

DISPOSABLE CLEANROOM GARMENTS:

A Comprehensive Guide

From clean garment manufacturing, to packaging and overall performance, there are many quality factors to consider as you select the right disposable garments for your cleanroom and/or controlled environment.

Use this guide to assist you in choosing the best cleanroom apparel for your application and environment.





Table of Contents

- Clean vs Sterile 3
- Manufacturing & Sterility Data Support 6
- Lakeland CleanMax™ Features & Benefits 9
- Why Packaging Matters for Your Controlled Environment 11
- Why Choose Lakeland? 13
- Quick Selection Guide 15
- Request a Sample/Consultation 17

All cleanrooms are controlled environments, but not all controlled environments are clean.

CLEAN vs STERILE

Your cleanroom classification requires you to meet ISO14644 standard and IEST (Institute of Environmental Sciences and Technology) recommended practices, but have you thought about the particle counts on your cleanroom garments as a result of the manufacturing process? The primary objective of cleanroom gowning is to eliminate contamination risks. Are you positive your cleanroom garments are not introducing more contaminants? **Just because something is sterile, doesn't mean it's particle free.**

What is a Sterile Garment?

A 'sterile' garment can be manufactured in any type of facility; it simply undergoes a sterilization process once the garment is complete. It is important to note, however, that just because something is sterile, doesn't mean it is inherently free of particles or contaminants. In many cases, sterile cleanroom garments are not clean-processed and therefore, the garments have a heavy particle load and can introduce foreign particles into your cleanroom and/or controlled environment.



What is a 'Clean and Sterile' Garment?

A 'clean and sterile' garment is both sterile and clean manufactured. This means the garment is sewn and constructed in a controlled clean manufacturing environment. All of the assembly operators are trained in good cleanroom hygiene and clean manufacturing principles. Each employee is gowned in the class appropriate cleanroom apparel. Work surfaces are disinfected and wiped clean at predetermined intervals throughout production. A clean manufacturing facility ensures that operators are not shedding any particles onto the garments during the construction and manufacturing process. Once the production lot is completed it undergoes a validated gamma radiation dose to achieve sterilization.

Garments that are manufactured to be 'clean and sterile' offer significantly less excursions and lower surface particle counts in contrast to garments that are not clean manufactured.

CleanMax™ by Lakeland Industries

Lakeland Industries has spent over 40 years being an industry leader protecting people in the workplace and now we've extended our expertise to protect both your people and your cleanroom and/or controlled environment. CleanMax™ is a high quality microporous laminate material that is light-weight and breathable but is impervious to liquids, harsh chemicals and microorganisms.

Benefits of Choosing Lakeland CleanMax™

- Excellent comfort and protection
- PPE Cat 3 Type 5 & 6
- All sterile garments are sterilized to a level of 10^{-6} SAL
- All garments meet IEST-RP-CC003 Category I Cleanliness
- CleanMax™ Clean Manufactured and CleanMax™ Sterile are both clean-processed garments, ready for use in ISO Class 5 – 8 Cleanrooms



Clean manufactured and clean manufactured sterile garments are beneficial in meeting the strict cleanroom requirements of the pharmaceutical, biotech, life sciences, medical device, nanotechnology, microelectronics and industries utilizing controlled environments.

MANUFACTURING & STERILITY DATA SUPPORT

You only want the best for your cleanroom and/or controlled environment, so don't be afraid to ask for the data.

Not only should you insist on clean-manufactured garments for your cleanroom and/or controlled environment, it should be easy for you to see the data supporting the sterility of your garments.

At Lakeland, we make it easy for you to see and access the chain of custody for garment sterility. **In fact, it's as easy as 1-2-3.**

1. Locate the QR code for you garment (it can be found on the garment tag, the individual package and on the box used for shipping.)
2. Scan the QR code to access the Lakeland website database.
3. View and print your sterility certificate as needed.

When you choose Lakeland CleanMax™ apparel, we make it easy for you to access and print sterility certification.



Look for the Red Indicator Dot

Quickly assess the sterility of your garments with a gamma indicator dot, which acts as a visual indication that the product has been exposed to gamma radiation. Lakeland CleanMax™ Sterile offers individually wrapped garments with an expiration date and a self-adhesive, nontoxic indicator sticker that changes from yellow to red upon exposure to a validated dose of gamma radiation. Moreover, each case is also equipped with a date of irradiation and a sterility indicator to ensure that upon arrival, your garments meet the necessary sterility requirements for your cleanroom classification.

