

## Sterile disposable coveralls with hood and overboots, combining protection and comfort

- **Enhanced protection:** The BioClean-D™ Sterile Kit S-BAKCT's three-piece design comprises a hood, coverall and overboots, providing head-to-toe personal protection
- **Improved fit and practicality:** Tie fastenings and thumb loops enable wearers to adjust the fit to suit their needs and easily maintain a secure hold
- **Elevated comfort:** Designed with comfort in mind, this sterile kit also features an elasticated back, cuffs and ankles, as well as a convenient front zip with a protective flap
- **Sterility assurance:** The kit is sterilized by gamma irradiation, with a sterility assurance level (SAL) of 10<sup>-6</sup>



### Key Features and Benefits

- **Three-piece design:** Head-to-toe personal protection
- **Lightweight low-linting material:** Lower contamination risks
- **Tie fastenings and slip-resistant sole:** A secure fit and safer use

### Industries

- Controlled and Critical Environments
- Laboratory and Research
- Production and Manufacturing





# BioClean-D™ Sterile Kit S-BAKCT

## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

|                            |  |
|----------------------------|--|
| Material                   | CleanTough™  |
| Color                      | White  |
| Audit Standards            | ISO 9001:2015  |
| Standards                  | ASTM F739, EN 1149-5:2008, EN 13935-2, EN ISO 13688:2013, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009   |
| Packaging Overview         | One hood, one coverall with collar, and one pair of overboots per sealed inner bag; one inner bag per sealed outer PE bag; 15 outer bags (kits) per carton   |
| Storage                    | Store in a dry cool place 40°C away from direct sunlight and fluorescent light.  |
| 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               | Hood Elasticated face opening, reinforced edges Coverall Zip front with flap cover. Thumb loops on wrist Elasticated back, cuffs and ankles Overboots Elasticated top with secure ties at top and slip-resistant soles |
| 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) | ≥ 0.5µm (counts/min) <2000 |

### ASTM F739-12 TEST METHOD RESULTS

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



# BioClean-D™ Sterile Kit S-BAKCT

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

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## Performance Standards and Regulatory Compliance



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