BioClean-D™ Overboots - Sterile S-BDOB

Lightweight sterile overboots with an elasticated opening, for secure, fitted personal protection

- **Reduced contamination risks:** BioClean-D™ Overboots S-BDOB are made from lightweight low-linting CleanTough™ material, lowering the risk of contamination in the cleanroom environment
- **Optimized fit:** These protective overboots' elasticated opening ensures a secure fit, for dependable personal protection that remains firmly in place
- **Enhanced features:** Equipped with easy tie fastenings and a slip-resistant sole, these overboots ensure a firm, adjustable hold and help prevent possible workplace injuries
- **Sterility assurance:** The boots are sterilised by gamma irradiation, with sterility assurance level (SAL) of 10-6
- **CAUTION:** Please contact Ansell Customer Service for specific chemotherapy drug permeation times and recommendations

Key Features and Benefits

- **Lightweight low-linting CleanTough™ fabric:** Fewer contamination risks
- **Elasticated opening:** A more secure, more comfortable fit
- **Slip-resistant sole and easy tie fastenings:** Secure fit, for safer use

Industries

- Controlled and Critical Environments
- Production and Manufacturing
- Pharmaceutical Manufacturing
- Biotechnology Manufacturing
- Medical Device Manufacturing

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BioClean-D™ Overboots - Sterile S-BDOB

TECHNICAL DATA SHEET

PRODUCT INFORMATION

Material	CleanTough™
Audit Standards	Manufacturing QMS Audit Standards ISO 9001, PPE Regulation 2016 425 Module D
Standards	ASTM F739, Partial Body Protection Only, CE 0598, EN ISO 13688:2013, EN 1149-5:2008, EN 1149-5:2018, EN 13934-1, EN 13935-2, EN 530, EN 6530, EN 7854, EN 863, EN 9073-4, EN ISO 13688:2013+A1:2021, EN ISO 14325, ISO 11137-1:2006, Category III, EN 13034:2005 + A1:2009, EN 13034:2005 + A1:2009
Packaging Overview	One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; five outer bags per lined carton (75 pairs)
Country Of Origin	Sri Lanka
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10^{-6}
Cleanroom Class	Class 10/ISO 4 & EU GMP Grade A
Shelf Life	Three (3) years from date of manufacture.
Construction	Bound seams with single needle stitching
Characteristics	*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, and so are ideal for use in a static-safe environment.

PARTICLE SHEDDING TEST RESULTS

TEST	RESULT
Particle Shedding (Helmke Drum Test)	≥ 0.5µm (counts/min) <260

ASTM F739-12 TEST METHOD RESULTS

DRUG	Mean Breakthrough Time (MBT), Minutes Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 µg/cm² /min
CISPLATIN	>240
CARMUSTINE	<6
CYCLOPHOSHAMIDE	217 (275,162,215)
DOXORUBICINHYDROCHLORIDE	>240
5-FLUOROURACIL	>240
METHOTREXATE	>240
ETOPOSIDE	>240
PACLITAXEL	<10
THIOTEPA	30 (28,30,33)

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

SIZE CHART

Universal

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MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS
Abrasion Resistance	10 to 100 cycles	1
Flex Cracking Resistance	5,000 to 15,000 cycles	3
Puncture Resistance	8 N	1
Trapezoidal Tear Resistance Cross Direction (CD)	CD 29.3 N	2
Trapezoidal Tear Resistance Machine Direction (MD)	MD 55.5 N	3
Tensile Strength Cross Direction (CD)	CD 48 N	1
Tensile Strength Machine Direction (MD)	MD 97 N	2
Repellence to Liquids – 30% H_2SO_4	96.3%	3
Repellence to Liquids – 10% NaOH	97.6%	3
Repellence to Liquids – O-Xylene	95.7%	2
Repellence to Liquids – Butan-1-ol	96.6%	3
Penetration by Liquids – 30% H_2SO_4	0%	3
Penetration by Liquids – 10% NaOH	0%	3
Penetration by Liquids – O-Xylene	0%	3
Penetration by Liquids – Butan-1-ol	0%	3
Seam Strength[2]	70 N	2
Electrostatic Charge Half Decay Time, t_{50} (secs)	0.07	PASS

1. Seam not destroyed

ORDERING INFORMATION

	SIZE	Universal
S-BDOB	REORDER NO.	S-BDOB

Performance Standards and Regulatory Compliance

P PARTIAL BODY PROTECTION ONLY · CE 0598 · EN 1149-5 · ISO ISO 11137-1 · TYPE PB [6] · TYPE PB [6]

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