Lakeland CleanMax® Coverall with Attached Hood
Compatible with ISO Class 4-8 Cleanrooms and all Controlled Environments
IEST-RP-CC003 Category 1 Particle Cleanliness



Part Number: CTL428CS

- Zipper closure with placket
- Attached hood
- Elastic wrists
- Thumb loops
- Elastic ankles


Individually Bagged, 25/Case
GARMENTS SOLD IN CASE QUANTITY ONLY

Clean Manufactured Sterile
Clean Manufactured in Silicone Free Environment
For Critical Environments

PROTECTIVE CLOTHING CATEGORY III
CE 2777 UK CA 0321



EN 13034 :2005 +A1:2009
EN ISO 13982-1 :2004 +A1:2010
EN 1073-2:2002 TIL = Class 1
EN 14126:2003 (Type 5B, 6B)



Date of Manufacture:
Expiration Date: Five Years from Manufacture Date

Lot Number:

Size:

CTL428CS

Made in China



STERILE R
Irradiation Sterilization



Sterilization Certificate

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Lakeland's Non-Sterile Disposables

At Lakeland, we understand that not all manufacturing facilities require sterilized garments. As such, we are proud to offer Lakeland CleanMax™ Clean Manufactured garments without sterilization. These garments are identical to our sterile garments, but they forgo the sterilization process. Lakeland CleanMax™ Clean Manufactured offers the same clean garments as our sterile garments for your cleanroom and/or controlled environment without the added cost of sterilization.

Choosing clean-manufactured garments for your cleanroom and/or controlled environment means maximum protection from unnecessary excursions during donning and foreign particle contamination.

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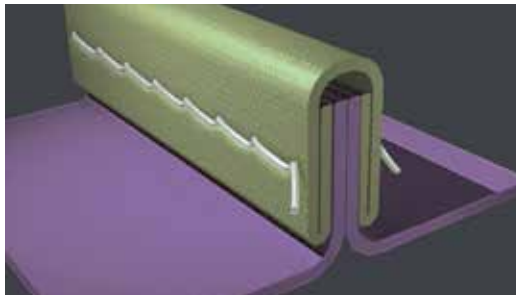


LAKELAND CLEANMAX™ FEATURES & BENEFITS

Cleanroom disposables are not created equal -- here are just some of the details that set Lakeland above the competition.

Clean manufactured garments. Garments that are clean manufactured offer significantly less particle counts in contrast to garments that are not clean manufactured.

All bound seams. CleanMax™ garments feature bound seams, which are precisely sewn with an additional outer binding. This increases seam strength and provides a better barrier from break through and protection from strike through than simple serged seams.



Folded for easier donning. Garments are folded to minimize excursions during donning and doffing; and prevent surface contamination.

Less wrinkles, mean less excursions. Garments are individually packaged and expertly folded to prevent excessive wrinkling and the potential for increased excursions.

Smooth surface area prevents particles from sticking. CleanMax™ garments are smoother than other leading brands, which means particulates are less likely to harbor on the garment surface.



Smooth storm flap for added level of protection. Very few disposable cleanroom garments have the added protection of a placket storm flap. Protect your employees with less particulate breakthrough on the zipper of the gown.

No pre-washing required. Lakeland's clean manufacturing process means that our garments are not required to undergo a laundry process, which can cause excessive wrinkling, creasing and can compromise the integrity of the garment.

Thumbloops. Elastic wrists with thumb loops help secure the coveralls and frocks in place to prevent the potential exposure of skin while worn during normal activities.

Resistance to blood borne pathogens and more. Get the added safety of CleanMax™, which offers resistance to blood and body fluid penetration, viral penetration and blood borne pathogens.

Chemical penetration resistance. CleanMax™ offers chemical penetration resistance to oils, bleach and 50 percent sodium hydroxide.

Cuffed ankle allows for six inches of freedom. Expertly designed to reduce surface contamination during the donning process, the cuffed ankle provides six inches of freedom when you are stepping into the gown.

