

BIOCLEAN-D DROP-DOWN Sterile Garment with Hood S-BDSH

About

The BioClean-D Drop-down Garment with Hood is a sterile anti-static disposable garment manufactured from low-linting CleanTough material. Its unique design offers true aseptic donning, with internal coloured tabs to indicate safe touch points to prevent touching the outside surface. The innovative up and over donning design eliminates the risk of the garment touching the floor, and strategically placed quick release tabs (to hold and remove during zip closure) ensure aseptic donning through out the donning process.

Specifications

MATERIAL:

Anti-static BioClean-D CleanTough white material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CHARACTERISTICS:

Anti-static to EN 1149-5* & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Grade A

STERILIZATION:

Gamma irradiation

Features

- Elasticated back, hood, cuffs and ankles
- Foot-loop to aid smooth closure of zip
- Thumb loops to ensure a secure hold
- Quick release press stud tabs for aseptic donning
- Low-linting CleanTough material

EN 1149-5:





EXCEPTIONAL COMFORT AND PROTECTION

ANTI-STATIC & LOW-LINTING

UNIQUE UP AND OVER DESIGN

ASEPTIC DONNING TECHNIQUE

SILICONE-FREE

Ansell





Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Tested against permeation standard ASTM F739-12
- Processed in an NEBB certified ISO Class 4 environment
- 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
- Sterilized in accordance with ISO 11137-1:2006

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°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 15,00 | 00 cycles | 3 | |
| Trapezoidal Tear Resistance | MD 55.5 | N | 3 | |
| Trapezoidal Tear Resistance | CD 29.3 | Z | 2 | |
| Tensile Strength | MD 97 N | | 2 | |
| Tensile Strength | CD 48 | 7 | 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 | |
| Seam Strength ² | 70 N | | 2 | |
| Electrostatic Charge Half Decay Time, †50 (secs) | 0.07 | | PASS | |





Particle Shedding Test Results

| TEST | RESULT | CATEGORY (IEST-RP-CC003.3) |
|--------------------------------------|--------|-------------------------------|
| Particle Shedding (Helmke Drum Test) | <2000 | Category I |

BioClean-DTM 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 μ g/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-BDSH-XS | 76-84cm (30"-33") | 158-164cm (5'2"-5'4") | X-Small |
| S-BDSH-S | 84-92cm (33"-36") | 164-170cm (5'4"-5'6") | Small |
| S-BDSH-M | 92-100cm (36"-39") | 170-176cm (5'6"-5'9") | Medium |
| S-BDSH-L | 100-108cm (39"-42") | 176-182cm (5'9"-6'0") | Large |
| S-BDSH-XL | 108-116cm (42"-45") | 182-188cm (6'0"-6'2") | X-Large |
| S-BDSH-XXL | 116-124cm (45"-48") | 188-194cm (6'2"-6'4") | XX-Large |
| S-BDSH-XXXL | 124-132cm (48"-51") | 194-200cm (6'4"-6'6") | XXX-Large |
| S-BDSH-XXXXL | 132-140cm (51"-54") | 200-206cm (6'6"-6'8") | XXXX-Large |
| S-BDSH-5XL | 140-148cm (54"-57") | 206-212cm (6'8"-6'10") | 5X-Large |
| S-BDSH-6XL | 148-156cm (58"-61") | 212-218cm (6'10"-6'12") | 6X-Large |
| S-BDSH-7XL | 156-164cm (61"-64") | 218-224cm (7'1"-7'3") | 7X-Large |
| S-BDSH-8XL | 164-172cm (64"-67") | 224-230cm (7'3"-7'5") | 8X-Large |

Packing

One piece per sealed inner PE bag; one inner bag per sealed outer PE bag; 20 outer bags per per lined carton (20 pieces). Please note: sizes XXXL, XXXXL, 5XL, 6XL, 7XL & 8XL 15 coveralls per carton.

Sizes XXXXL, 5XL, 6XL, 7XL & 8XL subject to minimum order quantity and extended lead time.

*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.

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



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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.

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