroom class (ie: grade A/B or ISO 4-5, grade C/D or ISO 6-8) will define the critical requirements against which the garment system needs to be assessed so that they will be in line with the quality risk assessment. For example, a trained operator may have to be able to work at least 3 hours in the same set of cleanroom garments without causing unacceptable (cGMP) levels of contamination of the garments and the aseptic working environment. The garment design and features need to match the requirement. The garment's packaging system may have to be suitable for the layout of the cleanroom and its material pass-through systems, or may have to be suitable for manual spray disinfection.

Step 2 - Assessing barrier properties:

The main function of cleanroom garments is to make sure that the particles and micro-organisms shed by the operators stay inside the cleanroom garments and do not contaminate the cleanroom. The barrier properties of the garments must meet the requirements of the cleanroom classification and should be assessed using validated test methods. The Body box test (IEST-RP-CC003.4) is the only test method available to assess particle shedding when a garment is actually being worn by an operator. It allows evaluation of both the particle shedding of the garment and its PFE & BFE of the particles shed by the operator. The following tests may also prove valuable: particle filtration efficiency (PFE) test (EN 143, TSI 8130) or the bacterial filtration efficiency (BFE) test (ASTM F2101).

Step 3 - Assessing garment linting:

since the cleanroom garments themselves may be a source of contamination, their linting properties should be assessed. The Helmke Drum test method as per IEST-RP - C003.4 is a good way to assess the particle shedding of cleanroom garments, especially for garments that are washed multiple times.

Step 4 - Sterility assurance:

for GMP grade A/B cleanrooms that require sterile cleanroom garments, it should be made sure that the garments have been sterilized according to a validated sterilization process (as per ANSI/AAMI/ISO 11137-1) and that they offer a sterility assurance level (SAL) of 10⁻⁶. A simple autoclaving or irradiation may not be enough.

Step 5 - Stability testing:

It is important to check how the garment characteristics and properties will change over time (due to ageing, wear, wash-dry-sterilisation cycles). Therefore the performances listed above should be validated under worst-case conditions, i.e. for single-use garment assessing garments from different batches and at the end of their shelf-life, and for reusable garments after 10, 20, 30, 40 and 50 wash-dry-sterilisation cycles to assess and define the end-of life of the garments.

Step 6 - Checking the packaging system:

both the integrity and stability of the packaging system the garments come it should be checked in order to make sure that they do not represent a contamination risk and allow a seamless transportation from the warehouse to the gowning area.

Step 7 - Checking the folding:

the aseptic folding should be checked to make sure they allow an easy gowning.

Step 8 - Updating procedures:

upon selection of the appropriate cleanroom garments, the gowning procedures and trainings should be adapted to the new garments.

Step 9 - Integration in the contamination control strategy:

document the garment validation process and integrate the certificates, test reports and documents provided by the garment manufacturer into the contamination control strategy and include them in the revision and audit processes.



Seam construction and performance

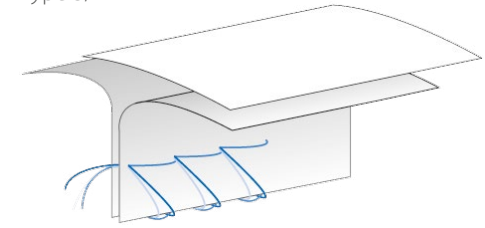
Garment seam design and quality is a very important consideration. All protective garments employ seams in their construction and due attention must be devoted to ensuring that the seam technology employed is up to requisite standard. It is not enough for a garment to be manufactured using the best barrier fabric if the seams are weak or leak. Different seaming configurations and connection systems are available which provide the necessary strength and impenetrability for different hazard and usage situations. The same considerations apply to closure systems such as zips and storm flaps, and to garment interfaces and boundaries in the neck, hood, wrist and ankle areas.

All Category III chemical protective clothing must undergo a seam strength test as well as the relevant “whole suit” inward leakage test. Tight, reliable seams are an absolutely critical element in the overall barrier protection performance of a garment therefore when selecting a garment, it is important to verify the seam performance in addition to the fabric performance. Just because a seam is tight doesn't mean that it is impermeable and vice versa. Stitched seams on their own, for example, are never so fully tight that gas or particulates cannot penetrate. By properly over taping a stitched seam, however, it can be made as tight and strong as the parent fabric material.

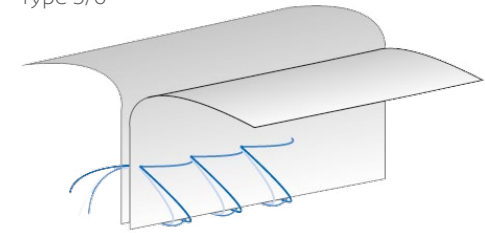
Stitched & Overtaped seams

Seams can be stitched and overtaped. The tapes used for DuPont products with this type of seam offer a barrier equal to that of the fabrics.

