

# 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







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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<br>Breakthrough of the test chemical is deemed to have occurred when the permeation<br>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<br>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<br>Direction (CD)             | >10 N          | 1                 | EN ISO 9073-4           |
| Trapezoidal Tear Resistance Machine<br>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<br>(Spray Test) <sup>1</sup> | Pass           | N/A               | EN ISO 17491-4          |
| Seam Strength <sup>2</sup>                                      | >50 N          | 2                 | ISO 13935-2             |
| Electrostatic Charge Half Decay Time,<br>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        | XS, S, M, L, XL, 2XL   | 3XL, 4XL                 |
|---------|-------------|--|--------------------------|
| S-BDCHT | REORDER NO. | S-BDCHT-XS, S-BDCHT-S, S-<br>BDCHT-M, S-BDCHT-L, S-<br>BDCHT-XL, S-BDCHT-2XL | S-BDCHT-3XL, S-BDCHT-4XL |

## **Performance Standards and Regulatory Compliance**











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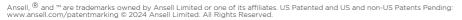
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