

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, and only for size 3XL 15 kits per carton *More sustainable packaging: Packed in recyclable plastic packaging and delivered in recycled cardboard shipper cases. Inner and outer bags and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location. |
| 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 | Malaysia |
| 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. |

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/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. *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-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"-46"), Height: 182-188cm (6'0"-6'2")
 S-BDHB-2XL; Size: 2XL, Chest: 116-124cm (46"-49"), Height: 188-194cm (6'2"-6'4")
 S-BDHB-3XL; Size: 3XL, Chest: 124-132cm (49"-52"), Height: 194-200cm (6'4"-6'6")



BioClean-D™ Sterile Kit S BDHB

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 ₂ SO ₄ | >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 ₂ SO 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 | BioClean-D Sterile Anti-Static Kit | BioClean-D Sterile Anti-Static Kit |
|--------|-------------|------------------------------------|------------------------------------|
| S BDHB | REORDER NO. | S, M, L, XL, 2XL | 3XL |

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Performance Standards and Regulatory Compliance



EN 1149-5



TYPE 5



TYPE 6

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