

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

BioClean-D Non-Sterile Coverall,

Collar & Thumb Loop

About

The BioClean-D[™] Coverall with Collar is a disposable garment featuring a front zip with protective flap, elasticated back, cuffs and ankles and thumb loops to ensure a secure hold. The BioClean-D Coverall provides exceptional comfort and protection, even when handling cytotoxic drugs.

Specifications

MATERIAL: Antistatic CleanTough™ material

COLOUR: White

CONSTRUCTION: Bound seams with single needle stitching

CLASSIFICATION: PPE Cat 3 Type 5 & 6

CHARACTERISTICS: Antistatic to EN 1149-1 & low particulating

COMPATIBILITY: ISO Class 4

Features

- Low-linting & durable CleanTough™ material
- Thumb loops to ensure a secure hold
- Zip with sealable cover
- Elasticated back, cuffs and ankles
- Tested against permeation standard ASTM D6978-05





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COVERALL

EXCEPTIONAL COMFORT & PROTECTION

PPE CAT 3 TYPE 5 & 6

ANTISTATIC

LOW-LINTING & DURABLE



Billy Bioclean™ represents Bioclean's™ GMP compatible disposable garments





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Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certification
- Conforms to Category 3 Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Tested against standard EN ISO 13982-1 protective clothing for use against solid particles (Type 5)
- Tested against standard EN ISO 13034 protective clothing against liquid chemicals (Type 6)
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standard EN 1149-1 protective clothing electrostatic properties
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment

Performance Test Results

Shelf Life & Storage

Five (5) years from date of manufacture. Store in a dry, cool place (<40°C) away from direct sunlight and fluorescent light.

TEST	RESULT		PERFORMANCE CLASS (EN 14325)		
Abrasion Resistance	10 to 100 cycles		1		
Flex Cracking Resistance	5,000 to 15,000) cycles	3		
Trapezoidal Tear Resistance	CD 29.5 N		2		
Trapezoidal Tear Resistance	MD 50.8 N		3		
Tensile Strength	CD 59.4 N		1		
Tensile Strength	MD 79.3 N		2		
Puncture Resistance	5.9 N		2		
Repellence to Liquids	30% H ² SO ⁴	96.9%	3		
	10% NaOH	98.0%	3		
	O-Xylene	94.6%	2		
	Butan-1-ol	95.4%	3		
Penetration by Liquids	30% H ² SO ⁴	0%	3		
	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		
Resistance to Ignition	Pass		N/A		
Seam Strength ²	103.2 N		3		
Surface Resistivity	1.1 x 10 ¹⁰ Ω		N/A		

¹All interfaces with additional PPE were taped during testing, as required by the standards. ²Seam not destroyed.







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Particle Shedding Test Results

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

CleanTough[™] Material - ASTM D6978-05 Test Results

Breakthrough detection time (minutes)

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO-RUBICIN HYDRO- CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

Product Numbers



