

BioClean-D Sterile Coverall

Collar and Thumb Loop

STERILE COVERALL
 with Collar
S-BDCCT

About

The BioClean-D™ Coverall with Collar is a single use 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.

**EXCEPTIONAL
 COMFORT &
 PROTECTION**

PPE CAT 3 TYPE 5 & 6

ANTISTATIC

**LOW-LINTING &
 DURABLE**

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 & 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 back, cuffs and ankles
- Tested against permeation standard ASTM D6978-05



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



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 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: 10⁻⁶

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

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	5.9N		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.

Product Numbers

S-BDCCT-S	Small	20 pcs/cs
S-BDCCT-M	Medium	20 pcs/cs
S-BDCCT-L	Large	20 pcs/cs
S-BDCCT-XL	X-Large	20 pcs/cs
S-BDCCT-XXL	2X-Large	20 pcs/cs
S-BDCCT-XXXL	3X-Large	20 pcs/cs
S-BDCCT-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/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