

## 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<sup>™</sup> 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



- 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™
Color	White
Audit Standards	ISO 9001
Standards	CE 0598, EN 1149-5:2008, 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 carton
	All sizes subject to MOQ (Minimum Order Quantity) and extended lead time.
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°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 slipresistant 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)	≥ 0.5µm (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.

#### **SIZE CHART**

S-BDKM-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")
S-BDKM-M; Size: M, Chest: 92-100cm (36"-39"), Height 170-176cm (5'6"-5'9")
S-BDKM-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")
S-BDKM-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")
S-BDKM-XXL; Size: XXL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")
S-BDKM-XXXL; Size: XXXL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")
S-BDKM-XXXXL; Size: XXXXL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")





## BioClean-D™ Sterile <u>Kit S-BDKM</u>

#### **MATERIAL PERFORMANCE TEST RESULTS**

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Flex Cracking Resistance	5,000 to 15,000 cycles	3
Puncture Resistance	8 N	1
Trapezoidal Tear Resistance Cross Direction (CD)	CD 29.3 N	2
Trapezoidal Tear Resistance Machine Direction (MD)	MD 55.5 N	3
Tensile Strength Cross Direction (CD)	MD 55.5 N	1
Tensile Strength Machine Direction (MD)	MD 97 N	2
Repellence to Liquids – 30% H <sub>2</sub> SO <sub>4</sub>	96.3%	3
Repellence to Liquids – 10% NaOH	97.6%	3
Repellence to Liquids – O-Xylene	95.7%	2
Repellence to Liquids – Butan-1-ol	96.6%	3
Penetration by Liquids – 30% H <sub>2</sub> SO <sub>4</sub>	0%	3
Penetration by Liquids – 10% NaOH	0%	3
Penetration by Liquids – O-Xylene	0%	3
Penetration by Liquids – Butan-1-ol	0%	3
Inward leakage of aerosols of fine particles <sup>1</sup>	Pass	N/A
Resistance to penetration by spray (Spray Test) <sup>1</sup>	Pass	N/A
Seam Strength <sup>2</sup>	70 N	2
Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs)	0.07	PASS

- 1. All interfaces with additional PPE were taped during testing, as required by the standards.
- 2. Seam not destroyed.

#### **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**









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