Critical Environment Apparel

CleanMax®

High-quality disposable cleanroom PPE to protect the integrity of your environment

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CleanMax® Sterility Documentation

Quickly access sterility documentation with a simple scan

Page 8

Lakeland®

CLEANMAX®

Cleanroom Apparel

Available in Clean Manufactured Non-Sterile or Clean Manufactured Sterile configurations

STERILE R Irradiation Sterilization

CleanMax® Applications

ISO Class 4-8 Cleanrooms

Pharmaceutical Compounding

Controlled Environments

Biomedical Research

Biotechnology and Life Sciences

Microelectronics

Access sterility certificates by scanning the QR code on CleanMax® packaging

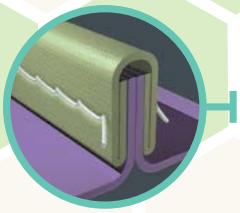
Available in clean manufactured sterile and non-sterile configurations

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) | EN 1149-5:2018 EN 1149-3:2004

CE 2777 UKCA 0321

All Lakeland® CleanMax® Apparel is:

- IEST-RP-CC003 Category I Particle Cleanliness
- Latex and silicone-free
- Compatible with ISO Class 4-8 cleanrooms and all controlled environments
- Individually double-bagged to allow zonal donning
- Resistant to viral, blood and body fluid penetration
- Resistant to blood borne pathogens
- Chemical penetration resistance to oils and bleach
- Certified to Anti-Static Standard EN 1149-5



Bound Seams

CleanMax® features bound seams, which are precisely sewn with an additional outer binding. This increases seam strength and provides a better barrier from particulates than simple serged seams.

Tunneled Elastic Wrists

CleanMax® features tunneled elastic for better sealing properties.

Lakeland Industries has spent over 40 years as a leader in protecting people, products, and environments. Our CleanMax® products are composed of a high-quality microporous laminate material that is lightweight, breathable, and impervious to liquids, harsh chemicals, and microorganisms.

Both sterile and non-sterile configurations of CleanMax® meet IEST-RP-C003 Category 1 particulate cleanliness standards and are ready for immediate use in ISO Class4-8 cleanrooms.

All sterile configurations are gamma radiation sterilized to a 10^{-6} Sterility Assurance Level. These garments provide excellent comfort as well as superior protection, so you can easily don and doff your garments to reduce excursions and risk of contamination.

All sterile garments are double-bagged to allow zonal donning procedures.

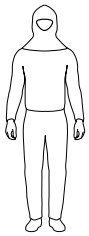
CleanMax® Configurations

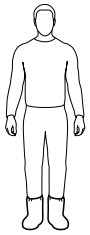

CTL191


CTL414


CTL417


CTL428


CTL713


CTL903


CTL850

Clean Manufactured Non-Sterile Garments

Frock – CTL191CM
- Mandarin collar
- Zipper closure
- No pockets
- Tunneled elastic wrists with thumb loops

Sizes: MD – 5X
Case Pack: 30

Coverall – CTL414CM
- Zipper closure
- Attached hood and boots
- Tunneled elastic on wrists (with thumb loops), and back half of waist

Sizes: MD – 5X
Case Pack: 25

Coverall – CTL417CM
- Zipper closure
- Tunneled elastic on wrists (with thumb loops), ankles, and back half of waist

Sizes: MD – 5X
Case Pack: 25

Coverall – CTL428CM
- Zipper closure
- Attached hood
- Tunneled elastic on wrists (with thumb loops), ankles, and back half of waist

Sizes: MD – 5X
Case Pack: 25

Hood – CTL713CM
- Covers shoulders
- One size
- Ties to customize fit

Case Pack: 100

Boot Cover – CTL903CMP
- Tunneled elastic top
- 19" high
- Non-skid vinyl sole

Sizes: SM/MD, LG/XL, 2XCase Pack: 50 pair

Sleeve CTL850CMP-18
- Bound seams
- Tunneled elastic
- Thumb loops

Size: 18" length
Case Pack: 50 pair

Clean Manufactured Sterile Garments

STERILE R Irradiation Sterilization

Clean Sterile
- Certificate of Radiation included
- Gamma radiation indicator dots on each package
- IPA resistant ink

Coverall – CTL414CSD
- Zipper closure
- Attached hood and boots
- Tunneled elastic on wrists (with thumb loops), and back half of waist

Sizes: MD – 5X
Case Pack: 25

Coverall – CTL417CSD
- Zipper closure
- Tunneled elastic on wrists (with thumb loops), ankles, and back half of waist

