

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

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

- Added protection: BioClean-D<sup>™</sup> 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 slipresistant 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



- **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 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	30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; five outer bags per lined carton (150 pieces
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 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)	≥ 0.5µm (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 $0.1~\mu g/cm2$ /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	2,500 to 5,000 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-L	REORDER NO.	S-BDOB-L

## **Performance Standards and Regulatory Compliance**







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