

BIOCLEAN-DTM OVERBOOTS Sterile S-BDOB

About

Offering exceptional comfort and protection, the single use BioClean-D[™] Sterile Disposable Overboots are constructed from antistatic low-linting CleanTough[™] material, and feature a slipresistant sole and easy tie fastenings.

Specifications

MATERIAL: Antistatic CleanTough[™] material & slipresistant SafeStep[™] sole

COLOUR: White

CONSTRUCTION: Bound seams with single needle stitching

CLASSIFICATION: PPE Cat 3 Type PB [6]

CHARACTERISTICS: Antistatic to EN1149-1* & low particulating

COMPATIBILITY: ISO Class 4 & EU GMP Grade A

STERILIZATION: Gamma irradiation

Features

- Low-linting
- Durable CleanTough[™] material
- Slip-resistant sole
- Tested against permeation standard ASTM D6978-05



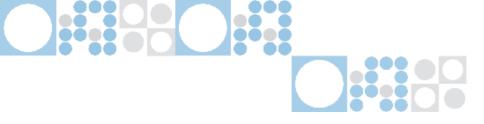
EXCEPTIONAL COMFORT & PROTECTION

PPE CAT 3 TYPE PB [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 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

Performance Test Results

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.

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	CD 29.5 N		2	
Trapezoidal Tear Resistance	MD 50.8 N		3	
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	
Resistance to Ignition	Pass		N/A	
Seam Strength ¹¹	103.2 N		3	
Surface Resistivity	1.1 x 10 ¹⁰ Ω		N/A	

¹Seam 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 μ g/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

TO ORDER

Re-Order	Chest	Height
S-BDOB	N/A	N/A

Size Universal

Packing

One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; five outer bags per lined carton (75 pairs)

*NOTE: BioClean CleanTough material is static dissipative and, with a surface resistance of $10^8 \ \Omega$, S-BDOB are ideal for use in a static-safe environment. However S-BDOB should not be relied upon to earth the wearer.

CONTACT

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BioClean[™] is a brand of Nitritex Ltd. For more information, please visit<u>www.bioclean.com</u>

S-BDOB/1711/PDS20