



# BioClean-D™ Coverall with Hood and Integrated Boots – Sterile S-BDFC

## Sterile cleanroom coverall with hood and integrated boots, for chemical and liquid splash protection

- **Reduced contamination risks:** Lightweight CleanTough™ material means the BioClean-D Coverall with Hood and Integrated Boots – Sterile S-BDFC is low-linting and ISO cleanroom-compliant, reducing contamination risks
- **Optimized protection:** This sterile coverall features a front zip with a protective flap, resisting liquid splashes and chemicals\*, while thumb loops and an elasticated hood, back, cuffs and ankles ensure a secure fit
- **Enhanced features:** This antistatic coverall features integrated boots and slip-resistant soles, for added workplace safety in laboratory settings
- **Sterility assurance level:** Special packaging eliminates cross contamination, while gamma irradiation sterilization ensures a minimum SAL of  $10^{-6}$



### Key Features and Benefits

- **CleanTough™ fabric:** For a lightweight, low-linting sterile coverall
- **Front zip and protective flap:** Contaminant and liquid splash defenses
- **Integrated boots and anti-slip soles:** Head-to-toe personal protection

### Industries

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

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## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

Material	CleanTough™
Audit Standards	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
Standards	ASTM F739, CE 0598, EN 13934-1, EN 13935-2, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013, ISO 11137-1:2006, EN ISO 14325, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
Packaging Overview	One piece aseptically folded per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per lined carton (20 pieces). Please note: sizes 3XL & 4XL 15 pieces per carton <b>More sustainable packaging:</b> 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	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
Shelf Life	Three (3) years from the date of manufacture.
Construction	Seams joined with single-needle stitches
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 Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 µg/cm <sup>2</sup> /min
CISPLATIN	>240
CARMUSTINE	<6
CYCLOPHOSAMIDE	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

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-2XL Chest: 116-124cm (45"-48") Height: 188-194cm (6'2"-6'4") Size: 2XL  
 S-BDFC-3XL Chest: 124-132cm (48"-51") Height: 194-200cm (6'4"-6'6") Size: 3XL  
 S-BDFC-4XL Chest: 132-140cm (51"-54") Height: 200-206cm (6'6"-6'8") Size: 4XL



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## 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	IN ISO 17491-4
Seam Strength <sup>2</sup>	>50 N	2 (Main Fabric)	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	S, M, L, XL,2XL	3XL, 4XL
S-BDFC	REORDER NO.	S-BDFC-S, S-BDFC-M, S-BDFC-L, S-BDFC-XL, S-BDFC-2XL	S-BDFC-3XL, S-BDFC-4XL

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## 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.

