

BioClean-D™ Sterile Kit S BDHB

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 allround personal protection, while slipresistant 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)	≥ 0.5Qm (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/cm² /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 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

^{1.} All interfaces with additional PPE were taped during testing, as required by the standards.

ORDERING INFORMATION

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

For additional information visit us at www.ansell.com, or call us at

Europe, Middle East & Africa Region

Ansell Healthcare Europe NV T: +32 (0) 2 528 74 00 F: +32 (0) 2 528 74 01

Asia Pacific Region

Ansell Global Trading Center T: +603 8310 6688 F: +603 8310 6699

North America Region

Ansell Healthcare Products LLC US T: +1 800 800 0444 US F: +1 800 800 0445 CA T: +1-800-363-8340

Latin America & Caribbean Region

Ansell Commercial Mexico S.A. de C.V. T: +52 442 248 1544 / 248 3133

Australia

Ansell Limited T: +61 1800 337 041 F: +61 1800 803 578

Ansell Nitritex T: +44 1638 663338 F: +44 1638 668890

Performance Standards and Regulatory Compliance

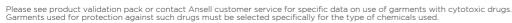






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^{2.} Seam not destroyed