

#### USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

# **BioClean-C Sterile Chemotherapy Protective Apron - Sleeveless**

#### **About**

Providing protection against chemotherapy drugs, the BioClean-C<sup>™</sup> Sterile Chemotherapy Protective Apron is manufactured from lightweight, low-linting and hard wearing CleanTough<sup>™</sup> material, featuring tie tapes at the rear and an adjustable neck fastening.

#### **Specifications**

MATERIAL:

CleanTough™ material

COLOUR:

Blue

CONSTRUCTION:

Adjustable neck, tie fastening at waist

**CLASSIFICATION:** 

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Grade A

STERILIZATION:

Gamma irradiation

#### **Features**

- Tested against ASTM D6978-05 using a minimum of nine cytotoxic drugs
- Tie tapes at rear
- · Adjustable neck fastening
- Processed to ensure ISO Class 4 compatibility
- Lightweight, low-linting & hard wearing CleanTough™ material







# CHEMOTHERAPY Sterile Protective Apron S-BCDA

LIGHTWEIGHT & LOW-LINTING

> TESTED AGAINST ASTM D6978-05

ADJUSTABLE NECK FASTENING

PROTECTION AGAINST A RANGE OF CYTOTOXIC DRUSG



Dr Isolator™ represents BioClean's™ GMP compatible Chemo Safety Wear



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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 14325 protective clothing against chemicals
- 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<sup>-6</sup>

#### **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 58.4 N		3
Trapezoidal Tear Resistance	CD 42.5 N		3
Tensile Strength	CD 43 N		1
Tensile Strength	MD 68 N		2
Puncture Resistance	9 N		1
Repellence to Liquids	30% H <sub>2</sub> SO <sub>4</sub> 99.0%		3
	10% NaOH	98.4%	3
	O-Xylene	91.4%	2
	Butan-1-ol	93.9%	2
Penetration by Liquids	30% H <sub>2</sub> SO <sub>4</sub>	0%	3
	10% NaOH	0%	3
	O-Xylene	0%	3
	Butan-1-ol	0%	3
Seam Strength <sup>1</sup>	90 N		3

<sup>&</sup>lt;sup>1</sup>Seam not destroyed

### **Particle Shedding Test Results**

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<1700	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

#### **Product Numbers**

S-BCDA-S	Small	50 pc/cs
S-BCDA-M	Medium	50 pc/cs
S-BCDA-L	Large	50 pc/cs



