



# BioClean-D™ Drop-down Sterile Garment with Hood and Facemask S-BDSH3

## Drop-down Garment - Sterile

The BioClean-D™ Drop-down Garment with Hood and Face Mask is a sterile antistatic disposable garment manufactured from low-linting CleanTough material. Its unique design offers true aseptic donning, with internal coloured tabs to indicate safe touch points to prevent touching the outside surface. The innovative up and over donning design eliminates the risk of the garment touching the floor, and strategically placed quick release tabs (to hold and remove during zip closure) ensure aseptic donning through out the donning process.

Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations.

### Key Features and Benefits

- Integrated cleanroom face mask consist of 3ply with ties for secure hold
- Elasticated back, hood, cuffs and ankles
- Foot-loop to aid smooth closure of zip
- Thumb loops to ensure a secure hold
- Quick release press stud tabs for aseptic donning
- Low-linting CleanTough material

### 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 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013
Packaging Overview	One piece per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per per lined carton (20 pieces).
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	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 <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-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 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 <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
S-BDSH3	REORDER NO.	S-BDSH3-XS	S-BDSH3-S	S-BDSH3-M	S-BDSH3-L	S-BDSH3-XL	S-BDSH3-XXL

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## Performance Standards and Regulatory Compliance



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Please see product validation pack or contact Ansell customer service for specific data on use of garments with cytotoxic drugs. Garments used for protection against such drugs must be selected specifically for the type of chemicals used.

