



BioClean-D™ Coverall with Hood and Integrated Boots – Sterile S-BDEC

Sterile cleanroom coverall with hood and integrated boots, for chemical and liquid splash protection

- **Reduced contamination risks:** Lightweight CleanTough™ material means the BioClean-D Coverall with Hood and Integrated Boots – Sterile S-BDEC is low-linting and ISO cleanroom-compliant, reducing contamination risks
- **Optimized protection:** This sterile coverall features a front zip with a protective flap, resisting liquid splashes and chemicals*, while thumb loops and an elasticated hood, back, cuffs and ankles ensure a secure fit
- **Enhanced features:** This antistatic coverall features integrated boots and slip-resistant soles, for added workplace safety in laboratory settings
- **Sterility assurance level:** Special packaging eliminates cross contamination, while gamma irradiation sterilization ensures a minimum SAL of 10⁻⁶

*Contact customer service for chemotherapy drug permeation times and recommendations.



Key Features and Benefits

- **CleanTough™ fabric:** For a lightweight, low-linting sterile coverall
- **Front zip and protective flap:** Contaminant and liquid splash defenses
- **Integrated boots and anti-slip soles:** Head-to-toe personal protection

Industries

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





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TECHNICAL DATA SHEET

PRODUCT INFORMATION

Material	CleanTough™
Audit Standards	ISO 14001, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D, NEBB Certified Cleanrooms
Standards	ASTM F739, CE 0598, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013, ISO 11137-1:2006, EN ISO 14325, Category III, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
Packaging Overview	One piece aseptically folded per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per lined carton (20 pieces). Please note: sizes 3XL & 4XL 15 pieces per carton
Country Of Origin	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 ⁻⁶
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
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
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-BDEC-S Chest: 84-92cm (33"-36") Height: 164-170cm (5'4"-5'6") Size: S
 S-BDEC-M Chest: 92-100cm (36"-39") Height: 170-176cm (5'6"-5'9") Size: M
 S-BDEC-L Chest: 100-108cm (39"-42") Height: 176-182cm (5'9"-6'0") Size: L
 S-BDEC-XL Chest: 108-116cm (42"-45") Height: 182-188cm (6'0"-6'2") Size: XL
 S-BDEC-2XL Chest: 116-124cm (45"-48") Height: 188-194cm (6'2"-6'4") Size: 2XL
 S-BDEC-3XL Chest: 124-132cm (48"-51") Height: 194-200cm (6'4"-6'6") Size: 3XL
 S-BDEC-4XL Chest: 132-140cm (51"-54") Height: 200-206cm (6'6"-6'8") Size: 4XL



BioClean-D™ Coverall with Hood and Integrated Boots – Sterile S-BDFC

MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Flex Cracking Resistance	5,000 to 15,000 cycles	3
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	N/A
Resistance to penetration by spray (Spray Test) ¹	Pass	N/A
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.

2. Seam not destroyed

ORDERING INFORMATION

	SIZE	S, M, L, XL	3XL, 4XL
S-BDFC	REORDER NO.	S-BDFC-S, S-BDFC-M, S-BDFC-L, S-BDFC-XL	S-BDFC-3XL, S-BDFC-4XL

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Performance Standards and Regulatory Compliance

CE 0598



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