# 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.

Applications:

EU GMP ISO 5 Grade A

Aseptic Processing Parental Drug
Manufacturing

Biotechnology

Pharmaceutical Compounding Ophthalmic product manufacturing

Aseptic Hood work







STERILER

#### 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%
- 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
- Telescopic 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



### KIMTECH PURE\* A5 Sterile Cleanroom Sleeves.

### **Technical Data**

#### **Quality Standards**

- Suitable for ISO 5 Grade A Sterile Cleanrooms
- Manufactured in ISO9001 and ISO13485 certified facility
- $\bullet$  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)	ASTM F2100	96%
Particle Filtration Efficiency (0.5 µm)	ASTM F2299	94%
Abrasion resistance	EN 530 Method 2	Class 3 of 5
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%

Test performed on Fabric used in all KIMTECH PURE\* A5 Sterile Cleanroom Apparel. Type 6 EN13034 applicable to Coveralls and Hoods only.

## KIMTECH PURE\* A5 Sterile Cleanroom Sleeves

Code	Case Count
36077	100 individually packed pairs per case

Also available in the KIMTECH PURE\* A5 Sterile Cleanroom apparel range: Coveralls, Hoods, Integrated Hood & Masks, Sleeve Protectors and Boot Covers.

Visit www.KIMTECH.eu for more product information: includes data-packs, gowning posters and certificates of conformance  $\theta$  irradiation.

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