

## Sterile cleanroom coverall with hood and overboots, for head-to-toe protection

- **Reduced contamination risks:** The BioClean-D Sterile Kit S BDHB features CleanTough™ material, for lightweight, low-linting coveralls that offer good barrier protection and are less susceptible to contamination, making them ideal for cleanroom use
- **Added features:** This sterile coverall kit features an integrated hood and separate overboots, for enhanced all-round personal protection, while slip-resistant soles prevent workplace injuries
- **Optimized packaging:** All garments are provided in a single package, making them more convenient and reducing overall packaging waste
- **Enhanced fit:** The BioClean™ coverall is equipped with a front zip with a protective flap, elasticated back, cuffs and ankles, as well as thumb loops to provide wearers with a more secure and comfortable fit



### Key Features and Benefits

- **CleanTough™ material:** For a lightweight, low-linting sterile coverall
- **Integrated hood and separate overboots:** Comprehensive coverage
- **Single kit for all garments:** Convenient handling, less packaging waste

### Industries

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



# BioClean-D™ Sterile Kit S BDHB

## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

|                            |  |
|----------------------------|--|
| Material                   | CleanTough™  |
| Color                      | White  |
| Audit Standards            | Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D   |
| Standards                  | ASTM F739, EN ISO 13688:2013, EN 1149-5:2008, EN 13935-2, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009                                   |
| Packaging Overview         | One coverall with hood and one pair of overboots per sealed inner bag; one inner bag per sealed outer PE kit bag; 20 kits per carton.                            |
| Country Of Origin          | Malaysia   |
| Sterilization Method       | GAMMA irradiation (25 kGy)   |
| Sterilization Minimum Dose | 25kGy  |
| Sterility Assurance Level  | 10 <sup>-6</sup>   |
| 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. |

### 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   |
| 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-BDHB-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
S-BDHB-M; Size: M, Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
S-BDHB-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
S-BDHB-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
S-BDHB-XXL; Size: XXL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
S-BDHB-XXXL; Size: XXXL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
S-BDHB-XXXXL; Size: XXXXL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")



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## MATERIAL PERFORMANCE TEST RESULTS

| TEST   | RESULT                 | PERFORMANCE CLASS |
|--|------------------------|-------------------|
| Abrasion Resistance  | 10 to 100 cycles       |                   |
| Flex Cracking Resistance                                     | 5,000 to 15,000 cycles |                   |
| Puncture Resistance  | 8 N                    | 1                 |
| 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                 |
| 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                   |                   |
| Resistance to penetration by spray (Spray Test) <sup>1</sup> | Pass                   |                   |
| 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

## ORDERING INFORMATION

|        | SIZE        | BioClean-D Sterile Anti-Static Kit |
|--------|-------------|------------------------------------|
| S BDHB | REORDER NO. | S, M, L, XL, 2XL                   |

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## Performance Standards and Regulatory Compliance



EN 1149-5



TYPE 5



TYPE 6

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