Sizes: MD – 5X
Case Pack: 25

Coverall – CTL428CSD
- Zipper closure
- Attached hood
- Tunneled elastic on wrists (with thumb loops), ankles, and back half of waist

Sizes: MD – 5X
Case Pack: 25

Hood – CTL713CSD
- Covers shoulders
- One size
- Ties to customize fit

Case Pack: 100

Boot Cover – CTL903CSPD
- Tunneled elastic top
- 19" high
- Non-skid vinyl sole

Sizes: SM/MD, LG/XL, 2X
Case Pack: 50 pair

Sleeve CTL850CSPD-18
- Bound seams
- Tunneled elastic
- Thumb loops

Size: 18" length
Case Pack: 50 pair

Note: All CleanMax® sterilised garments are individually double-bagged for improved donning control.

Disposable Cleanroom Suits: Tips for Cleanroom Apparel Selection

Confidence in your cleanroom starts with understanding how to select the right disposable apparel for your unique needs. In just a few minutes, our team of cleanroom industry experts 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 Manufactured Sterile
- Aseptic or Terminally Sterile Cleanroom Environments
- ISO Class 4-8 Cleanroom
- Sterility assurance level of 10^{-6} SAL

CleanMax® Clean Manufactured Non-Sterile
- ISO Class 4-8 or below Non-Aseptic Cleanrooms or Controlled Environments

Garment Configurations

Apparel	ISO 8	ISO 7	ISO 6	ISO 5 Non-Sterile	ISO 5 Sterile (Aseptic)	ISO 4	ISO 3	ISO 1 & 2
Hair cover	R	R	R	R	R	R	R	AS
Barrier gloves	AS	AS	AS	AS	R	R	R	R
Facial cover	AS	AS	AS	R	R	R	R	AS
Hood	AS	AS	AS	R	R	R	R	AS
Frock	R	R	AS	AS	NR	NR	NR	NR
Coverall	AS	AS	R	R	R	R	R	R
Shoe cover	R	R	AS	AS	NR	NR	NR	NR
Boot	AS	AS	R	R	R	R	R	R
Typical Frequency of Change*	**2X/week**	**2X/week**	**3X/week**	**1X/day**	**Per Entry**	**Per Entry**	**Per Entry**	**Per Entry**

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

CleanMax® Features and Benefits

Clean Manufacturing Difference

Clean manufacturing helps ensure that operators and PPE are not adding particulates to the environment. All CleanMax® - both sterile and non-sterile - are clean-manufactured under cGMP controlled conditions. ***Beware!!! Not all sterile garments available are clean-manufactured!***

Smooth Storm Flaps

Covering the zipper further helps protect the critical chest and front area of the coverall from potential particle breakthrough.

Secure Thumb Loops

Elastic wrists with thumb loops help secure coveralls and frocks in place to prevent potential skin exposure during wear.

Chemical Penetration Resistance

CleanMax® offers chemical penetration resistance to oils, bleach, and other chemicals.

Fabric tested for resistance to penetration of infectious agents and a range of chemotherapy drugs.

Premium Packaging for Peace of Mind

CleanMax® configurations are individually packaged and expertly folded to prevent excessive wrinkling and the potential for excessive excursions. All sterilized garments are double bagged for zonal donning procedures.

Bound Seams Throughout

CleanMax® features bound seams, which are precisely sewn with an additional outer binding, to provide a better barrier from breakthrough and protection from strike-through.

Smooth Surface Area

CleanMax® is smoother than other brands, meaning particulates are less likely to harbor on the garment's surface.

Cuffed Ankles for Efficient Donning

The cuffed ankle on CleanMax® provides six inches of freedom when you step into your coverall.

Anti-Static to EN 1149-5

All CleanMax® garments are anti-static to EN Standard EN 1149-5. Charge decay (according to test EN 1149-3) is t_{50} <4 s - i.e. 50% of a charge dissipates in less than 4 seconds to reduce the possibility of an electrostatic discharge (ESD)

Download the Disposable Cleanroom Garment Guide

CleanMax® Breathability and Filtration Properties

Physical Property	Test Method	Units	CleanMax® Sterile Test Results
Air Permeability	ASTM D737	cfm	<0.562 cfm/ft^2
Water Vapor Transmission	ASTM 96-80	g/m2-24hrs	663.38
Bacterial Filtration Efficiency	ASTM F2101	%	99.9%
Particle Filtration Efficiency	ASTM F2299	%	99.6%

