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.



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



CLEAN-DON* blue line on the inside indicates correct place to grasp for aseptic gowning. Saves time and reduces 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<u>work</u>









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%
- 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

KIMTECH PURE* A5 Sterile Integrated Hood & Mask. **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 $\mu m)$ - Hood section (after sterilization)	ASTM F2100	96%
Bacterial Filtration Efficiency (3.0 $\mu m)$ - Mask section (after sterilization)	ASTM F2100	94%
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 Integrated Hood & Mask

Code	Case Count	
Integrated Hood & Mask (36072)	75 individual units per case	
Standard Hood with ties (88807)	100 individual units 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 $\dot{\theta}$ irradiation.

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