

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 ⁻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)	≥ 0.5µm (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 µg/cm ² /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.

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")

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 ₂ SO ₄	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 ₂ SO ₄	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 ¹	Pass	
Resistance to penetration by spray (Spray Test) ¹	Pass	
Seam Strength ²	70 N	2
Electrostatic Charge Half Decay Time, t ₅₀ (secs)	0.07	PASS

- All interfaces with additional PPE were taped during testing, as required by the standards.
- 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



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