

Sterile Drop-Down Garment

with Hood, CleanTough Fabric, Gama Irradiated

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

About

The BioClean-D™ Drop-down Garment with Hood is a sterile antistatic disposable garment manufactured from low-linting durable CleanTough™ material. It's unique design offers the world's first true aseptic gowning technique. With internal coloured tabs to indicate safe touch points to prevent touching the outside surface, innovative up and over donning design to eliminate the risk of the garment touching the floor, strategically placed quick release tabs to hold and remove during zip closure and removable zip tab to complete and ensure aseptic donning.

Specifications

MATERIAL:

CleanTough™ material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CHARACTERISTICS:

Antistatic to EN 1149-1 & 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 & durable CleanTough™ material
- Tested against permeation standard ASTM D6978-05



**EXCEPTIONAL
 COMFORT AND
 PROTECTION**

**ANTISTATIC &
 LOW-LINTING**

**UNIQUE UP AND
 OVER DESIGN**

**ASEPTIC DONNING
 TECHNIQUE**



Billy Bioclean™ represents
 Bioclean's™ GMP compatible
 disposable garments

Quality Standards

- Manufactured in a facility holding ISO 9001:2008
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment
- Tested against standard EN 1149-1 protective clothing - electrostatic properties
- 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

| 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 | MD 50.8 N | | 3 |
| Trapezoidal Tear Resistance | CD 29.5 N | | 2 |
| Tensile Strength | MD 79.3 N | | 2 |
| Tensile Strength | CD 59.4 N | | 1 |
| Puncture Resistance | 5.9 N | | 2 |
| Repellence to Liquids | 30% H ₂ SO ₄ | 96.9% | 3 |
| | 10% NaOH | 98.0% | 3 |
| | O-Xylene | 94.6% | 2 |
| | Butan-1-ol | 95.4% | 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 |
| Resistance to Ignition | Pass | | N/A |
| Seam Strength ² | 103.2 N | | 3 |
| Surface Resistivity | 1.1 x 10 ¹⁰ Ω | | N/A |

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 | Category I |



CleanTough™ Material - ASTM D6978-05 Test Results

Breakthrough detection time (minutes)

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm²/min

| CISPLATIN | CARMUSTINE | CYCLO- PHOSPHA- MIDE | DOXO-RUBICIN HYDRO- CHLORIDE | 5- FLUORO- URACIL | METHO- TREXATE | ETOPOSIDE | PACLITAXEL | THIOTEPA |
|-----------|------------|----------------------------|------------------------------------|-------------------------|-------------------|-----------|------------|----------|
| >480 | >480 | >480 | >480 | >480 | >480 | >480 | >480 | >480 |

