BioClean-D Drop-down Sterile Garment with Hood S-BDSH

Drop-down Garment - Sterile

The BioClean-D Drop-down Garment with Hood 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.



- 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	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
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). Please note: sizes XXXL, XXXXL, 5XL, 6XL, 7XL & 8XL 15 coveralls 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.

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
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
Puncture Resistance	8 N	1
Repellence to Liquids – 30% H_2SO_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_2SO_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
Seam Strength[2]	70 N	2
Electrostatic Charge Half Decay Time, t_{50} (secs)	0.07	PASS

1.
2. Seam not destroyed

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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/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-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: XXL, Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")
S-BDSH-XXXL; Size: XXXL, Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")
S-BDSH-XXXXL; Size: XXXXL, Chest: 132-140cm (51"-54"), Height: 200-206cm (6'6"-6'8")

ORDERING INFORMATION

	SIZE	XS, S, M, L, XL, XXL	XXXL, XXXXL, 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-XXXL, S-BDSH-XXXXL, S-BDSH-5XL, S-BDSH-6XL, S-BDSH-7XL, S-BDSH-8XL

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Performance Standards and Regulatory Compliance

ISO 11137-1

EN 1149-5: 2008

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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.

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