



KIMTECH PURE* A5 Sterile Apparel

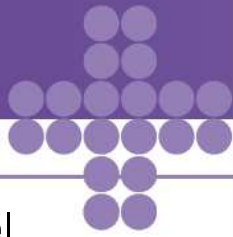


DATA PACK



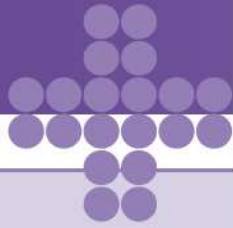
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KIMTECH
PURE* BRAND



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CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Cleanroom Coveralls.

The KIMTECH PURE* A5 Sterile Cleanroom Coveralls simplify aseptic gowning to save time and reduce the risk of contamination.



CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning.



Telescope fold and snaps prevent legs and arms falling to the floor during gowning.



Vacuum Packed and double bagged for added sterility assurance. Reduces space so more products fit into gowning area storage.



PERSONAL & PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- Certified PPE Cat III directive 89/686/EEC
- Type 6 limited chemical splash protection
- Type 5 particle protection
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- Unhooded coverall available in size S to 4XL
- Blue Indicator line to avoid touching outside
- Presented unzipped with inside-out fold
- Arms and legs telescope folded with snaps
- Waist and back panel elastics
- Elastic cuffs and thumb loops
- High strength, bound and triple stitched seams
- High performance SMS breathable barrier
- Individually vacuum packed and double bagged.
- 25 items per double case liner.

Applications:

EU GMP
ISO 5 Grade A

Aseptic
Processing

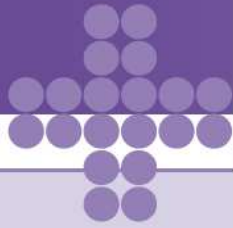
Parenteral
Drug
Manufacturing

Biotechnology

Pharmaceutical
Compounding

Ophthalmic
product
manufacturing

Aseptic Hood
work



CLEAN-DON®, the Revolution in Aseptic Gowning.

KIMTECH PURE® A5 Sterile Integrated Hood & Mask.

The KIMTECH PURE® A5 Sterile Integrated Hood & Mask simplifies aseptic gowning to save time and reduce the risk of contamination.



CLEAN-DON® blue line on the inside indicates correct place to grasp for aseptic gowning. Saves time and reduces contamination risk.



No gaps between hood and mask ensures exhaled air is filtered.
Elastics provide a comfortable, secure and universal fit.



Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.



EN 13034:2005
Type 6

STERILE

PERSONAL & PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10⁻⁶
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- Certified PPE Cat III directive 89/686/EEC
- Type 6 Pb limited chemical splash protection
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- Integrated hood and mask
- Stretch fit elastics for universal size
- Blue Indicator line to avoid touching outside
- Pull down ties on back to assist gowning
- Presented inside-out fold to avoid contamination
- High strength, bound and triple stitched seams
- High performance SMS with cloth-like feel
- Individually vacuum packed
- 25 items per double-bag, 3 double bags per case

Applications:

EU GMP
ISO 5 Grade A

Aseptic
Processing

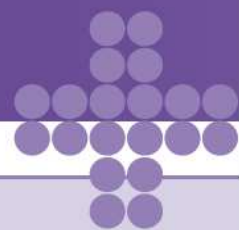
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Pharmaceutical
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Ophthalmic
product
manufacturing

Aseptic Hood
work



CLEAN-DON®, the Revolution in Aseptic Gowning.

KIMTECH PURE® A5 Sterile Cleanroom Boot Covers.

The KIMTECH PURE® A5 Sterile Boot Covers improves worker safety and comfort, while reducing the risk of contamination.



New Version Ideal for wet applications.
Wrap-around Vinyl foot is seamed above the floor line to reduce risk of liquid penetration and trip hazards.
Standard vinyl sole also available.



3 sizes for better safety and comfort.
Better fit and comfort to improve worker safety by reducing risk of trip hazards.



Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.



PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10⁻⁶
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- CE 89/686/EEC Category I PPE – simple design
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- New Vinyl foot version available in 3 sizes.
- Standard Vinyl sole version available in 3 sizes.
- Elastic opening presented inside-out folded.
- Two extra-long ties.
- SMS material cloth-like feel keeps gloves in place
- High strength, bound and triple stitched seams
- Individually vacuum packed pairs
- 25 pairs per double-bag, 4 double bags per case

Applications:

EU GMP
ISO 5 Grade A

Aseptic
Processing

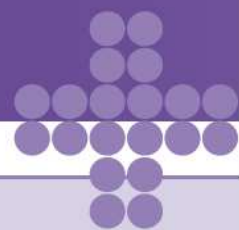
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work



CLEAN-DON*, the Revolution in Aseptic Gowning.

KIMTECH PURE* A5 Sterile Cleanroom Sleeves.

The KIMTECH PURE* A5 Sterile Cleanroom Sleeves simplify aseptic gowning to save time and reduce the risk of contamination.



CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning. Thumb-loops and material's cloth-like feel keep sleeves and gloves in place.



Telescoped fold makes aseptic gowning easier, preventing contact with the outside surface to reduce contamination risk.



Vacuum packed for added sterility assurance. Reduces space so more products fit into gowning area storage.



PROCESS PROTECTION:

- Suitable for EU GMP ISO 5 Grade A cleanrooms
- Gamma Irradiated, Sterility Assurance Level 10^{-6}
- Low Lint fabric, Helmke Drum test Category I
- Bacterial Filtration Efficiency 96%
- Manufactured and Packed in ISO 5 cleanroom
- Vacuum packed for sterility assurance, saves space
- CE 89/686/EEC Category I PPE – simple design
- Breathable barrier combines comfort and protection

DESIGN FEATURES:

- 45cm long sleeve protectors, pair packed.
- Blue Indicator line to avoid touching outside
- Telescope inside-out fold for easy gowning
- Elastic cuffs and thumb loops
- SMS material cloth-like feel keeps gloves in place
- High strength, bound and triple stitched seams
- Individually vacuum packed pairs
- 25 pairs per double-bag, 4 double bags per case

Applications:

EU GMP
ISO 5 Grade A

Aseptic
Processing

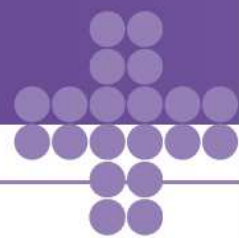
Parenteral
Drug
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Biotechnology

Pharmaceutical
Compounding

Ophthalmic
product
manufacturing

Aseptic Hood
work



KIMTECH PURE* A5 Sterile Cleanroom Apparel Technical Data

Quality Standards

- Suitable for ISO 5 Grade A Sterile Cleanrooms
- Manufactured in ISO9001 and ISO13485 certified facility
- Sterility Assurance Level 10^{-6} and Helmke Drum test Category I
- Sterilization in accordance with EN556-1, EN ISO11737-1,-2, EN ISO 11140-1

Fabric Tests			Test Method		Result
Particle shedding test (Helmke Drum)			IEST-RP-CC003.3		Category I
Bacterial Filtration Efficiency (3.0 µm) - SMS material in A5 fabric			ASTM F2100		96%
Bacterial Filtration Efficiency (3.0 µm) - Mask in iHAM			ASTM F2100		94%
Particle filtration Efficiency (0.5 µm) - SMS material A5 fabric			ASTM F2299		94%
Particle Filtration Efficiency (0.5 µm) - Mask in iHAM			ASTM F2299		93%
Abrasion resistance			EN 530 Method 2		Class 3 of 3
Flex cracking resistance			ISO 7854 Method B		Class 5 of 6
Trapezoidal tear resistance			ISO 9073-4		Class 2 of 3
Puncture resistance			EN 863		Class 1 of 3
Tensile strength			EN ISO 13934-1		Class 1 of 3
Resistance to ignition			EN 13274-4 Method 3		Pass
Seam strength			EN ISO 13935-2		Class 3 of 3
EN ISO 6350:2005 – Resistance of penetration by liquids/chemicals.	CAS number	Penetration Class	Penetration %	Repellency Class	Repellency %
1-butanol 100%	71-36-3	3	<1%	1	>80%
Ethanol 70%	64-17-5	3	<1%	2	>90%
Ethylene glycol 100%	107-21-1	3	<1%	2	>90%
Incidin Plus 100%	N/A	3	<1%	2	>90%
Isopropyl Alcohol 70%	67-63-0	2	<5%	1	>80%
Sekusept plus	N.A	3	<1%	2	>90%
Sodium Hydroxide 10%	1310-73-2	3	<1%	3	>95%
Sulphuric Acid 30%	7664-93-9	3	<1%	2	>90%

