

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 permetion of the safe recommendations for specific chemotherapy drug
- **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







BioClean-D Coverall with Hood - Sterile S-BDCHT

TECHNICAL DATA SHEET

PRODUCT INFORMATION

Material	CleanTough™
Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Standards	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
Packaging Overview	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
Country Of Origin	China
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.
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_2SO_4	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 ₂ SO ₄	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 ¹	Pass	N/A
Resistance to penetration by spray (Spray Test) ¹	Pass	N/A
Seam Strength ²	70 N	2
Electrostatic Charge Half Decay Time, t ₅₀ (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)	≥ 0.5µm (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 $\mu g/cm^2/min$
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



