

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

BioClean-D Coverall

with Hood and Thumb Loops

COVERALL
with Hood
BDCHT

About

The BioClean-D™ Coverall with Hood is a disposable garment featuring a front zip with protective flap, elasticated hood, 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 hood, back, cuffs and ankles
- Tested against permeation standard ASTM D6978-05





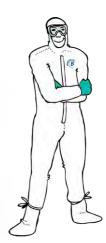


EXCEPTIONAL COMFORT & PROTECTION

PPE CAT 3 TYPE 5 & 6

ANTISTATIC

LOW-LINTING & DURABLE



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



Carter-Health Disposables, LLC Phone: (407) 296.6689

Web: www.Carter-Health.com

Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certifications
- 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

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.

Performance Test Results

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	MD 50.8 I	N	3	
Trapezoidal Tear Resistance	CD 29.5 N		2	
Tensile Strength	MD 79.3 N		2	
Tensile Strength	CD 59.4 N		1	
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 particles1	Pass		N/A	
Resistance to penetration by spray (Spray Test) 1	Pass		N/A	
Resistance to Ignition	Pass		N/A	
Seam Strength2	103.2 N		3	
Surface Resistivity	1.1 x 10 ¹⁰)Ω	N/A	

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







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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	CYCLOPHOS PHAMIDE	DOXO-RUBICIN HYDRO- CHLORIDE	5 FLUOROUR ACIL	METHOTRE XATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480



