

BIOCLEAN-D™

STERILE COVERALL

with Hood

S-BDCHT

About

The BioClean-D™ Coverall with Hood is a single use 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 & 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 &
PROTECTION**

PPE CAT 3 TYPE 5 & 6

ANTISTATIC

**LOW-LINTING &
DURABLE**



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	5.9 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.

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-PHOSPHAMIDE	DOXO-RUBICIN HYDRO-CHLORIDE	5-FLUORO-URACIL	METHO-TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

TO ORDER

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

*Size subject to minimum order quantity and lead time

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BioClean™ is a brand of Nitritex Ltd.

For more information, please visit www.bioclean.com

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