

Annex 1 revision — Contamination risk factors

Advantages of Tyvek® IsoClean® single-use garments over reusable garments

For DuPont™ Tyvek® IsoClean®, the production of raw materials is well controlled by DuPont as the sole manufacturer.



Manufacturing of the garments

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

Tyvek® IsoClean® sterile garments are packaged in a pouch with a five-year shelf life, then in double poly case liners, and finally in a single-use sealed box, which represents 4 layers of protection significantly reducing the risk of contamination.



Packaging & transport of the garments

Most reusable garments, that are autoclaved are packed in a single bag with a six-month shelf life and then in a reusable crate, which can lead to transfer of contamination.

Tyvek® IsoClean® provides a consistent barrier against dry particles and microorganisms, delivering the ideal balance of protection, durability and comfort. Thanks to excellent fabric properties the coverall and accessories are a barrier that protects both the wearer and the environment.



Working in the cleanroom

Reusable polyester garments have a higher risk of contamination in the cleanroom due to their high permeability. Additionally, 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.

Tyvek® IsoClean® clean and sterile garments are only washed and sterilized prior to wearing, so there is no risk of ineffective washing or sterilizing of a garment that has already been worn.



Washing & sterilizing the garments

Reusable garments are washed and sterilized many times over their lifetime, increasing the risk of contamination. Changes in garment performance can be invisible to the naked eye. Download our study on www.tyvek.co.uk/invisible to make informed garment decisions.

Tyvek® IsoClean® garments are only worn once, so there is no risk of inadequately repairing damaged garments.



Repairing contaminated garments

Inadequate repairs on reusable garments can lead to holes and decrease of barrier. Requalifying repaired garments can also be expensive and disruptive.

Coverall

○ Model IC 183 B WH DS

Clean-processed and gamma-sterilized.
Bound internal seams.
Tunnelled elastication at wrists and ankles.
Elasticated waist at back.
Tyvek® covered elasticated thumb loops.
Zipper closure.
Storm flap.
Aseptically folded.
CE-certified. Cat.III, Type 5-B, 6-B.
White.
25/box
SM-3XL



Labcoat

○ Model IC 270 B WH MS

Clean-processed and gamma-sterilized.
Bound internal seams.
Tunnelled at wrists.
Front snap closure.
Aseptically folded.
CE certified. Cat.I.
White.
30/box
SM-3XL



Hood

○ Model IC 668 B WH MS

Clean-processed and gamma-sterilized.
Bound internal seams.
Bound hood opening.
Full face opening.
Ties with loops.
Aseptically folded.
CE certified. Cat.III, PB [6].
White.
100/box
Universal sizing (00)



Hood/mask

○ Model 9820 MS

Clean-processed and gamma-sterilized.
HOOD:
Bound seams.
Bound head opening.
Ties with loops.
White.
MASK:
Pleated Polyethylene outer.
17,5 cm.
Sterile.
CE certified.Cat I.
Blue.
100/box
Universal sizing (00)



Bouffant

○ Model IC 729 S WH MS

Clean-processed and gamma-sterilized.
Elastic headband.
CE certified. Cat. I.
White.
250/box
Universal sizing (00)



Sleeve

○ Model IC 501 B WH MS

Clean-processed and gamma-sterilized.
Bound internal seams.
Tunnelled elastication at wrist and bicep.
Aseptically folded.
White.
CE certified. Cat.III, PB [6].
100/box
Universal sizing (00)



Overboot

○ Model IC 458 B WH MS

Clean-processed and gamma-sterilized.
Tunnelled elastication at shin.
Ties.
Elasticated ankle.
Gripper™ sole.
Bound internal seams.
Aseptically folded.
CE certified. Cat.III, PB [6].
White.
100/box
SM-XL



Sierra™ Mask

○ Model ML7360 WH OS

Gamma-sterilized.
Bound ties, metal nose piece.
23 cm.
White.
250/box
Universal sizing (00)



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