

### USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

# **BioClean-C Sterile Chemotherapy Protective Apron with Sleeves**

BIOCLEAN-CTO
CHEMOTHERAPY
Protective Apron with Sleeves
S-BCAS

#### **About**

The BioClean-C™ sterile Chemotherapy Protective Apron with Sleeves provides maximum protection against a range of cytotoxic drugs. Manufactured from lightweight, low-linting and hard wearing CleanTough™ material, the apron features an adjustable neck fastening, with tie tapes at the rear, ultrasonically bonded sleeve seams with protective tape and 100% polyester elasticated cuffs.

# **Specifications**

#### MATERIAL:

CleanTough™ material

#### **COLOUR:**

Blue

#### **CONSTRUCTION:**

100% polyester elasticated cuffs, ultrasonically bonded sleeve seams with protective tape

#### **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
- Ultrasonically bonded seams with protective tape
- Tie tapes at rear
- · Adjustable neck fastening
- · 100% polyester elasticated cuffs
- Lightweight, low-linting & hard wearing
   CleanTough™ material







TESTED AGAINST ASTM D6978-05

100% POLYESTER ELASTICATED CUFFS

ADJUSTABLE NECK FASTENING

ULTRASONICALLY BONDED SEAMS



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: 10-6

# **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 42.5 N		3	
Trapezoidal Tear Resistance	MD 58.4 N CD 43 N MD 68 N 9 N		3	
Tensile Strength			1	
Tensile Strength			2	
Puncture Resistance			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

#### **Product Numbers**

S-BCAS-S	Small	40 pcs/cs
S-BCAS-M	Medium	40 pcs/cs
S-BCAS-L	Large	40 pcs/cs
S-BCAS-XI	X-Large	40 pcs/cs







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# **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



