

About

The BioClean-D sterile anti-static kit comprises of BioClean-D Coverall with Collar, Overboots and Hood with integrated Facemask. Providing all garment requirements in one package reducing packaging waste, the BioClean-D S-BDKM kit offers exceptional comfort and head-to-toe protection. Coverall with Collar features a front zip with protective flap, elasticated back, cuffs and ankles, and thumb loops to ensure a secure hold. The BioClean-D Hood is designed and constructed using three sections for a perfect fit and features an integrated face mask for complete coverage to eliminate gaps. Completing the kit are a pair of overboots which feature a slip-resistant sole and tie fastenings for quick and easy donning.

Specifications

MATERIAL:

Anti-static BioClean-D CleanTough Material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type 5 & 6 (Coverall) PPE Cat 3 Type PB [6] (Hood & Overboots)

CHARACTERISTICS:

Anti-static to EN1149-5* & low particulating

COMPATIBILITY:

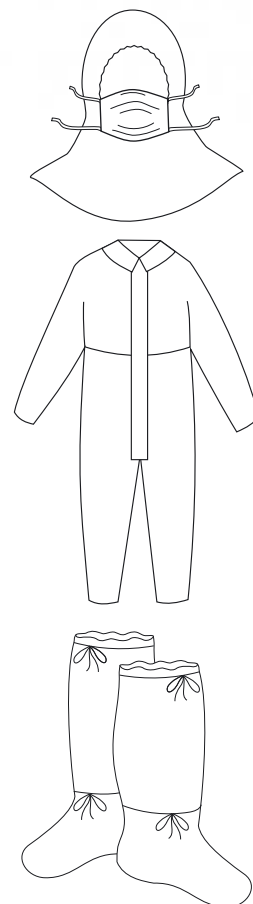
ISO Class 4 & EU GMP Grade A

STERILIZATION:

Gamma irradiation

Features

- Exceptional comfort and protection
- Low-linting and durable
- Thumb loop to ensure a secure hold
- Slip-resistant sole



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EN 13982-1:2004 + A1:2010 EN 13034:2005 + A1:2009 EN 13034:2005 + A1:2009 EN 1149-5:2008



TYPE 5



TYPE 6



TYPE PB[6]



Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Personal Protective Equipment PPE Regulation (EU)2016/425
- Tested against standard EN ISO 13034:2005+A1:2009 protective clothing against liquid chemicals (Type PB[6])
- Tested against standard EN ISO 13982-1:2004+A1:2010 protective clothing for use against solid particles (Type 5)
- Tested against standard EN ISO 13034:2005+A1:2009 protective clothing against liquid chemicals (Type 6)
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standards: EN 1149-5:2008*, protective clothing - electrostatic properties; EN 530, Abrasion resistance; EN 7854, Flex cracking resistance; EN 6530, Resistance to penetration by liquids; EN 13934-1, Tensile strength; EN 9073-4, Trapezoidal tear resistance; EN 863, Puncture resistance; and EN 13935-2, Seam strength
- Tested against permeation standard ASTM F739-12
- Processed in an NEBB certified ISO Class 4 environment
- Sterilized in accordance with ISO 11137-1:2006
- WARNING: The facemask included in the kit is intended for product protection only and is not personal protective equipment; it is not intended for use in hazardous environments.

Sterilization

Method: Gamma irradiation
Minimum Dose: 25kGy
Sterility Assurance Level: 10^{-6}

Shelf Life & Storage

Three (3) years from date of manufacture. Store in a dry, cool place ($<40^{\circ}\text{C}$) away from direct sunlight and fluorescent light.

Performance Test Results – BioClean-D CleanTough White Material

TEST	RESULT		PERFORMANCE CLASS (EN 14325)
Abrasion Resistance	10 to 100 cycles		1
Flex Cracking Resistance	5,000 to 15,000 cycles		3
Trapezoidal Tear Resistance	CD 29.3 N		2
Trapezoidal Tear Resistance	MD 55.5 N		3
Tensile Strength	MD 97 N		2
Tensile Strength	CD 48 N		1
Puncture Resistance	8 N		1
Repellence to Liquids	30% H ₂ SO ₄	96.3%	3
	10% NaOH	97.6%	3
	O-Xylene	95.7%	2
	Butan-1-ol	96.6%	3
Penetration by Liquids	30% H ₂ SO ₄	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Inward leakage of aerosols of fine particles ¹	Pass		N/A
Resistance to penetration by spray (Spray Test) ¹	Pass		N/A
Seam Strength ²	70 N		2
Electrostatic Charge Half Decay Time, t_{50} (secs)	0.07		PASS

¹All interfaces with additional PPE were taped during testing, as required by the standards.

²Seam not destroyed.

Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<2000 (Coverall) <260 (Hood & Overboots)	Category I

BioClean-D™ CleanTough White Material - ASTM F739-12 Test Method Results

Mean Breakthrough Time (MBT), Minutes

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 µg/cm²/min

CISPLATIN	CARMUSTINE	CYCLO- PHOSPHA- MIDE	DOXO- RUBICIN HYDRO- CHLORIDE	5- FLUORO- URACIL	METHO- TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>240	<6	217 (275,162,215)	>240	>240	>240	>240	<10	30 (28,30,33)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

TO ORDER

Re-Order	Chest	Height	Size
S-BDKM-S	84-92cm (33"-36")	164-170cm (5'4"-5'6")	S
S-BDKM-M	92-100cm (36"-39")	170-176cm (5'6"-5'9")	M
S-BDKM-L	100-108cm (39"-42")	176-182cm (5'9"-6'0")	L
S-BDKM-XL	108-116cm (42"-45")	182-188cm (6'0"-6'2")	XL
S-BDKM-XXL	116-124cm (45"-48")	188-194cm (6'2"-6'4")	XXL
S-BDKM-XXXL	124-132cm (48"-51")	194-200cm (6'4"-6'6")	XXXL
S-BDKM-XXXXL	132-140cm (51"-54")	200-206cm (6'6"-6'8")	XXXXL

Packing

One hood with integrated face mask, one coverall with collar, and one pair of overboots per sealed inner bag; one inner bag per sealed outer PE bag; 15 outer bags (kits) per carton

*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

All sizes subject to MOQ (Minimum Order Quantity) and extended lead time.

For additional information visit us at www.bioclean.com, or contact us at;

Nitritex Ltd
Minton Enterprise Park
Oaks Drive
Newmarket, Suffolk
CB8 7YY
United Kingdom
Tel: +44 1638 663338

Ansell US
111 Wood Avenue South
Suite 210
Iselin, NJ 08830
USA
Tel: +1 800 800 0444

Nitritex (M) Sdn.Bhd
2 Jalan Jurunilai U1/20
Seksyen U1, Hicom Glenmarie Industrial Park
40150 Shah Alam, Selangor
Malaysia
Tel: +603 5569 3857/3859

S-BDKM/1807/PDS2

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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.