

BIOCLEAN-D SLEEVE COVERS Sterile S-BDSC-L

About

Offering comfort, protection and quick and simple donning, the single use BioClean-D Sterile Disposable Sleeve Covers are constructed from anti-static lightweight low-linting CleanTough material, featuring elasticated openings for a firm fit.

Specifications

MATERIAL:

Anti-static BioClean-D CleanTough white material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Anti-static to EN 1149-5* & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Class A

STERILIZATION:

Gamma irradiation

Features

- Extra long length 500mm
- Excellent ESD Properties
- Lightweight & low-linting

EN 13034:2005



EN 1149-5: 2008









Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425
 Module D certifications
- Conforms to Category 3 Personal Protective Equipment PPE Regulation (EU)2016/425
- Tested against standard EN ISO 13034:2005+A1:2009 protective clothing against liquid chemicals (Type PB[6])
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standards: EN 1149-5:2008*, protective clothing electrostatic properties; EN 530, Abrasion resistance; EN 7854, Flex
 cracking resistance; EN 6530, Resistance to penetration by liquids; EN
 13934-1, Tensile strength; EN 9073-4, Trapezoidal tear resistance; EN
 863, Puncture resistance; and EN 13935-2, Seam strength
- Processed in an NEBB certified ISO Class 4 environment
- Tested against permeation standard ASTM F739-12
- 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 - BioClean-D CleanTough White Material

TEST	RESULT		PERFORMANCE CLASS (EN 14325)	
Abrasion Resistance	10 to 100 d	cycles	1	
Flex Cracking Resistance	5,000 to 15,00	00 cycles	3	
Trapezoidal Tear Resistance	MD 55.5 N		3	
Trapezoidal Tear Resistance	CD 29.3 N		2	
Tensile Strength	MD 97 N		2	
Tensile Strength	CD 48 N		1	
Puncture Resistance	8 N		1	
Repellence to Liquids	30% H ₂ SO ₄	96.3%	3	
	10% NaOH	97.6%	3	
	O-Xylene	95.7%	2	
	Butan-1-ol	96.6%	3	
Penetration by Liquids	30% H ₂ SO ₄	0%	3	
	10% NaOH	0%	3	
	O-Xylene	0%	3	
	Butan-1-ol	0%	3	
Seam Strength ¹	70 N		2	
Electrostatic Charge Half Decay Time, 150 (secs)	0.07		PASS	

¹Seam not destroyed.





Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)	
Particle Shedding (Helmke Drum Test)	<260	Category I	

BioClean-DTM CleanTough White Material - ASTM F739-12 Test Method Results

Mean Breakthrough Time (MBT), Minutes

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 μ g/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO- RUBICIN HYDRO- CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	ТНІОТЕРА
>042	<6	217 (275,162,215)	>240	>240	>240	>240	<10	30 (28,30,33)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

TO ORDER

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

Packing

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

*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, are ideal for use in a static-safe environment.

For additional information visit us at www.bioclean.com, or call us at +44 1638 663338

Nitritex Ltd

Minton Enterprise Park, Oaks Drive Newmarket, Suffolk, CB8 7YY United Kingdom Tel: +44 1638 663338

Ansell US

111 Wood Avenue South Suite 210 Iselin, NJ 08830 USA Tel: +1 800 800 0444

Nitritex (M) Sdn Bhd

No.2, Jalan Jurunilai U1/20, Seksyen U1 Hicom Glenmarie Industrial Park 40150 Shah Alam, Selangor Malaysia Tel: +603 5569 3857/3859



S-BDSC-L/1906/PDS39

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of disposable garments for a specific application.

**Please see product validation pack or contact Ansell customer service for specific data on use of garments with cytotoxic drugs. Garments used for protection against such drugs must be selected specifically for the type of chemicals used.

Ansell, $^{\circ}$ and TM are trademarks owned by Ansell Limited or one of its affiliates. $^{\circ}$ 2012 – 2019 Ansell Limited. All Rights Reserved.