



# 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, NEBB Certified Cleanrooms
Standards	ASTM F739, ISO 11137-1:2006, EN 13934-1, EN 13935-2, 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 3XL, 4XL, 5XL, 6XL, 7XL & 8XL 15 coveralls per carton.
Storage	Store in a dry cool place 40°C away from direct sunlight and fluorescent light.
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	5 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 <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. \*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-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-2XL; Size: 2XL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
 S-BDSH-3XL; Size: 3XL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
 S-BDSH-4XL; 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	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
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. Seam not destroyed
2. The material is static dissipative. 3. Tested in accordance with EN1149-5

## ORDERING INFORMATION

	SIZE	XS, S, M, L, XL, 2XL	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-2XL	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



ISO 11137-1

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