Type 3/4



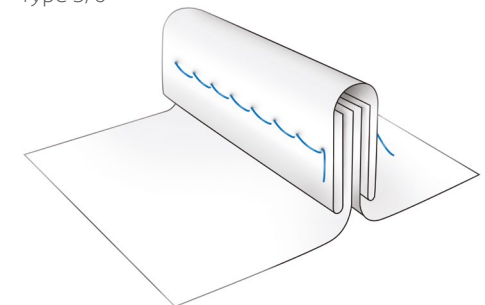
Type 5/6



Stitched seams

Stitching offers good balance between seam strength and seam barrier.

Type 5/6



Bound seams

Seam construction for cleanroom garments to keep the particles generated by the operators inside the garments and to maximise the particle & bacterial filtration efficiencies.

Figure 1 Three types of seam construction, Source: DuPont

Product Part Numbers

IC	0183	B	WH	LG	0025	DS
Fabric	Style	Seam Construction	Color	Size	Case Count	Options
<p>The first two characters are the fabric description.</p> <p><i>Abbreviations</i></p> <p>DuPont™ Tyvek® IsoClean®</p>	<p>DuPont offers a wide array of garment styles—from hoods, aprons and coveralls to fully encapsulated suits. Each garment style has a unique three-digit code.</p>	<p><i>Abbreviations</i></p> <p>S Serged or Sewn B Bound T Taped or Double Taped</p>	<p>Several DuPont fabrics are available in color options.</p> <p><i>Abbreviations</i></p> <p>BU Blue GR Green GY Grey LY Lime Yellow OR Orange WH White YL Yellow HV High visibility Orange</p>	<p>Many DuPont garments are available in a range of sizes; refer to catalog descriptions for details.</p> <p><i>Abbreviations</i></p> <p>SM Small MD Medium LG Large XL Extra large 2XL 2 Extra large 3XL 3 Extra large 4XL 4 Extra large 5XL 5 Extra large 6XL 6 Extra large 7XL 7 Extra large 00 Universal</p>	<p>The number of garments per case.</p>	<p><i>Abbreviations such as</i></p> <p>DS or MS Clean and Sterile: clean-processed, individually packaged and sterilized by gamma radiation</p> <p>00 or 0B Bulk packaged, not sterile</p> <p>0S or TS Sterile: individually packaged and sterilized by gamma radiation</p>



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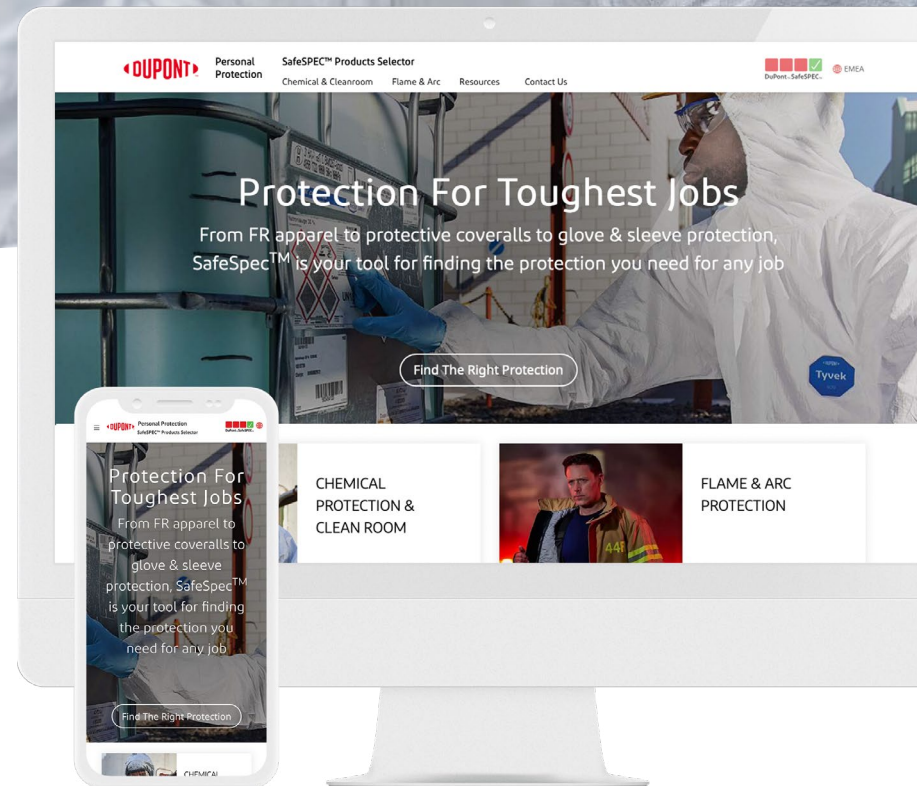
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DuPont™ SafeSPEC™ - We're here to help

Our powerful web-based tool can assist you with finding the appropriate DuPont garment for chemical or cleanroom environment.
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