WHY PACKAGING MATTERS FOR YOUR CONTROLLED ENVIRONMENT

How a cleanroom garment is packaged is critical for the safety and integrity of your people and your controlled environment. It's not enough to have a clean and sterile manufacturing process, the packaging process must also be designed to:

- Reduce excursions
- Decrease gowning time and error
- Safeguard against contamination

The packaging must not contribute to the particle load on the garment.



Lakeland CleanMax™ products are packaged to ensure maximum garment protection.

- Each package includes an **easy open strip** allowing for less handling when removing the garment from packaging during the donning process.
- Garments are **folded and left unzipped** to allow for easier donning.
- Garments are **individually packaged** without excessive wrinkling and to maintain cleanliness.
- The packaging **can be wiped down with IPA** without the fear of the print smearing or creating cross contamination.
- Individually packaged garments are placed in a **sealed heavy-duty outer bag** to protect the integrity of the garment and to facilitate staged entry into the gown room cleanroom.
- The coveralls and frocks are positioned so wearers **can only grab the inside of the garment**, right below the collar area. This eliminates any contamination on the exterior surface.
- As the garment is pulled out of the packaging, the **folded garment will fall easily**, ready for the next step in the donning process.
- The **bib on the hood is folded over** so wearers can **remove the hood** from the package and don **by touching only the inside** of the garment.
- **Boots are packaged in pairs** with the upper of the boot folded over so the wearer can **grab the boot by the inside** of the upper to easily slide over shoes and up the calf.

Protect your cleanroom and/or controlled environment, your product and your people with packaging designed to minimize excursions and contamination.

WHY CHOOSE LAKELAND?

Lakeland CleanMax™ garments provide the comfort, quality and protection you expect, all backed by our 40+ years as a manufacturer of disposable protective apparel.

Availability is Essential

Product availability is critical for your controlled environment. Losing valuable production hours because you lack cleanroom apparel is not an option. Our team at Lakeland and our network of exceptional distributors will help you find the right garment for your application and ensure you get your order when you need it with our inventory management program.



Customer Service is Our Strength

At Lakeland, superior customer service is one of our biggest strengths. With a small, highly trained team dedicated to customer satisfaction, we are always ready to assist. Whether it is pairing the right customer with the right distributors, obtaining technical data for audits, or securing sterility certificates, our team at Lakeland will work directly with you to meet your needs. Moreover, we are ready to help you protect your people and your environment if your product or garment needs change over time.

At Lakeland, we are here to support your team and to help you feel secure in your investment to protect your people, your cleanroom and/or controlled environment and your product.





QUICK SELECTION GUIDE: WHO SHOULD USE CLEANMAX™?

Confidence in your cleanroom starts with understanding how to select the right disposable apparel for your unique needs. Part of the benefit of working with Lakeland is ongoing access to our team of cleanroom industry experts. In just a few minutes, we will work with you to determine the type of garment required for your application and environment, and discuss how we can help you protect your team effectively with clean-manufactured garments.

Applications for CleanMax™ Cleanroom Apparel

CleanMax™ Clean Sterile

- Aseptic or Terminally Sterile Cleanroom Environments
- ISO Class 5-8 Cleanroom
- Sterility assurance level of 10⁻⁶ SAL

