

BIOCLEAN-D STERILE COVERALL with Hood & Integrated Boots

About

The BioClean-D Coverall with Hood and Integrated Boots is a disposable garment offering exceptional comfort and headto-toe protection. Featuring a front zip with protective flap, elasticated hood, back, cuffs and ankles, and thumb loops to ensure a secure hold. The integrated boots feature slip-resistant soles to ensure every step is taken with confidence.

Specifications

MATERIAL:

Antistatic BioClean-D CleanTough white material & polyurethane soles

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type 5 & 6

CHARACTERISTICS:

Antistatic to EN 1149-5* & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Grade A

STERILIZATION:

Gamma irradiation

Features

- Lightweight and low-linting CleanTough material
- Thumb loops to ensure a secure hold
- Zip with sealable cover
- Elasticated hood, back, cuffs and ankles
- Slip resistant soles

EN 13982-1:2004







HEAD-TO-TOE PROTECTION

EXCELLENT ESD PROPERTIES

PPE CAT 3 TYPE 5 & 6

SILICONE-FREE





Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425
 Module D certifications
- Conforms to Category 3 Personal Protective Equipment PPE Regulation (EU)2016/425
- Tested against standard EN ISO 13982-1:2004+A1:2010 protective clothing for use against solid particles (Type 5)
- Tested against standard EN ISO 13034:2005+A1:2009 protective clothing against liquid chemicals (Type 6)
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against permeation standard ASTM F739-12
- Tested against standards: EN 1149-5:2008*, protective clothing electrostatic properties; EN 530, Abrasion resistance; EN 7854, Flex
 cracking resistance; EN 6530, Resistance to penetration by liquids; EN
 13934-1, Tensile strength; EN 9073-4, Trapezoidal tear resistance; EN
 863, Puncture resistance; and EN 13935-2, Seam strength.
- Processed in an NEBB certified ISO Class 4 environment
- Sterilized in accordance with ISO 11137-1:2006

Sterilization

Method: Gamma irradiation Minimum Dose: 25kGy Sterility Assurance Level: 10⁻⁶

Shelf Life & Storage

Three (3) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

Performance Test Results - BioClean-D CleanTough White Material

TEST	RESULT		PERFORMANCE CLASS (EN 14325)	
Abrasion Resistance	10 to 100 d	cycles	1	
Flex Cracking Resistance	5,000 to 15,00	00 cycles	3	
Trapezoidal Tear Resistance	MD 55.5	N	3	
Trapezoidal Tear Resistance	CD 29.3	N	2	
Tensile Strength	MD 97	Ν	2	
Tensile Strength	CD 48	Ν	1	
Puncture Resistance	8 N		1	
B. II	30% H ₂ SO ₄	96.3%	3	
Repellence to Liquids	10% NaOH	97.6%	3	
	O-Xylene	95.7%	2	
	Butan-1-ol	96.6%	3	
Penetration by Liquids	30% H ₂ SO ₄	0%	3	
, 4	10% NaOH	0%	3	
	O-Xylene	0%	3	
	Butan-1-ol	0%	3	
Inward leakage of aerosols of fine particles ¹	Pass		N/A	
Resistance to penetration by spray (Spray Test) 1	Pass		N/A	
Seam Strength ²	70 N		2	
Electrostatic Charge Half Decay Time, †50 (secs)	0.07		PASS	

¹All interfaces with additional PPE were taped during testing, as required by the standards.

²Seam not destroyed.





Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<2000	Category I

BioClean-DTM CleanTough White Material - ASTM F739-12 Test Method Results

Mean Breakthrough Time (MBT), Minutes

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 μ g/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO- RUBICIN HYDRO- CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>240	<6	217 (275,162,215)	>240	>240	>240	>240	<10	30 (28,30,33)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

TO ORDER

Re-Order	Chest	Height	Size
S-BDFC-XS*	76-84cm (30"-33")	158-164cm (5'2"-5'4")	XS*
S-BDFC-S	84-92cm (33"-36")	164-170cm (5'4"-5'6")	S
S-BDFC-M	92-100cm (36"-39")	170-176cm (5'6"-5'9")	M
S-BDFC-L	100-108cm (39"-42")	176-182cm (5'9"-6'0")	L
S-BDFC-XL	108-116cm (42"-45")	182-188cm (6'0"-6'2")	XL
S-BDFC-XXL	116-124cm (45"-48")	188-194cm (6'2"-6'4")	XXL
S-BDFC-XXXL	124-132cm (48"-51")	194-200cm (6'5"-6'7")	XXXL
S-BDFC-XXXXL	132-140cm (51"-54")	200-206cm (6'6"-6'8")	XXXXL

Packing

One piece 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 15 pieces per carton.

NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, S-BDFC are ideal for use in a static-safe environment. However the S-BDFC should not be relied upon to earth the wearer.

For additional information visit us at www.bioclean.com, or contact us at;

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S-BDFC/1906/PDS28

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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.

^{*}Please note size XS is subject to minimum order quantity and lead time.