CleanMax® Resistance to Blood, Body Fluids and Chemotherapy Drugs

Physical Property	Test Method	Units	Test Results
Synthetic Blood Penetration	ASTM F 1670**	Time to Penetration (> 60 minutes)	Pass
Viral Penetration Resistance	ASTM F 1671	Time to Penetration (> 60 minutes)	Pass
Resistance to Penetration by Blood and Bodily Fluids using Synthetic Blood	ISO 16603**	Pressure in kPa	Pass –no strikethrough at 20kPa
Resistance to Penetration by Blood Borne Pathogens	ISO 16604	Pressure in kPa	Pass –no strikethrough at 20kPa
Resistance to Permeation of Chemotherapy Drugs	ASTM D6978	Minimum Breakthrough Time >240 minutes	Pass*

** ISO 16604 and ASTM F 1671 are the correct tests to measure resistance against blood borne pathogens and contaminated liquids.

ASTM 1670 and ISO 16603 are screening tests. We include them here purely for comparison purposes.

*Tested drugs include Cisplatin, Cyclophosphamide, Cyclosporin A, Doxorubicin Hydrochloride, Etosposide (Toposar), Flourouracil, Methotrexate, Mitomycin C, Paclitaxel

CE Testing

CleanMax® Physical Properties – according to European CE Methods

Physical Property	Test Method	CE Class
Fabric Weight: 63gsm		
Abrasion Resistance	EN 530 method 2	Class 2
Flex Cracking	ISO 7854 method B	Class 4*
Trapezoidal Tear (MD/CD)	ISO 9073-4	Class 3 / 2
Tensile Strength (MD/CD)	ISO 13934-1	Class 2 / 1
Puncture Resistance	EN 863	Class 1
Seam Strength	ISO 13935-2	Class 3
Anti-Static	EN 1149-5	Pass (tested to EN 1149-3 Charge Decay t_{50} <4s)

* Flex Cracking: Sterilized garments achieve Class 5

CleanMax® Resistance to infectious agents and pathogens according to tests in Standard EN 14126

Physical Property	Test Method	CE Class
Resistance to Penetration by Blood Borne Pathogens	ISO 16604	Class 6 of 6
Resistance to Biologically-Contaminated Aerosols	ISO 22611	Class 3 of 3
Resistance to Dry Microbial Contact	ISO 22612	Class 3 of 3
Resistance to Wet Bacterial Penetration	EN 14126 Annex A / ISO 22610	Class 6 of 6

CE 2777 UKCA 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) | EN 1149-5:2018 EN 1149-3:2004

CleanMax® Bulk Packaging!

Bulk packaging in a single overlay bag is available for CleanMax® non-sterile frocks, coveralls, boots, and hoods reducing packaging, waste and carbon footprint.

Does Your Cleanroom Apparel Meet Current IEST Standards?

Download our free white paper to find out:

Isolation Gown Applications

Hospital/Medical

Pharmaceutical Compounding

Serged Seam

GENERAL PURPOSE ISOLATION GOWN

Lakeland's general purpose isolation gowns are constructed from spun bonded polypropylene fabric. Designed with the wearer's comfort in mind, this gown is both lightweight and breathable while offering protection from dirt, dry particulates, and light splashes in non-hazardous environments.

Key features and benefits:

- Spun bonded polypropylene
- Lightweight, breathable, and comfortable fit
- Wrap-around design with neck and waist ties for full coverage
- Certified as Category I PPE
- Latex and silicone free

Style Number: C2192IG

Sizes: Universal Fit (S-L) and XL

Case Pack: 100/Case (5 bags with 20 per case)

C21921G

General Purpose Isolation Gown – C21921G
- Wrap around design
- Neck and Waist ties
- Elastic wrists

Sizes: Universal fit (SM-LG) & XL
Case Pack: 100

AAMI LEVEL 2 NON-SURGICAL CE CERTIFIED ISOLATION GOWN

For use when exposure to fluids is expected to be low to moderate

Lakeland's AAMI Level 2 Non-surgical CE Certified Isolation Gown is constructed from SMMS fabric. Designed with the end-user's comfort in mind, this non-surgical gown is both lightweight and breathable. Lakeland's Isolation Gown offers basic protection when exposure to fluids is expected to be low to moderate.