CleanMax™ Clean Manufactured

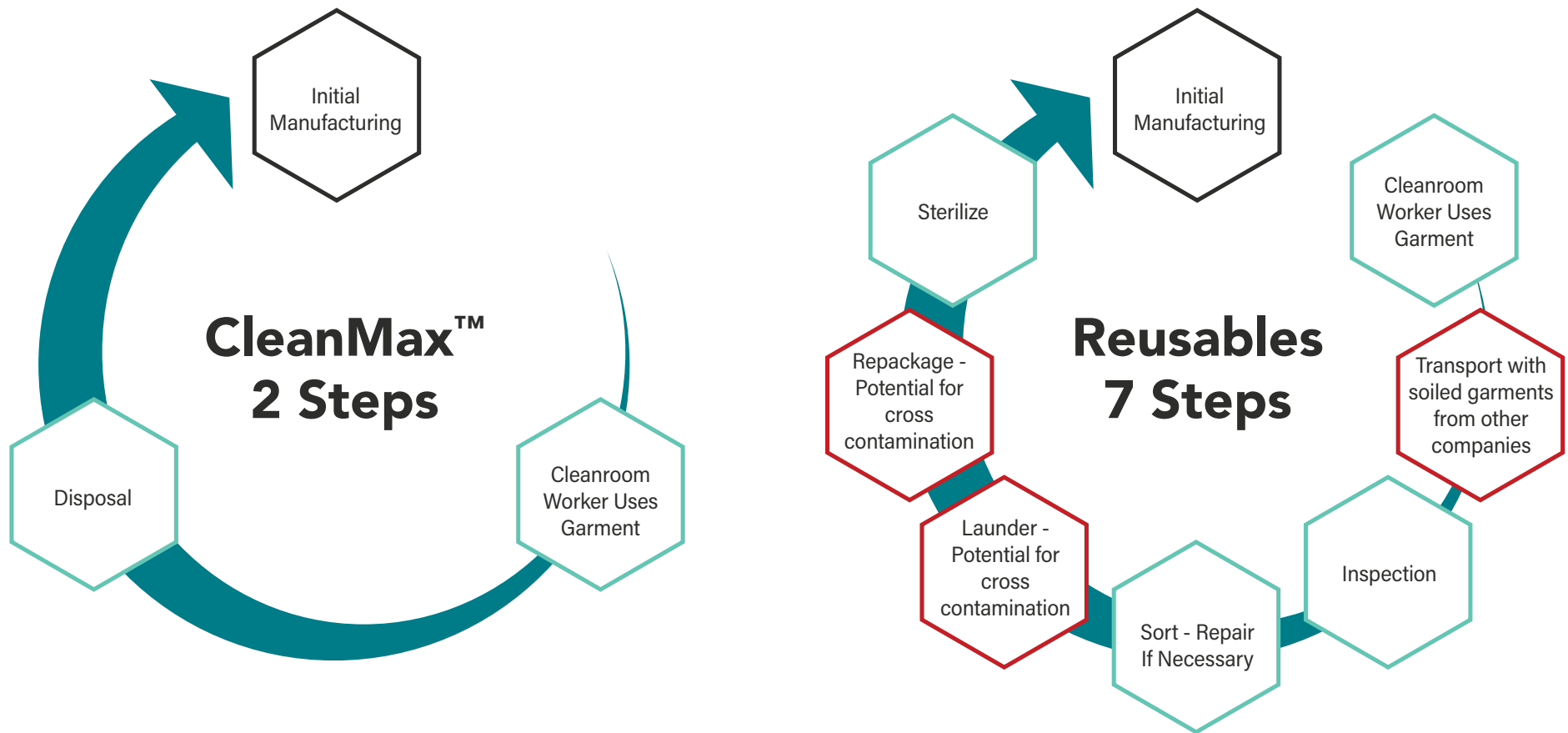
- ISO Class 5-8 or Below Non-Aseptic Cleanrooms or Controlled Environments

| Apparel | ISO 8 | ISO 7 | ISO 6 | ISO 5 Non-Sterile | ISO 5 Sterile (Aseptic) | ISO 4 | ISO 3 |
|----------------|-------|-------|-------|-------------------|-------------------------|-------|-------|
| Hair Cover | R | R | R | R | R | R | R |
| Barrier Gloves | AS | AS | AS | AS | R | R | R |
| Facial Cover | AS | AS | AS | R | R | R | R |
| Hood | AS | AS | AS | R | R | R | R |
| Frock | R | R | AS | AS | NR | NR | NR |
| Coverall | AS | AS | R | R | R | R | R |
| Shoe Cover | R | R | AS | AS | NR | NR | NR |
| Boot | AS | AS | R | R | R | R | R |

Chart shows Lakeland garments relevant to ISO 5. Recommendations from IEST-RP-CC003. **R** = Recommended, **NR** = Not Recommended, **AS** = Application Specific

CleanMax™ vs Reusables: Which is Better?

Each time a cleanroom garment is handled, a chance for contamination occurs. A reusable garment goes through multiple steps in the laundering process leading to greater risk of contamination.



Choose Lakeland CleanMax™ and feel secure in your investment in your most critical assets: your people, your controlled environment and your product.

REQUEST A SAMPLE/ CONSULTATION

Take the first step toward proven protection with Lakeland CleanMax™ clean manufactured garments for controlled environments.

