



PROTECTIVE CLOTHING FOR USP <797> CLEANROOM GOWNING

DuPont understands your need to reduce risk in your controlled environment. The DuPont Controlled Environments product portfolio offers a comprehensive selection of clean-processed and sterile single-use protective clothing to support your USP <797> cleanroom gowning needs.

DuPont™ Tyvek® IsoClean®

Tyvek® IsoClean® offers clean-processed and sterile protective clothing and accessories designed for use in pharmaceutical, medical device and biotech settings that require high standards for particle and microbiological contamination control. Tyvek® IsoClean® garments offer an ideal balance of protection, durability and comfort. In addition, they feature the lowest linting and particle shedding of any garments in the DuPont portfolio.

Tyvek® IsoClean® protective apparel is available in sterile and non-sterile options and in a wide variety of styles, such as coveralls, frocks, lab coats, hoods, gowns, bouffants, shoe and boot covers and sleeve protectors.

What Is USP <797> and Whom Does it Affect?

Chapter 797 in the USP National Formulary “Pharmaceutical Compounding – Sterile Preparations” describes the guidelines, procedures, and compliance requirements for compounding sterile preparations, and it sets the standards for all settings in which sterile preparations are compounded. USP <797> affects all disciplines (physicians, nurses, pharmacists, pharmacy technicians) involved in all sterile pharmacy settings or settings where compounded sterile preparations are prepared.

ISO 5 Controlled Environments*

Tyvek® IsoClean®
clean and sterile bouffant
(IC729SWH000250CS)

Tyvek® IsoClean®
clean and sterile hood
(IC668BWH000100CS)

Controlled Environment
sterile face mask
(ML7360WH0002500S)

Tyvek® IsoClean®
clean and sterile coverall
(IC253BWH#0025CS)

Garments folded to facilitate aseptic donning

Bound seam garments offer better particle barrier than serged seams.

Tyvek® IsoClean®
clean and sterile boot cover
(IC458BWH#0100CS)

Elastic wrists and ankles are covered by garment materials so the elastic is not exposed.

Gripper™ soles offer a higher level of slip resistance than standard PVC soles.



ISO 7/8 Controlled Environments*

Tyvek® IsoClean®
bouffant
(IC729SWH0002500B)

Tyvek® IsoClean®
frock with snaps
(IC270BWH#003000) or

Tyvek® IsoClean®
frock with zipper
(IC264SWH#00300B)

Tyvek® IsoClean® shoe cover with Gripper™ sole
(IC451SWH#01000B)



*Gowning as described in IEST Recommended Practice IEST RPCC003.

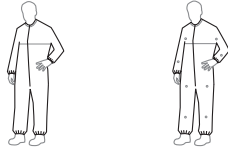


Tyvek® IsoClean® Clean-Processed and Sterile Garments

Clean-processed and sterile (option code CS) garments are specially processed to minimize particle shedding, then folded for aseptic donning and individually packaged in an ISO Class 4 cleanroom. The case quantity is packaged in a cardboard case with two polyethylene liners. Sterility is achieved by gamma irradiation. Irradiation dosage is validated in accordance with ISO 11137 for a Sterility Assurance Level (SAL) of 10⁻⁶.

Coveralls

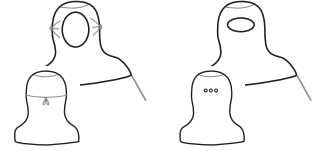
Bound seams, bound neck, dolman sleeve, covered elastic wrist, ankle, zipper closure, with or without snaps for aseptic donning. Multiple sizes available.



IC253BWH##0025CS IC254BWH##0025CS

Hoods

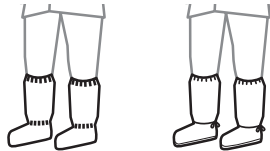
Bound seams, full-face or eyes-only opening, ties with loops or snaps for fit. Universal sizing (00).



IC668BWH##0100CS IC666BWH##0100CS

Boot Covers

Serged or bound seams, elastic ankle or ties at ankle, Gripper™ sole, 18" high.

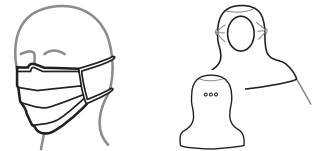


IC447SWH##0100CS IC458BWH##0100CS

Face Masks or Combos

Face Mask

9" or 7" size, bound Tyvek® ties, pleated rayon outer facing, metal nose piece, adhesive at nose. Universal sizing (00).



ML7300WH##02500S 9820 Option PI
ML7360WH##02500S

Hood/Mask Combo

Bound seam hood with head opening, ties with loops for fit, face mask / pleated / blue, 7" size. Universal sizing (00).

Controlled Environment Accessories

Bouffant

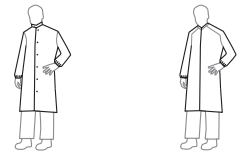
Serged seams, elastic headband, 21.5" diameter. Universal sizing (00). Available in sterile and non-sterile option codes.



IC729

Frocks

Elastic wrists, bound seams with snaps, serged seams with zipper. Available in sterile and non-sterile option codes.



IC270 IC264

Sleeves

Bound seams, covered elastic wrist, bicep 18" length. Universal sizing (00). Available in sterile and non-sterile option codes.



IC501

Cuff Tape

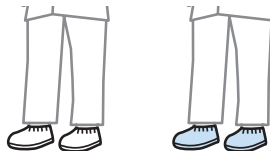
Made of Tyvek® IsoClean®, 20" long x 3" wide, 400/cs.



IC994790WH

Shoe Covers

Serged seams, elastic opening, 5.5" height, white, blue. Bulk packaged.



PE440SWH PE440SBU



DuPont™ SafeSPEC™

DuPont™ SafeSPEC™ for Controlled Environment is a comprehensive online database available to aid in the selection of protective clothing for controlled environments.

safespeccleanroom.dupont.com

Customer Service:

United States 1-800-931-3456
Canada 1-800-387-9326

It is the user's responsibility to determine the level of toxicity and the proper personal protective equipment needed. This information is intended for use by persons having the technical expertise to undertake evaluation under their own specific end-use conditions, at their own discretion and risk.

Anyone intending to use this information should first check that the garment selected is suitable for the intended use. The end-user should discontinue use of garment if fabric becomes torn, worn or punctured, to avoid potential chemical exposure. Since conditions of use are beyond our control, we make no warranties, expressed or implied, including but not limited to warranties of merchantability or fitness for a particular purpose and assume no liability in connection with any use of this information.

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