



# 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<sup>-6</sup>
- **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 <sup>-6</sup>  |
| 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) | ≥ 0.5Qm (counts/min) <260 |

#### ASTM F739-12 TEST METHOD RESULTS

| DRUG                     | Mean Breakthrough Time (MBT), Minutes<br>Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 Qg/cm <sup>2</sup> /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 <sub>2</sub> SO <sub>4</sub>   | 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 <sub>2</sub> SO <sub>4</sub>  | 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 <sup>2</sup>                                   | 70 N                   | 2                 |
| Electrostatic Charge Half Decay Time, t <sub>50</sub> (secs) | 0.07                   | PASS              |

1. Seam not destroyed

## ORDERING INFORMATION

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

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## Performance Standards and Regulatory Compliance



CE 0598



ISO 11137-1



TYPE PB [6]



TYPE PB [6]

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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.