CE 2777 UK CA 0321

Type 6 [PB]

EN 13034:2005 +A1:2009

Anti-Static Properties

EN1149-5:2018 EN1149-1:2006

2

Key features and benefits:

- SMMS
- Lightweight, breathable, and comfortable fit
- Wrap around design with neck and waist ties for full coverage
- Elastic cuff at wrist
- Taped seams
- Latex and silicone free
- Non-sterile

Style Numbers: C8192TIG (Universal fit), C8192TIG-XL
Sizes: Universal Fit (SM-LG) and XL
Color: Blue
Case Pack: 100/Case (5 bags with 20 per case)

C8192TIG

AAMI Level 2 CE Certified Isolation Gown
C8192TIG
- Wrap around design
- Neck and waist ties
- Elastic wrists

Sizes: Universal fit (SM-LG) & XL
Case Pack: 100

Liquid Barrier Performance Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities - ANSI/AAMI PB70:2012

	Test Method	Requirement	Lakeland AAMI Level 2 Isolation Gown Test Results	Anticipated Risk of Exposure
LEVEL 1				
Requirements at 4% AQL	AATCC 42:2017 "Impact Penetration"	≤ 4.5 g	Average Fabric - 0.0 g	**Low**
LEVEL 2				
Requirements at 4% AQL	AATCC 42:2017 "Impact Penetration"	≤ 1.0 g	Average Fabric - 0.0 g	**Moderate**
	AATCC 127:2018 "Hydrostatic Pressure"	≥ 20 cm	Average Fabric - 59.09 cm	

Physical Properties according to EN Standard Tests Methods

Physical Property	Test Method	CE Minimum Requirements	Lakeland Isolation Gown Test Results	CE Class According to EN 14325
Abrasion Resistance	EN530	>10	>100 <500	Class 2
Tear Resistance	ISO9073-4	MD/XD >10	MD 65N / XD41N	Class 3
Tensile Strength	ISO13934-1	MD/XD >30	MD 92N / XD 59N	Class 1
Puncture Resistance	EN863	>5N	8N	Class 1
Liquid Test - Penetration (%) Sulphuric Acid 30% and Sodium Hydroxide10%	ISO6530	<10%	0%	Class 3
Liquid Test - Repellency (%) Sulphuric Acid 30% and Sodium Hydroxide10%	ISO6530	>80%	>95%	Class 3

This gown should not be used in a surgical setting. For use when exposure to fluids is expected to be low to moderate. This gown should not be used in a clinical setting where Level 3 or 4 protection is warranted, or in any setting involving invasive procedures or where there is a high risk of contamination. This product has not been FDA cleared or approved. This product has been authorized by the FDA under the EUA for use as PPE in healthcare settings by healthcare personnel. This AAMI Level 2 Non-surgical isolation gown may help protect healthcare professionals and/or patients from the transfer of SARS-COV-2 virus in low or minimal risk level situation to prevent the spread of COVID-19. This product is only authorized for the duration of the declaration. This product should not be used in the presence of a high intensity heat source or flammable gas.

CleanMax® Sterility Documentation with Lakeland

Accessible 24/7 with a Simple Scan!

Why a QR Code?

As a cleanroom operator or quality assurance professional, accessing sterility documentation for your protective clothing should be simple.

Lakeland recognized the need for our customers to quickly find and store sterility documentation and developed a simple QR code system for our CleanMax® product.

QR code is easily located on the garment packaging and shipping box.

How Does It Work?

The three-step approach includes:

- Locating the QR code on any CleanMax® garment label, packaging, or shipping box.
- Scanning the QR code with a smart phone or tablet.
- Viewing and printing or saving the sterility document associated with your lot number.

Where Can I Get a Sample?

You can request a sample of Lakeland CleanMax® by calling Customer Service on **+44 (0)1430 478140** or emailing **sales@lakeland.com**. Our product specialists are standing by to help you find the right product for your application and would be happy to answer any questions you may have.

Request a Validation Pack

Our validation pack includes all the documentation required for approval of CleanMax® cleanroom clothing. Call **44 (0)1430 478140** or contact **sales@lakeland.com** to request your pack.

Lakeland®

lakeland.com | info@lakeland.com

Why Packaging Matters for Your Controlled Environment

Cleanroom PPE packaging is critical to the safety of your staff and the integrity of your controlled environment. It's not enough to have clean and sterile manufacturing processes, the packaging process must be designed to:

