BioClean-D™ Longer Length Overboots - Sterile S-BDOB-L

Sterile longer-length protective overboots, for more complete personal protection

- **Added protection:** BioClean-D™ Longer Length Overboots - Sterile S-BDOB-L are 500mm in length, granting wearers more complete personal protection
- **Reduced contamination risks:** Made from low-linting CleanTough™ fabric, these protective overboots reduce the risk of contamination when entering the cleanroom environment
- **Optimized fit:** Designed with tie fastenings at the top and at ankle level, they are easy to wear and offer a secure, adjustable fit
- **Enhanced features:** Thanks to their slip-resistant sole, they offer greater wearer safety, averting potential workplace injuries
- **Sterility assurance:** The boots are sterilized by gamma irradiation, with sterility assurance level (SAL) of 10-6

Key Features and Benefits

- **Longer length (500mm):** For more complete protective coverage
- **Lightweight low-linting fabric:** Fewer contamination risks
- **Tie fastenings and slip-resistant sole:** Good fit and safer use

Industries

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

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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 1149-5:2018, EN 13934-1, EN 13935-2, 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, UKCA
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). **More sustainable packaging:** Packed in recyclable plastic packaging and delivered in recycled cardboard shipper cases. Inner and outer bags and liner are made from polyethylene (PE) based film. Always check your local recyclable status as these materials may not be considered suitable for recycling in your location.
Storage	Keep away from direct sunlight; store in a dry place and keep in the original packaging. Keep away from ozone sources. If products are properly stored, as indicated, they won't lose their performances or change characteristics significantly. If products could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.
Country Of Origin	China
Sterilization Method	GAMMA irradiation (25 kGy)
Sterilization Minimum Dose	25kGy
Sterility Assurance Level	10⁻⁶
Cleanroom Class	Class 10/ISO Class 4 & EU GMP Grade A/B and other sterile cleanrooms
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)	≥ 0.5Qm (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 Qg/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. *For Bioclean D and Bioclean 2000, the chemical permeation results relates to the fabric performance for reference only. Seams and closures may have lower breakthrough times. We recommend garments with sealed seams such as Bioclean-C to be worn over the coverall for added protection against chemotherapy drugs handling.

SIZE CHART

Universal

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MATERIAL PERFORMANCE TEST RESULTS

TEST	RESULT	PERFORMANCE CLASS	PERFORMANCE STANDARD
Abrasion Resistance	>10 cycles	1	EN 12947-2
Flex Cracking Resistance	>50,000 cycles	6	EN ISO 7854
Puncture Resistance	>5 N	1	ISO 13996
Trapezoidal Tear Resistance Cross Direction (CD)	>10 N	1	EN ISO 9073-4
Trapezoidal Tear Resistance Machine Direction (MD)	>10 N	1	EN ISO 9073-4
Tensile Strength Cross Direction (CD)	>30 N	1	EN ISO 13934-1
Tensile Strength Machine Direction (MD)	>30 N	1	EN ISO 13934-1
Repellence to Liquids – 30% H₂SO₄	>90%	3	ISO 6530
Repellence to Liquids – 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids – O-Xylene	>80%	2	ISO 6530
Repellence to Liquids – Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids – 30% H₂SO₄	<1%	3	ISO 6530
Penetration by Liquids – 10% NaOH	<1%	3	ISO 6530
Penetration by Liquids – O-Xylene	<1%	3	ISO 6530
Penetration by Liquids – Butan-1-ol	<1%	3	ISO 6530
Seam Strength[2]	>50 N	2	ISO 13935-2
Electrostatic Charge Half Decay Time, t₅₀ (secs)	PASS	N/A	EN1149-3

1. Seam not destroyed
2. The material is static dissipative. Tested in accordance with EN1149-5

ORDERING INFORMATION

	SIZE	Universal
S-BDOB-L	REORDER NO.	S-BDOB-L

Performance Standards and Regulatory Compliance

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

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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.