

# BIOCLEAN-D™

## SLEEVE COVERS

Sterile

# S-BDSC-L

### About

Offering exceptional comfort and protection, single use BioClean-D™ Sterile Disposable Sleeve Covers are constructed from antistatic low-linting CleanTough™ material, and feature elasticated upper arms and cuffs. The 'one size fits' all cover has been tailored for quick and simple donning.

### Specifications

**MATERIAL:**

Antistatic CleanTough™ material

**COLOUR:**

White

**CONSTRUCTION:**

Bound seams with single needle stitching

**CLASSIFICATION:**

PPE Cat 3 Type PB [6]

**CHARACTERISTICS:**

Antistatic to EN 1149-1 & low particulating

**COMPATIBILITY:**

ISO Class 4 & EU GMP Class A

**STERILIZATION:**

Gamma irradiation

### Features

- Extra long length 500mm
- Exceptional antistatic properties
- Low-linting
- Durable CleanTough™ material
- Tested against permeation standard ASTM D6978-05

EXCEPTIONAL  
COMFORT &  
PROTECTION

PPE CAT 3 TYPE PB [6]

ANTISTATIC

LOW-LINTING &  
DURABLE



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 13034 protective clothing against liquid chemicals (Type PB[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
- 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	CD 59.4 N		1
Tensile Strength	MD 79.3 N		2
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
Resistance to Ignition	Pass		N/A
Seam Strength <sup>1</sup>	103.2 N		3
Surface Resistivity	$1.1 \times 10^{10}\Omega$		N/A

<sup>1</sup>Seam not destroyed.

## Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<260	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  $0.01 \mu\text{g}/\text{cm}^2/\text{min}$

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

## TO ORDER

Re-Order S-BDSC-L	Chest N/A	Height N/A	Size Universal
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### Packing

One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)

## CONTACT

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BioClean™ is a brand of Nitritex Ltd.  
For more information, please visit [www.bioclean.com](http://www.bioclean.com)

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