

### BioClean-D™ Sterile Kit S-BDKM

# Sterile coverall featuring a collar, hood, overboots and integrated face mask

- Added features: The BioClean-D Sterile Kit S-BDKM features a disposable coverall, overboots with a slip-resistant sole, a hood and an integrated face mask, delivering head-to-toe personal protection
- Optimized packaging: All garments are presented in a single package, making handling more convenient and minimizing overall packaging waste
- Enhanced fit: The BioClean™ coverall included in this kit is designed with a front zip, elasticated back, cuffs, and ankles, offering a comfortable fit, while thumb loops ensure a secure hold
- Reduced contamination risks: As it is made from CleanTough™ material, which is both lightweight and low-linting, this sterile coverall is ideal for cleanroom use



### **Key Features and Benefits**

- Hood with integrated face mask: Added product and personal protection
- Single kit for all garments: Lesser overall packaging waste
- Slip-resistant sole: Reduced risk of workplace injuries

### **Industries**

- Controlled and Critical Environments
- Laboratory and Research
- Production and Manufacturing







## BioClean-D™ Sterile Kit S-BDKM

### **TECHNICAL DATA SHEET**

### **PRODUCT INFORMATION**

Material	CleanTough™
	White
Color	
Audit Standards	ISO 9001
Standards	CE 0598, EN 1149-5:2018, EN 13935-2, EN 13034:2005 + A1:2009, EN ISO 13982-1:2004 + A1:2010, ISO 11137-1:2006, ISO 9001:2015, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
Packaging Overview	S - 2XL: One hood with integrated face mask, one coverall with collar, and one pair of overboots per sealed inner bag; one inner bag per sealed outer PE bag; 15 outer bags (kits) per carton 3XL and above: One hood with integrated face mask, one coverall with collar, and one pair of overboots per sealed inner bag; one inner bag per sealed outer PE bag; 12 outer bags (kits) per cartonAll sizes subject to MOQ (Minimum Order Quantity) and extended lead time. *More sustainable packaging: Packed in recyclable plastic packaging and delivered in recycled cardboard shipper cases. Inner and outer bags and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country Of Origin	Malaysia
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10-6
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture. Store in a dry, cool place ( $<40^{\circ}$ C) away from direct sunlight and fluorescent light.
Construction	Hood Elasticated face opening, reinforced edges with incorporated facemask Coverall Zip front with flap cover. Thumb loops on wrist Elasticated back, cuffs and ankles Overboots Elasticated top with secure ties and slip-resistant soles
Characteristics	*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, and so are ideal for use in a static-safe environment.

### **PARTICLE SHEDDING TEST RESULTS**

TEST	RESULT	
Particle Shedding (Helmke Drum Test)	≥ 0.5Qm (counts/min) <2000	

### **ASTM F739-12 TEST METHOD RESULTS**

DRUG	Mean Breakthrough Time (MBT), Minutes	
CISPLATIN	>240	
CARMUSTINE	<6	
CYCLOPHOSHAMIDE	217 (275, 162, 215)	
DOXORUBICINHYDROCHLORIDE	>240	
5-FLUOROURACIL	>240	
METHOTREXATE	>240	
ETOPOSIDE	>240	
PACLITAXEL	<10	
THIOTEPA	30 (28, 30, 33)	

Results achieved under controlled laboratory conditions, by accredited external testing laboratory. \*For Bioclean D and Bioclean 2000, the chemical permeation results relates to the fabric performance for reference only. Seams and closures may have lower breakthrough times. We recommend garments with sealed seams such as Bioclean-C to be worn over the coverall for added protection against chemotherapy drugs handling.

### **SIZE CHART**





## **BioClean-D™ Sterile Kit S-BDKM**

### MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS	PERFORMANCE STANDARD
Abrasion Resistance	>10 cycles	1	EN 12947-2
Flex Cracking Resistance	>50,000 cycles	6	EN ISO 7854
Puncture Resistance	>5 N	1	ISO 13996
Trapezoidal Tear Resistance Cross Direction (CD)	>10 N	1	EN ISO 9073-4
Trapezoidal Tear Resistance Machine Direction (MD)	>10 N	1	EN ISO 9073-4
Tensile Strength Cross Direction (CD)	>30 N	1	EN ISO 13934-1
Tensile Strength Machine Direction (MD)	>30 N	1	EN ISO 13934-1
Repellence to Liquids - 30% H <sub>2</sub> SO <sub>4</sub>	>90%	3	ISO 6530
Repellence to Liquids - 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids - O-Xylene	>90%	3	ISO 6530
Repellence to Liquids - Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids - 30% H <sub>2</sub> SO <sub>4</sub>	<1%	3	ISO 6530
Penetration by Liquids - 10% NaOH	<1%	3	ISO 6530
Penetration by Liquids - O-Xylene	<1%	3	ISO 6530
Penetration by Liquids - Butan-1-ol	<1%	3	ISO 6530
Inward leakage of aerosols of fine particles <sup>1</sup>	PASS	N/A	EN ISO 13982-2
Resistance to penetration by spray (Spray Test) <sup>1</sup>	PASS	N/A	EN ISO 17491-4
Seam Strength <sup>2</sup>	>50 N	2	ISO 13935-2
Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs)	PASS	N/A	EN1149-3

- 1. All interfaces with additional PPE were taped during testing, as required by the standards.
- 2. Seam not destroyed., 3. The material is static dissipative. Tested in accordance with EN1149-5

### **ORDERING INFORMATION**

	SIZE	BioClean-D Sterile Anti-Static Kit	BioClean-D Sterile Anti-Static Kit
S-BDKM	REORDER NO.	S, M, L, XL, 2XL	3XL, 4XL

**Performance Standards and Regulatory Compliance** 









### For additional information visit us at www.ansell.com, or call us at

Europe, Middle East & Africa Region

Ansell Healthcare Europe NV T: +32 (0) 2 528 74 00 F: +32 (0) 2 528 74 01

### Asia Pacific Region

Ansell Global Trading Center T: +603 8310 6688 F: +603 8310 6699

### North America Region

Ansell Healthcare Products LLC US T: +1 800 800 0444 US F: +1 800 800 0445 CA T: +1-800-363-8340

### Latin America & Caribbean Region

Ansell Commercial Mexico S.A. de C.V. T: +52 442 248 1544 / 248 3133

### Australia

Ansell Limited T: +61 1800 337 041 F: +61 1800 803 578

Ansell Nitritex T: +44 1638 663338 F: +44 1638 668890





Ansell,  $^{\textcircled{R}}$  and  $^{\textcircled{M}}$  are trademarks owned by Ansell Limited or one of its affiliates. US Patented and US and non-US Patents Pending: www.ansell.com/patentmarking  $^{\textcircled{M}}$  2024 Ansell Limited. All Rights Reserved.

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of gloves for a specific application.