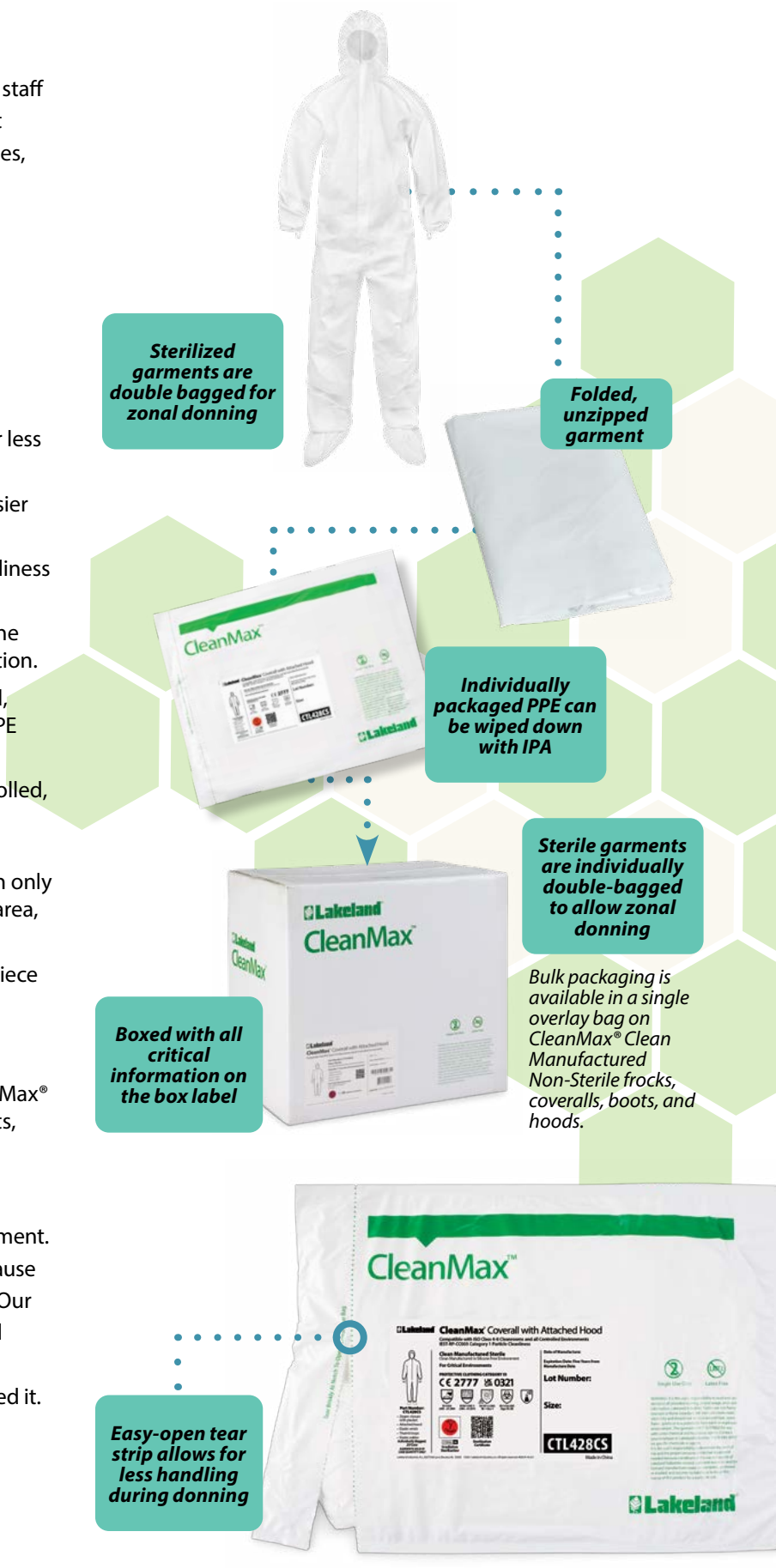
- Reduce excursions
- Decrease gowning time and error
- Safeguard against contamination

Lakeland® CleanMax is packaged to ensure maximum garment protection

- Each package features an easy-open strip, allowing for less handling when removing the PPE from packaging.
- Garments are folded and left unzipped to allow for easier donning.
- Garments are individually packaged to maintain cleanliness and avoid excessive wrinkling.
- 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 PPE and to facilitate staged entry into the gown room.
- Sterilized garments are double-bagged to allow controlled, zonal donning of garments and ensure biological contamination is not introduced by the wearer.
- Coveralls and frocks are positioned so that wearers can only grab the inside of the garment, right below the collar area, eliminating any contamination of the exterior surface.
- As the PPE is pulled out of the packaging, the folded piece will fall easily so that it's ready for the next step of the donning process.
- For customers with less critical environments, bulk packaging is available in a single overlay bag on CleanMax® Clean Manufactured Non-Sterile frocks, coveralls, boots, and hoods.

Availability is Essential

Product availability is critical for your controlled environment. It's unacceptable to lose valuable production hours because your supplier is unable to deliver PPE when you need it. Our team at Lakeland, along with our network of exceptional distributors, will help you find the right PPE for your application and ensure you get your order when you need it.



Protecting your products, people, and controlled environments.

Lakeland®

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