



Armschoner BioClean-C

pure¹¹-Nr.: 03504, Hersteller: BioClean



Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1103504
- Material: Clean-Tough
- Gammabestrahlt
- Mit elastischem Gummibund am Oberarm und Polyester-Trikotmanschette am unteren Ende
- Für bequemen Sitz
- Maximaler Komfort und Schutz
- Zyto-geeignet
- Einzeln verpackt

Empfohlene Reinraumklassen

ISO 3 4 5 6 7 8 9

GMP A/B C D

Produktvarianten

pure¹¹-Nr.: 03504B

Farbe: Blau / Herst.-Nr.: S-BCSC / VE: 90 Paar

Quelle: <https://www.pure11.de/armschoner-bioclean-c-0>

About

The BioClean-C Sterile Chemotherapy Protective Sleeve Covers have been specially developed for protection against a range of chemotherapy drugs** and to be compatible with ISO Class 4 cleanrooms. Constructed from lightweight low-linting CleanTough blue material, the sleeve covers feature elasticated arms for stability on the arm and has been tailored for quick and simple donning.

Specifications

MATERIAL:

BioClean-C CleanTough blue material & 100% polyester cuffs

COLOUR:

Blue

CONSTRUCTION:

Ultrasonically bonded seams covered with protective tape

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Low particulating

COMPATIBILITY:

ISO Class 4

STERILIZATION:

Gamma irradiation

Features

- Ultrasonically bonded seams with protective tape
- Elasticated for secure fit
- Lightweight low-linting CleanTough material
- Tested against permeation standard ASTM F739-12
- Silicone-free

ULTRASONICALLY
BONDED SEAMS

LIGHTWEIGHT & LOW-
LINTING

TESTED AGAINST
PERMEATION
STANDARD ASTM
F739-12

EN 13054:2005
+A1:2009



TYPE PB[6]



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

Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Personal Protective Equipment Regulation (EU) 2016/425
- Tested against standard EN ISO 13034:2005 + A1:2009 protective clothing against liquid chemicals (Type PB [6])
- Tested against standard EN 14325 protective clothing against chemicals
- Tested against permeation standard ASTM F739-12
- Processed in an NEBB certified ISO Class 4 environment
- Tested against standards: EN 530, Abrasion 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-C CleanTough Blue Material

TEST	RESULT		PERFORMANCE CLASS (EN 14325)
Abrasion Resistance	10 to 100 cycles		1
Trapezoidal Tear Resistance	CD 32.3 N		2
Trapezoidal Tear Resistance	MD 50.6 N		3
Tensile Strength	CD 47 N		1
Tensile Strength	MD 94 N		2
Puncture Resistance	10 N		1
Repellence to Liquids	30% H ₂ SO ₄	99.0%	3
	10% NaOH	98.4%	3
	O-Xylene	91.4%	1
	Butan-1-ol	93.9%	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 ¹	74 N		2

Particle Shedding Test Results

TEST	RESULT	CATEGORY (IEST-RP-CC003.3)
Particle Shedding (Helmke Drum Test)	<260	Category I

BioClean-C™ CleanTough Blue 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 $0.1 \mu\text{g}/\text{cm}^2/\text{min}$

CISPLATIN	CARMUSTINE	CYCLO-PHOSPHAMIDE	DOXORUBICIN HYDROCHLORIDE	5-FLUOROURACIL	METHOTREXATE	ETOPOSIDE	PACLITAXEL	THIOTEPA
>240	>240	>240	>240	>240	>240	<6	>240	55 (46,88,31)

Results achieved under controlled laboratory conditions, by accredited external testing laboratory.

TO ORDER

Re-Order S-BCSC	Chest N/A	Height N/A	Size Universal
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Packing

One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)

For additional information visit us at www.bioclean.com, or call us at +44 1638 663338

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S-BCSC/1905/PDS33



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