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

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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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)	≥ 0.5Qm (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% H_2SO_4	>90%	3	ISO 6530
Repellence to Liquids – 10% NaOH	>90%	3	ISO 6530
Repellence to Liquids – O-Xylene	>90%	2	ISO 6530
Repellence to Liquids – Butan-1-ol	>90%	3	ISO 6530
Penetration by Liquids – 30% H_2SO_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

Performance Standards and Regulatory Compliance

P PARTIAL BODY PROTECTION ONLY · CE 0598 · EN 1149-5

ISO 11137-1 · TYPE PB [6]

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