



Armschoner BioClean-D

pure¹¹-Nr.: 03501, Hersteller: BioClean



Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1103501
- Material: Clean-Tough
- Gammabestrahlt
- Antistatisch
- Elastische Armbündchen für bequemen und sicheren Sitz
- Maximaler Komfort und Schutz
- Extra-lang
- Partikelarm
- Gegen Permeation getestet (Standard: ASTM D6978-05)
- Doppelt unterverpackt
- Einzeln verpackt

Empfohlene Reinraumklassen

ISO 3 4 5 6 7 8 9

GMP A/B C D

Produktvarianten

pure¹¹-Nr.: 03501W

Farbe: Weiß / Herst.-Nr.: S-BDSC-L / VE: 90 Paar

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

BIOCLEAN-D SLEEVE COVERS Sterile S-BDSC-L

About

Offering comfort, protection and quick and simple donning, the single use BioClean-D Sterile Disposable Sleeve Covers are constructed from anti-static lightweight low-linting CleanTough material, featuring elasticated openings for a firm fit.

Specifications

MATERIAL:

Anti-static BioClean-D CleanTough white material

COLOUR:

White

CONSTRUCTION:

Bound seams with single needle stitching

CLASSIFICATION:

PPE Cat 3 Type PB [6]

CHARACTERISTICS:

Anti-static to EN 1149-5* & low particulating

COMPATIBILITY:

ISO Class 4 & EU GMP Class A

STERILIZATION:

Gamma irradiation

PPE CAT 3 TYPE PB [6]

ANTI-STATIC

LOW-LINTING

Features

- Extra long length 500mm
- Excellent ESD Properties
- Lightweight & low-linting
- Silicone-free



Quality Standards

- Manufactured in a facility holding ISO 9001:2015 and (EU)2016/425 Module D certifications
- Conforms to Category 3 - Personal Protective Equipment PPE 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 ISO 14325 protective clothing against chemicals
- Tested against standards: EN 1149-5:2008*, protective clothing - electrostatic properties; EN 530, Abrasion resistance; EN 7854, Flex cracking 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
- Processed in an NEBB certified ISO Class 4 environment
- Tested against permeation standard ASTM F739-12
- 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-D CleanTough White Material

| 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 55.5 N | | 3 |
| Trapezoidal Tear Resistance | CD 29.3 N | | 2 |
| Tensile Strength | MD 97 N | | 2 |
| Tensile Strength | CD 48 N | | 1 |
| Puncture Resistance | 8 N | | 1 |
| Repellence to Liquids | 30% H ₂ SO ₄ | 96.3% | 3 |
| | 10% NaOH | 97.6% | 3 |
| | O-Xylene | 95.7% | 2 |
| | Butan-1-ol | 96.6% | 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 | 70 N | | 2 |
| Electrostatic Charge Half Decay Time, t_{50} (secs) | 0.07 | | PASS |

¹Seam not destroyed.

Particle Shedding Test Results

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

BioClean-D™ CleanTough White 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 µg/cm²/min

| CISPLATIN | CARMUSTINE | CYCLO- PHOSPHA- MIDE | DOXO- RUBICIN HYDRO- CHLORIDE | 5- FLUORO- URACIL | METHO- TREXATE | ETOPOSIDE | PACLITAXEL | THIOTEPA |
|-----------|------------|----------------------------|--|-------------------------|-------------------|-----------|------------|------------------|
| >042 | <6 | 217 (275,162,215) | >240 | >240 | >240 | >240 | <10 | 30 (28,30,33) |

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

TO ORDER

| | | | |
|-----------------|--------------|---------------|-------------|
| Re-Order | Chest | Height | Size |
| S-BDSC-L | N/A | N/A | Universal |

Packing

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

*NOTE: BioClean CleanTough material is static dissipative and, with a charge half decay time of 0.07 sec, are ideal for use in a static-safe environment.

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

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S-BDSC-L/1906/PDS39



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