

CleanMax™ Cleanroom Apparel

In all cleanroom environments, human sourced contamination is the easiest to control yet humans contribute the most contamination. Disposable, single-use cleanroom compatible, gamma compatible cleanroom garments are recommended for:

- Cleanroom operations that manufacture toxic chemicals or biologics
- Cleanroom operations that are too small to have a reusable cleanroom garment program
- Start-up cleanroom operations (i.e. universities, etc.)
- Compounding Pharmacies complying with USP 797 and USP 800
- Maintenance and cleaning operations that would significantly soil, stain or damage reusable cleanroom garments
- Protection from any liquids or bodily fluids

The IEST most recently published recommended practice for cleanroom garments, IEST-RP-CC003.4, <u>Garment Considerations for Cleanrooms and Other Controlled Environments</u> recommends six types of nonwoven fabrics:

- Spunbonded or thermal bond
- 2. Flash spun
- 3. Melt blown
- Spunbonded/melt blown/spunbonded (SMS)
- 5. Film laminate
- 6. Microporous film laminate



The IEST document recommends that when selecting disposable, single-use cleanroom garments for your specific application, one should evaluate the garments for:

- Cleanliness and cleanability
- Electrostatic properties
- Biological properties
- Durability
- Comfort
- Opacity
- Particle filtration efficiency
- Microbial penetration
- Chemical compatibility
- Fluid resistance

The IEST document identifies standard tests to be performed to assess the different properties. The IEST document also recommends the types of thread and seams used in construction of cleanroom garments.

Seam construction is an important consideration in the selection of cleanroom garments. It is recommended that disposable, single-use cleanroom garments have bound seams to encapsulate the raw edges of the disposable fabric. However, many disposable garments used in cleanrooms currently are manufactured with only serged seams and therefore may contaminate the cleanrooms with particles and fibers.

Lakeland disposable, single use cleanroom compatible, gamma compatible sterile and nonsterile garments are manufactured using clean manufacturing procedures to reduce viable and non-viable particles. The opaque microporous laminate fabric is lightweight for user comfort yet durable and fluid resistant to chemicals and bloodborne pathogens. The microporous laminate fabric coating is also static dissipative.

In all cleanroom applications, whether sterile or non-sterile, disposable, single-use cleanroom garments are worn, the operators must comply with strict adherence to the company's standard operating procedures for donning and doffing the cleanroom garments, behavior in the



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cleanroom and cleaning the cleanroom. If the operators fail to conform to the company's standard operating procedures, the cleanrooms will suffer.

With the innovations in nanotechnology, 3-D Printing, novel biologicals, pharmaceuticals and medical devices, smaller, more powerful computers manufactured in the semiconductor and microelectronics industries as well as the food industries, there will always be operators working in cleanrooms wearing cleanroom garments. The choice is yours, sterile or non-sterile, disposable, single- use cleanroom garments for specific cleanroom operations.

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