KIMTECH PURE* A5 Sterile Cleanroom Apparel

Description	Code.	Description	Code.
Coveralls, 25 per Case	88800 (S), 88801 (M), 88802 (L), 88803 (XL), 88804 (2XL), 88805 (3XL), 88806 (4XL)	Integrated Hood & Mask, 75 per Case	36072
Boots Vinyl Foot, 100 pairs per Case	12922 (S), 88808 (Universal), 12920 (XL)	Hood with Ties, 100 per Case	25797 / 88807
Boots Vinyl Sole, 100 pairs per Case	31683 (S), 31696 (Universal), 31697 (XL)	Sterile Sleeves, 100 pairs per Case	36077



Gowning Procedure

BEFORE GOWNING

- Step 1:** (Pre-Entry) Don Hair Net and Shoe Covers after removing all jewelry and cosmetics.
- Step 2:** (Gowning) Wash hands and gown first pair of sterile gloves. Sanitize gloves after gowning each article if required.
- Step 3:** Apply mask and hood assuring a snug fit.

Step 4: Open vacuum-packed apparel.
Tear at notched edge.



Step 5: Grasp the blue line.
Located on the inside middle back.

Step 6: Gently unfold overall utilizing blue indicator line.
Arms and legs are pre-drawn and snapped in place. Garment is already folded inside-out and unzipped.



BEGIN GOWNING
Snaps allow gathered-up arms and legs to expand during gowning



Step 7: Hold garment at waist



Step 8: Put one leg in and point toe through opening until snap releases



Step 9: Do the same with the other leg



Step 10: Insert one arm and extend until snap releases



Step 11: Do the same with the other arm



Step 12: Slip thumbs through thumb loops



Final Step: Cross legs and zip up overall



After A5 Sterile Cleanroom Apparel is Gowned:
Add boot covers



Complete gowning by adding goggles and a second pair of sterile gloves.

KIMTECH PURE* A5 Integrated Hood and Mask Donning Technique



Step 1

Select your integrated hood and mask;
inspect package for vacuum seal; tear
along notches toward the product to open



Step 2

Pull out integrated hood and unfold
to locate the blue signal indicator line



Step 3

Center your chin just above the blue
line then roll over your forehead.



Step 4

Grab ties with both hands then extend
arms out in a circular motion to position
under armpits.



Step 5

Pull ties across chest and secure as needed



Step 6

Gently adjust front flap to comfortable
position; pinch mask wire over bridge
of nose to ensure proper fit.



KIMTECH PURE* A5 Sterile Boot Cover with Grasp Ties Donning Technique



Step 1

Select your boot cover size; inspect package for vacuum seal; tear along notches toward the product to open; flex package to separate boot covers



Step 2

Pull out one boot cover by the cuff



Step 3

Grasp ties with one hand and make sure they don't touch the floor



Step 4

Open up boot cover; point toe towards opening and pull up over calf while holding the ties



Step 5

Hold up foot or rest on bench. Grasp ties at front of boot cover and wrap over cusp of shoe/boot; then wrap ties behind ankle and tie in front.



Step 6

Place donned boot on the clean side



Step 7

Pull the remaining boot cover out of package by the cuff and repeat Steps 3, 4 and 5. Proceed with final gowning steps



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