



# COMPOUNDING PPE

USP 705 • USP 797 • USP 800 • 503B CGMP COMPLIANT



# ...Find our products **fast**...

## CHEMO SAFETY WEAR

BioClean-C Chemotherapy Protective Apron with Sleeves	BCAS & S-BCAS	4
BioClean-C Chemotherapy Protective Apron	BCDA	5
BioClean-C Chemotherapy Protective Sleeve Cover	BCSC & S-BCSC	5

## DISPOSABLE GARMENTS

BioClean-D Drop-Down Garment	S-BDSH	6
BioClean-D Coverall with Hood	BDCHT & S-BDCHT	7
BioClean-D Hood	BDHD-L & S-BDHD-L	8

## OVERSHOES

BioClean-D Overboots	BDOB & S-BDOB	8
BioClean-D Overboots - Longer Length	BDOB-L & S-BDOB-L	8

## GLOVES

Double-donning		10
Double Protection		11
BioClean Ultimate	BUPS	12
BioClean P-Zero	BPZS	12
BioClean Emerald	BENS	13
BioClean N-Plus	BNPS	13
BioClean Fusion	S-BFAP	14

## ACCESSORY

BioClean Chemprep Sterile Prep Mat	S-BCPM	15
------------------------------------	--------	----

## ISOLATOR GLOVES

BioClean Clean Validated Sterile Nitrile Isolator/Rabs Glove	GGL	16
BioClean Clean Non-Sterile Nitrile Isolator/Rabs Glove	CGL	16
BioClean Clean Validated Sterile Nitrile Isolator/Rabs Mitten	GGL30NITM9	16
BioClean Clean Validated Sterile Sleeve/Glove System	GSG10NIT80	17
BioClean Clean Validated Sterile Sleeve/Glove System	GSG10NITXLMA	17

## GOGGLES

BioClean Clearview Sterile Single-Use Goggles	BCGS1	18
BioClean Clearview Sterile Autoclavable Goggles	BCAG	19
BioClean Clearview Autoclavable Panoramic Goggles	BCAP	19

## FACEMASK

BioClean MEA Sterile Facemask	MEA210-1	20
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# COMPOUNDING PPE PRODUCTS

The BioClean Compounding PPE range from Ansell features full head-to-toe coverage combinations of aprons, gloves, coveralls, hoods, overboots, sleeve covers, goggles and facemasks, and are available in sterile or non-sterile.

BioClean-D coveralls, hoods, overboots and sleeve covers are manufactured from specially constructed lightweight, low-linting **white** CleanTough material, and are classified as Category 3 PPE Type 5, 6 or PB[6] and provide the base protection layer. BioClean-C aprons and sleeve covers, manufactured from specially constructed lightweight, low-linting **blue** CleanTough material, are worn over BioClean-D garments providing additional essential protection without compromising comfort.

Both BioClean-D White CleanTough material and BioClean-C Blue CleanTough material have been tested to ASTM F739-12, Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact, using nine cytotoxic test chemicals. We know that exposure to even tiny doses of chemo drugs can be very harmful. This is why we insist on only using the most stringent standards as the benchmark for safety when it comes to garment and glove testing.

BioClean compounding PPE gloves are non-latex, designed to work as a double-gloving system for extra protection and have been tested against ASTM D6978, to ensure the safe handling of chemotherapy drugs. This standard is the internationally accepted standard specifically designed for the assessment of resistance of medical gloves to permeation by chemotherapy drugs, unlike the European standard EN 16523-1:2015 (formally EN 374-3: 2003) which is not specific to chemotherapy drugs and has no requirement to test against any cytotoxics.

Neither this document nor any other statement made herein by or on behalf of Ansell should be construed as a warranty of merchantability or that any Ansell product is fit for a particular purpose. Ansell assumes no responsibility for the suitability or adequacy of an end user's selection of a product for a specific application.

**Warning:** No glove/garment provides complete protection against all chemicals. Users must test the gloves/garments against the particular chemicals and environment in which they will be used.

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BCAS &  
S-BCAS

BIOCLEAN-C  
CHEMOTHERAPY  
PROTECTIVE  
APRON WITH  
SLEEVES

# Ultrasonically bonded & taped seams



{ BCAS & S-BCAS }

## BIOCLEAN-C CHEMOTHERAPY PROTECTIVE APRON WITH SLEEVES

- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs
- Ultrasonically bonded seams with protective tape
- PPE Category 3 Type PB[6]
- Adjustable neck fastening
- Tie tapes at rear
- CleanTough blue material

