

BioClean-D™ Hood

Sterile S_BDHD

About

The BioClean-D™ Hood is a sterile single use hood designed and constructed using three sections for a perfect fit. Made from antistatic durable low-linting CleanTough™ material, the hood features an elasticated face-opening with reinforced edges for exceptional comfort and protection.

Specifications

MATERIAL:

Antistatic CleanTough™ material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Antistatic to EN1149-1 & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Grade A

STERILIZATION:

Gamma irradiation

PPE CAT 3 TYPE PB [6]

THREE PIECE DESIGN

ANTISTATIC

**LOW-LINTING &
 DURABLE**

Features

- Low-linting
- Durable CleanTough™ material
- Tested against permeation standard ASTM D6978-05



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





Distributed By:

CARTER - HEALTH™

Healthcare Solutions and Services

We Keep It Clean

Carter-Health Disposables, LLC

Phone: (407) 296.6689

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Quality Standards

- Manufactured in a facility holding ISO 9001:2008 and 89/686/EEC Article 11b certifications
- Conforms to Category 3 - Complex Design Personal Protective Equipment PPE Directive 89/686/EEC
- Tested against standard EN ISO 13034 protective clothing against liquid chemicals (Type PB[6])
- Tested against standard EN ISO 14325 protective clothing against chemicals
- Tested against standard EN 1149-1 protective clothing - electrostatic properties
- Tested against permeation standard ASTM D6978-05 for cytotoxic drugs
- Processed in an NEBB certified ISO Class 4 environment
- 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	CD 29.5 N		2
Trapezoidal Tear Resistance	MD 50.8 N		3
Tensile Strength	CD 59.4 N		1
Tensile Strength	MD 79.3 N		2
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
Resistance to Ignition	Pass		N/A
Seam Strength ¹	103.2 N		3
Surface Resistivity	1.1 x 10 ¹⁰ Ω		N/A

¹Seam not destroyed.



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Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<260	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-PHOSPHAMIDE	DOXO-RUBICIN HYDRO-CHLORIDE	5-FLUORO-URACIL	METHO-TREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>480	>480	>480	>480	>480	>480	>480	>480	>480

