

## Ideal choice for aseptic controlled environments & cleanroom protection

The BioClean 2000 Cleanroom Coverall with Hood is a sterile disposable garment designed for use in aseptic controlled environment and cleanroom. The coverall is suitable for use in ISO 7 and 8 / Grade C & D cleanrooms and provides good protection for users in contact with chemicals.

- **Reduced contamination risks:** The BioClean™ 2000 features a low-linting coverall that offer good barrier protection and are less susceptible to contamination, making them ideal for cleanroom use
- **Added features:** This coverall features an integrated hood for enhanced personal protection and antistatic treated fabric
- **Optimized packaging:** All garments are provided in an individually vacuum sealed package, making them more convenient and reducing overall packaging waste

### Key Features and Benefits

- Produced and packed in NEBB certified cleanroom facility
- Recyclable packaging materials
- Sterility assurance level  $10^{-6}$
- The coverall is specially folded to aid aseptic donning

### Industries

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





# BioClean™ 2000 Coverall with Hood Model 111

## TECHNICAL DATA SHEET

### PRODUCT INFORMATION

Material	Polyethylene/non-woven polypropylene laminate
Color	White
Audit Standards	ISO 9001:2015, Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Standards	CE 0598, EN 1149-5:2018, EN ISO 13688:2013+A1:2021, EN ISO 13982-1:2004 + A1:2010, EN ISO 13982-1:2004 + A1:2010, EN 13034:2005 + A1:2009
Packaging Overview	One piece per sealed inner PE bag; 25 inner bags per lined carton (25 pieces). Packed in recyclable plastic packaging and delivered in recycled cardboard shipper cases. Inner and outer bags and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country Of Origin	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10 <sup>-6</sup>
Cleanroom Class	ISO 7 and 8/Grade C and D
Shelf Life	Three (3) years from date of manufacture.
Construction	Bound seams with single needle stitching
Characteristics	*NOTE: The material is static dissipative with charge decay time of T 50 < 4 seconds. (Tested in accordance with EN 1149-3:2006)

### PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5µm (counts/min)<12000 (Category II)

### 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

Size: S: Chest: 84-92cm (33"-36"), Height: 164-170cm (5'4"-5'6")  
 Size: M: Chest: 92-100cm (36"-39"), Height: 170-176cm (5'6"-5'9")  
 Size: L: Chest: 100-108cm (39"-42"), Height: 176-182cm (5'9"-6'0")  
 Size: XL: Chest: 108-116cm (42"-45"), Height: 182-188cm (6'0"-6'2")  
 Size: 2XL: Chest: 116-124cm (45"-48"), Height: 188-194cm (6'2"-6'4")  
 Size: 3XL: Chest: 124-132cm (48"-51"), Height: 194-200cm (6'4"-6'6")  
 Size: 4XL: Chest: 132-140cm (51"-55"), Height: 200-206 (6'6"-6'8")  
 Size: 5XL: Chest: 140-148cm (55"-58"), Height: 206-212 (6'8"-7'0")



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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
Inward leakage of aerosols of fine particles <sup>1</sup>	PASS	N/A	EN ISO 13982-2
Resistance to penetration by spray (Spray Test) <sup>1</sup>	PASS	N/A	EN ISO 17491-4
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. All interfaces with additional PPE were taped during testing, as required by the standards.

2. Seam not destroyed., 3. The material is static dissipative. Tested in accordance with EN1149-5.

## ORDERING INFORMATION

	SIZE	S	M	L	XL	2XL	3XL	4XL	5XL
Coverall with Hood Model 111	REORDER NO.	WH20-B-BC-111-02-ST1	WH20-B-BC-111-03-ST1	WH20-B-BC-111-04-ST1	WH20-B-BC-111-05-ST1	WH20-B-BC-111-06-ST1	WH20-B-BC-111-07-ST1	WH20-B-BC-111-08-ST1	WH20-B-BC-111-09-ST1

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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.

