



# BioClean-D Sterile Coverall with Hood & Integrated Boots S- BDFC

## Coverall with Integrated Boots - Sterile

The BioClean-D Coverall with Hood and Integrated Boots is a disposable garment offering comfort and head-to-toe protection. Featuring a front zip with protective flap, elasticated hood, back, cuffs and ankles, and thumb loops to ensure a secure hold. The integrated boots feature slip-resistant soles to ensure every step is taken with confidence.

Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.

- Antistatic lightweight low-linting CleanTough material
- Thumb loops to ensure a secure hold
- Zip with sealable cover
- Elasticated back, cuffs and ankles
- Slip resistant soles



### Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing



# BioClean-D Sterile Coverall with Hood & Integrated Boots S-BDFC

## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

	S-BDFC
Material	Polyethylene/non-woven polypropylene laminate
Color	White
Manufacturing/QMS Audit Standards	Manufacturing QMS Audit Standards ISO 9001 PPE Regulation 2016 425 Module D
Regulatory/Standards Compliance	ASTM F739, CE 0598, EN 1149-5:2008, EN 13934-1, EN 19935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, ISO 11137-1:2006, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
Storage and packaging	One piece per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per lined carton (20 pieces). Please note: sizes XXXL & XXXXL 15 pieces per carton
Country of Origin	Malaysia
Available sizes	S - 4XL
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Compatibility	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture.
Construction	Bound seams with single needle stitching
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.

### 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
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)	CD 48 N	1
Tensile Strength Machine Direction (MD)	MD 97 N	2
Puncture Resistance	8 N	1
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



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## 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 Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 Qg/cm <sup>2</sup> /min
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-BDFC-S Chest: 84-92cm (33"-36") Height: 164-170cm (5'4"-5'6") Size: S  
 S-BDFC-M Chest: 92-100cm (36"-39") Height: 170-176cm (5'6"-5'9") Size: M  
 S-BDFC-L Chest: 100-108cm (39"-42") Height: 176-182cm (5'9"-6'0") Size: L  
 S-BDFC-XL Chest: 108-116cm (42"-45") Height: 182-188cm (6'0"-6'2") Size: XL  
 S-BDFC-XXL Chest: 116-124cm (45"-48") Height: 188-194cm (6'2"-6'4") Size: XXL  
 S-BDFC-XXXL Chest: 124-132cm (48"-51") Height: 194-200cm (6'4"-6'6") Size: XXXL  
 S-BDFC-XXXXL Chest: 132-140cm (51"-54") Height: 200-206cm (6'6"-6'8") Size: XXXXL

## ORDERING INFORMATION

	SIZE	S, M, L, XL	XXL, XXXL
S-BDFC	REORDER NO.	S-BDFC-S, S-BDFC-M, S-BDFC-L, S-BDFC-XL	S-BDFC-XXL, S-BDFC-XXXL

### Performance Standards and Regulatory Compliance



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Please see product validation pack or contact Ansell customer service for specific data on use of garments with cytotoxic drugs. Garments used for protection against such drugs must be selected specifically for the type of chemicals used.

