



# BioClean-D™ Drop-down Sterile Coverall with Hood S-BDSH

## Sterile drop-down cleanroom coverall, featuring removable tabs for aseptic donning

- **Enhanced features:** The BioClean-D Drop-down Sterile Garment with Hood S-BDSH boasts drop-down design technology, preventing needless external surface contact, and is equipped with quick-release tabs and internal colored tabs, indicating safe touch points that further ensure aseptic donning
- **Reduced contamination risks:** This antistatic garment is manufactured from low-linting CleanTough™ material, which reduces particle contamination risks
- **Optimized fit:** This disposable cleanroom garment is also equipped with an elasticated back, hood, cuffs and ankles, with thumb loops to ensure a secure hold and fit

### Key Features and Benefits

- **Drop-down design\* technology:** Aseptic donning made easy
- **CleanTough™ fabric:** For an antistatic, low-linting sterile garment
- **Quick-release press stud tabs:** Aseptic donning further facilitated

Patent #US8683615, US9532614B2

### Industries

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





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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, ISO 11137-1:2006, EN 1149-5:2008, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013
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 XXXL, XXXXL, 5XL, 6XL, 7XL & 8XL 15 coveralls per carton.
Country Of Origin	Sri Lanka
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
Shelf Life	Tres (3) años a partir de la fecha de fabricación.
Construction	Costuras unidas con puntadas de una sola aguja
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 <sup>2</sup> /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-BDSH-XS; Size: XS, Chest: 76-84cm (30"-33"), Height: 158-164cm (5'2"-5'4")  
S-BDSH-S; Size: S, Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
S-BDSH-M; Size: M, Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
S-BDSH-L; Size: L, Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
S-BDSH-XL; Size: XL, Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
S-BDSH-XXL; Size: 2XL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
S-BDSH-XXXL; Size: 3XL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
S-BDSH-XXXXL; Size: 4XL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")  
S-BDSH-5XL; Size: 5XL, Chest: 140-148cm (54"-56"), Height: 206-212cm (6'8"-6'11")  
S-BDSH-6XL; Size: 6XL, Chest: 148-156cm (56"-58"), Height: 212-218cm (6'11"-7'2")  
S-BDSH-7XL; Size: 7XL, Chest: 156-164cm (61"-64"), Height: 218-224cm (7'2"-7'4")  
S-BDSH-8XL; Size: 8XL, Chest: 164-172cm (51"-54"), Height: 224-230cm (7'4"-7'6")



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## MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 a 100 ciclos	1
Flex Cracking Resistance	5,000 a 15,000 ciclos	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 <sub>2</sub> SO <sub>4</sub>	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 <sub>2</sub> SO <sub>4</sub>	0%	3
Penetration by Liquids – 10% NaOH	0%	3
Penetration by Liquids – O-Xylene	0%	3
Penetration by Liquids – Butan-1-ol	0%	3
Seam Strength <sup>2</sup>	70 N	2
Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs)	0.07	PASS

1. Seam not destroyed

## ORDERING INFORMATION

	SIZE	XS, S, M, L, XL, XXL	3XL, 4XL, 5XL, 6XL, 7XL, 8XL
S-BDSH	REORDER NO.	S-BDSH-XS, S-BDSH-S, S-BDSH-M, S-BDSH-L, S-BDSH-XL, S-BDSH-XXL	S-BDSH-3XL, S-BDSH-4XL, S-BDSH-5XL, S-BDSH-6XL, S-BDSH-7XL, S-BDSH-8XL

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## Performance Standards and Regulatory Compliance



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