



# BioClean-D™ Coverall with Hood - Sterile S-BDCHT

## Lightweight, sterile antistatic coverall with hood, for protection from varied chemicals

- **Reduced contamination risks:** The BioClean-D Coverall with Hood - Sterile S-BDCHT features a front zip with a sealable cover and a protective flap to reduce leakage through the seams, and is manufactured in compliance with ISO cleanroom standards
- **Specialized protection:** This disposable coverall is manufactured using Ansell's innovative CleanTough™ material to deliver a low-linting, antistatic, sterile coverall that protects against a range of chemicals\*
- **Enhanced fit:** This BioClean™ coverall is also equipped with an elasticated hood, back, cuffs and ankles, as well as thumb loops to ensure a secure hold and enhanced fit



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

### Key Features and Benefits

- **Protective flap and zip with sealable cover:** Fewer contamination risks
- **CleanTough™ fabric:** For a lightweight, low-linting disposable coverall
- **Thumb loops:** Secure hold and improved fit

### Industries

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





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## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

<b>Material</b>	CleanTough™
<b>Audit Standards</b>	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
<b>Standards</b>	ASTM F739, CE 0598, EN ISO 13688:2013, EN 1149-5:2008, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 14325, ISO 11137-1:2006, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
<b>Packaging Overview</b>	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 XXX-L, XXXX-L, 5XL, 6XL & 7XL 15 pieces per carton. Sizes XXXX-L, 5XL, 6XL & 7XL subject to minimum order quantity and lead time
<b>Country Of Origin</b>	China
<b>Sterilization Method</b>	GAMMA irradiation (25 kGy)
<b>Sterilization Minimum Dose</b>	25kGy
<b>Sterility Assurance Level</b>	10 <sup>-6</sup>
<b>Cleanroom Class</b>	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
<b>Shelf Life</b>	Three (3) years from date of manufacture.
<b>Construction</b>	Bound seams with single needle stitching
<b>Characteristics</b>	*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)	$\geq 0.5\text{Qm}$ (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-BDCHT-XS; Size: XS, Chest: 76-84cm (30"-33"), Height: 158-164cm (5'2"-5'4")  
 S-BDCHT-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
 S-BDCHT-M; Size: M, Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
 S-BDCHT-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
 S-BDCHT-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
 S-BDCHT-XXL; Size: XXL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
 S-BDCHT-XXXL; Size: XXXL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
 S-BDCHT-XXXXL; Size: XXXXL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")  
 S-BDCHT-5XL; Size: 5XL, Chest: 140-148cm (54"-57"), Height: 206-212cm (6'8"-6'10")  
 S-BDCHT-6XL; Size: 6XL, Chest: 148-156cm (58"-61"), Height: 212-218cm (6'10"-6'12")  
 S-BDCHT-7XL; Size: 7XL, Chest: 156-164cm (61"-64"), Height: 218-224cm (7'1"-7'3")

## ORDERING INFORMATION

	SIZE	XS, S, M, L, XL, XXL	BioClean-D Sterile Coverall with Hood
S-BDCHT	REORDER NO.	S-BDCHT-XS, S-BDCHT-S, S-BDCHT-M, S-BDCHT-L, S-BDCHT-XL, S-BDCHT-XXL	XL, XXL, XXXL, 4XL, 5XL, 6XL, 7XL

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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.

