



# BioClean-D™ Drop-down Sterile Coverall with Hood S-BDSH

## Sterile drop-down cleanroom coverall, featuring removable tabs for aseptic donning

- **Enhanced features:** The BioClean-D Drop-down Sterile Garment with Hood S-BDSH boasts drop-down design technology, preventing needless external surface contact, and is equipped with quick-release tabs and internal colored tabs, indicating safe touch points that further ensure aseptic donning
- **Reduced contamination risks:** This antistatic garment is manufactured from low-linting CleanTough™ material, which reduces particle contamination risks
- **Optimized fit:** This disposable cleanroom garment is also equipped with an elasticated back, hood, cuffs and ankles, with thumb loops to ensure a secure hold and fit

### Key Features and Benefits

- **Drop-down design\* technology:** Aseptic donning made easy
- **CleanTough™ fabric:** For an antistatic, low-linting sterile garment
- **Quick-release press stud tabs:** Aseptic donning further facilitated

Patent #US8683615, US9532614B2

### 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, NEBB Certified Cleanrooms                                                                                                                                   |
| Standards                  | ASTM F739, ISO 11137-1:2006, EN 13934-1, EN 13935-2, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013                                                                                                        |
| 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, 5XL, 6XL, 7XL & 8XL 15 coveralls per carton. |
| Storage                    | Store in a dry cool place 40°C away from direct sunlight and fluorescent light.                                                                                                                                    |
| Country Of Origin          | Sri Lanka                                                                                                                                                                                                          |
| 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                 | 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 rate has reached 0.1 Qg/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-BDSH-XS; Size: XS, Chest: 76-84cm (30"-33"), Height: 158-164cm (5'2"-5'4")  
S-BDSH-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
S-BDSH-M; Size: M, Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
S-BDSH-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
S-BDSH-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
S-BDSH-2XL; Size: 2XL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
S-BDSH-3XL; Size: 3XL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
S-BDSH-4XL; Size: 4XL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")  
S-BDSH-5XL; Size: 5XL, Chest: 140-148cm (54"-56"), Height: 206-212cm (6'8"-6'11")  
S-BDSH-6XL; Size: 6XL, Chest: 148-156cm (56"-58"), Height: 212-218cm (6'11"-7'2")  
S-BDSH-7XL; Size: 7XL, Chest: 156-164cm (61"-64"), Height: 218-224cm (7'2"-7'4")  
S-BDSH-8XL; Size: 8XL, Chest: 164-172cm (51"-54"), Height: 224-230cm (7'4"-7'6")



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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> O <sub>2</sub>  | >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 <sub>2</sub> O <sub>2</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             |
| Seam Strength <sup>2</sup>                                 | >50 N          | 2                 | ISO 13935-2          |
| Electrostatic Charge Half Decay Time, t <sub>50</sub>      | PASS           | N/A               | EN1149-3             |

1. Seam not destroyed

2. The material is static dissipative. 3. Tested in accordance with EN1149-5

## ORDERING INFORMATION

|        | SIZE        | XS, S, M, L, XL, 2XL                                           | 3XL, 4XL, 5XL, 6XL, 7XL, 8XL                                           |
|--------|-------------|----------------------------------------------------------------|------------------------------------------------------------------------|
| S-BDSH | REORDER NO. | S-BDSH-XS, S-BDSH-S, S-BDSH-M, S-BDSH-L, S-BDSH-XL, S-BDSH-2XL | S-BDSH-3XL, S-BDSH-4XL, S-BDSH-5XL, S-BDSH-6XL, S-BDSH-7XL, S-BDSH-8XL |

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## Performance Standards and Regulatory Compliance



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