



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

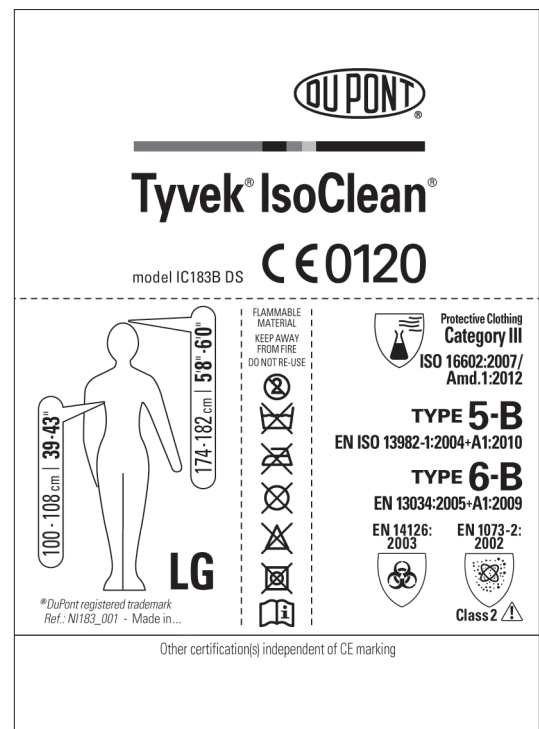
Selected DuPont™ Tyvek® IsoClean® garments are designed and manufactured to meet or exceed the European standards for Type 5 & 6 chemical protective clothing and are CE marked as Category III PPE in accordance with the PPE directive. Selected DuPont™ Tyvek® IsoClean® accessories (clean-processed and 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.



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
	<p>DuPont™ Tyvek® IsoClean® Frock with bound neck - model IC 270 B option 00 (Bulk packed)</p> <p>Frock available in white in sizes S to XXXL. Bound seams. Covered elastication at wrists. Front snap closure for easy donning and doffing. White.</p>	Cat. I	IC 270 B WH 00
	<p>DuPont™ Tyvek® IsoClean® Gown - model IC 701 S option 00 (Bulk Packed)</p> <p>Gown available in white and in one size. Serged seams. Bound neck with ties. Knitted Cuffs. Bound ties originating at center front waist.</p>	Cat. I	IC 701 S WH 00
	<p>DuPont™ Tyvek® IsoClean® Sleeve - model IC 501 B option 0B (Bulk Packed)</p> <p>Sleeve available in white and in one size. Bound seams. Covered elastic at both ends. 45 cm long.</p>	Cat. I	IC 501 B WH 0B
	<p>DuPont™ Tyvek® IsoClean Shoe cover - model IC 451 S WH option 0B (Bulk Packed)</p> <p>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</p>	Cat. I	IC 451 S WH 0B
	<p>DuPont™ Tyvek® IsoClean Boot cover - model IC 458 B WH option 0B (Bulk Packed)</p> <p>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</p>	Cat. I	IC 458 B WH 0B
	<p>DuPont™ Tyvek® IsoClean® Hood with ties - model IC 668 B option 0B (Bulk packed)</p> <p>Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit.</p>	Cat. I	IC668 B WH 0B
	<p>DuPont™ Tyvek® IsoClean® Bouffant - model IC 729 S option 0B (Bulk Packed)</p> <p>Bouffant available in white and in one size. Serged Seams. Elastic headband. 54 cm Diameter.</p>	Cat. I	IC 729 S WH 0B
	<p>DuPont™ Sierra™ Mask - model ML 7360 option BH</p> <p>Mask available in white and in one size. Bound Tyvek® Ties. Pleated Rayon Outer Facing. Metal Nose Piece.</p>	N/A	ML 7360 WH BH

N/A - Not Applicable.



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.

www.safespeccleanroom.dupont.co.uk

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