

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



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





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 1149-5:2008, 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 |
| 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 | 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 | Tres (3) años a partir de la fecha de fabricación. |
| Construction | Costuras unidas con puntadas de una sola aguja |
| 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/cm ² /min |
|--------------------------|--|
| CISPLATIN | >240 |
| CARMUSTINE | <6 |
| CYCLOPHOSAMIDE | 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



BioClean-D™ Overboots - Sterile S-BDOB

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% H ₂ SO ₄ | >90% | 3 | ISO 6530 |
| Repellence to Liquids – 10% NaOH | >90% | 3 | ISO 6530 |
| Repellence to Liquids – O-Xylene | >90% | 3 | ISO 6530 |
| Repellence to Liquids – Butan-1-ol | >90% | 3 | ISO 6530 |
| Penetration by Liquids – 30% H ₂ SO ₄ | <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, t ₅₀ (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 | REORDER NO. | S-BDOB |

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Performance Standards and Regulatory Compliance



CE 0598



ISO 11137-1 TYPE PB [6]

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