

# BioClean Sterile Bunny Suit

with Hood and Integrated Boots

**STERILE  
 COVERALL**  
 with Hood & Integrated Boots  
**S-BDFC**

## About

The BioClean-D™ Coverall with Hood and Integrated Boots 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 with Hood and Boots provides exceptional comfort and head-to-toe protection, even when handling cytotoxic drugs.

## Specifications

**MATERIAL:**

Antistatic CleanTough™ material

**COLOUR:**

White

**CONSTRUCTION:**

Bound seams with single needle stitching

**CHARACTERISTICS:**

Antistatic to EN 1149-1 & low particulating

**COMPATIBILITY:**

ISO Class 4 & EU GMP Grade A

**STERILIZATION:**

Gamma irradiation

## 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**

**HEAD-TO-TOE  
 PROTECTION**

**ANTISTATIC**

**INTEGRATED  
 OVERBOOTS**



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



## Quality Standards

- Manufactured in a facility holding ISO 9001:2008 certification
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Tested against standard EN 1149-1 protective clothing - electrostatic properties
- 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<sup>-6</sup>

## 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

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 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 <sub>2</sub> SO <sub>4</sub>	96.9%	3
	10% NaOH	98.0%	3
	O-Xylene	94.6%	2
	Butan-1-ol	95.4%	3
Penetration by Liquids	30% H <sub>2</sub> SO <sub>4</sub>	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Inward leakage of aerosols of fine particles <sup>1</sup>	Pass		N/A
Resistance to penetration by spray (Spray Test) <sup>1</sup>	Pass		N/A
Resistance to Ignition	Pass		N/A
Seam Strength <sup>2</sup>	103.2 N		3
Surface Resistivity	1.1 x 10 <sup>10</sup> Ω		N/A

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



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### Product Numbers

S-BDFC-XS	X Small	20 pcs/cs
S-BDFC-S	Small	20 pcs/cs
S-BDFC-M	Medium	20 pcs/cs
S-BDFC-L	Large	20 pcs/cs
S-BDFC-XL	X Large	20 pcs/cs
S-BDFC-XXL	2X Large	20 pcs/cs
S-BDFC-XXXL	3X Large	20 pcs/cs
S-BDFC-XXXXL	4X Large	20 pcs/cs

### 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/cm<sup>2</sup>/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

