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

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

Ansell

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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 ISO 13688:2013, EN 1149-5:2018, EN 13934-1, EN 13935-2, 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 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: Size 3XL and 4XL are 15 pieces per carton and subject to Minimum Order Quantity and lead time.
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^{-6}
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
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.

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/cm²/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. *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-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-2XL; Size: 2XL, Chest: 116-124cm (45″-48″), Height: 188-194cm (6′2″-6′4″)
S-BDCHT-3XL; Size: 3XL, Chest: 124-132cm (48″-51″), Height: 194-200cm (6′4″-6′6″)
S-BDCHT-4XL; Size: 4XL, Chest: 132-140cm (51″-54″), Height: 200-206cm (6′6″-6′8″)

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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_2SO_4	>90%	3	ISO 6530
Repellence to Liquids – 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids – O-Xylene	>80%	2	ISO 6530
Repellence to Liquids – Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids – 30% H_2SO_4	<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[1]	Pass	N/A	EN ISO 13982-2
Resistance to penetration by spray (Spray Test)[1]	Pass	N/A	EN ISO 17491-4
Seam Strength[2]	>50 N	2	ISO 13935-2
Electrostatic Charge Half Decay Time, t_{50} (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	XS, S, M, L, XL, 2XL	3XL, 4XL
S-BDCHT	REORDER NO.	S-BDCHT-XS, S-BDCHT-S, S-BDCHT-M, S-BDCHT-L, S-BDCHT-XL, S-BDCHT-2XL	S-BDCHT-3XL, S-BDCHT-4XL

Performance Standards and Regulatory Compliance

CE 0598 EN 1149-5 ISO 11137-1 TYPE 5 TYPE 6

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