### Non-Sterile

- ISO Class 4 compatible

### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL) 10<sup>-6</sup>

### Re-order Code

#### Non-sterile

BCAS-S  
BCAS-M  
BCAS-L  
BCAS-XL

#### Sterile

S-BCAS-S  
S-BCAS-M  
S-BCAS-L  
S-BCAS-XL

#### Size

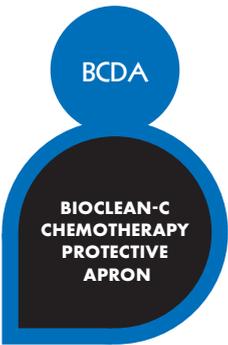
Small  
Medium  
Large  
XLarge

### Packing

40 individually packed aprons per carton

### Standards





{ BCDA }

**BIOCLEAN-C CHEMOTHERAPY PROTECTIVE APRON**

- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs
- Adjustable neck fastening
- PPE Category 3 Type PB[6]
- Tie tapes at rear
- CleanTough blue material
- ISO Class 4 compatible

**Re-order Code**

**Non-sterile**

BCDA-S  
BCDA-M  
BCDA-L

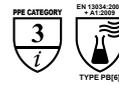
**Size**

Small  
Medium  
Large

**Packing**

50 individually packed aprons per carton

**Standards**



{ BCSC & S-BCSC }

**BIOCLEAN-C CHEMOTHERAPY PROTECTIVE SLEEVE COVER**

- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs
- Ultrasonically bonded seams with protective tape
- PPE Category 3 Type PB[6]
- Elasticated arm for a secure fit
- Elasticated polyester cuff for comfort
- CleanTough blue material

**Non-Sterile**

- ISO Class 4 compatible

**Sterile**

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL) 10<sup>-6</sup>

**Re-order Code**

Non-sterile	Sterile	Size
BCSC	S-BCSC	Universal

**Packing**

- **Non-sterile:** 30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; six outer bags per lined carton (180 pieces)
- **Sterile:** One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; six outer bags per lined carton (90 pairs)

**Standards**



S-BDSH

BIOCLEAN-D  
COVERALL  
DROP-DOWN  
GARMENT



{ S - B D S H }

#### BIOCLEAN-D DROP-DOWN GARMENT

- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs
- Anti-static, low-linting & durable CleanTough white material
- Thumb loop to ensure secure hold
- Quick release press stud tabs for touch-free donning
- Elasticated hood, back, cuffs and ankles
- Elasticated face opening with reinforced edges

#### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL)  $10^{-6}$

#### Re-order Code

Sterile	Size
S-BDSH-XS	X-Small
S-BDSH-S	Small
S-BDSH-M	Medium
S-BDSH-L	Large
S-BDSH-XL	X-Large
S-BDSH-XXL	2X-Large
S-BDSH-XXXL	3X-Large
S-BDSH-XXXXL	4X-Large*
S-BDSH-5XL	5X-Large*
S-BDSH-6XL	6X-Large*
S-BDSH-7XL	7X-Large*
S-BDSH-8XL	8X-Large*

#### Packing

20 individually packed pieces per carton  
(3XL, 4XL, 5XL, 6XL, 7XL & 8XL – 15 pieces per carton)

\*Size subject to minimum order quantity and lead time.

BDCHT & S-BDCHT

BIOCLEAN-D  
COVERALL  
WITH HOOD



# protection — FROM — head to foot

{ BDCHT & S-BDCHT }

## BIOCLEAN-D COVERALL WITH HOOD

- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs
- PPE Category 3 Type 5 & 6
- Anti-static, low-linting & durable CleanTough white material
- Thumb loop to ensure secure hold
- Zip with cover
- Elasticated back, cuffs and ankles
- Elasticated face opening with reinforced edges

### Non-sterile

- ISO Class 4 compatible

### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL)  $10^{-6}$

### Standards



### Re-order Code

Non-sterile	Sterile	Size
BDCHT-XS	S-BDCHT-XS	X-Small
BDCHT-S	S-BDCHT-S	Small
BDCHT-M	S-BDCHT-M	Medium
BDCHT-L	S-BDCHT-L	Large
BDCHT-XL	S-BDCHT-XL	X-Large
BDCHT-XXL	S-BDCHT-XXL	2X-Large
BDCHT-XXXL	S-BDCHT-XXXL	3X-Large
BDCHT-XXXXL	S-BDCHT-XXXXL	4X-Large*
BDCHT-5XL	S-BDCHT-5XL	5X-Large*
BDCHT-6XL	S-BDCHT-6XL	6X-Large*
BDCHT-7XL	S-BDCHT-7XL	7X-Large*

### Packing

20 individually packed pieces per carton  
(3XL, 4XL, 5XL, 6XL & 7XL – 15 pieces per carton)

\*Size subject to minimum order quantity and lead time.



BDHD-L & S-BDHD-L

BIOCLEAR-D HOOD

{ BDHD-L & S-BDHD-L }

### BIOCLEAR-D HOOD

- PPE Category 3 Type PB[6]
- Anti-static, low-linting & durable CleanTough white material
- Elasticated face opening with reinforced edges
- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drug

#### Non-sterile

- ISO Class 4 compatible

#### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL)  $10^{-6}$

#### Re-order Code

Non-sterile	Sterile	Size
BDHD-L	S-BDHD-L	Universal

#### Packing

- **Non-sterile:** 20 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; six outer bags per lined carton (120 pieces)
- **Sterile:** One piece per sealed inner PE bag; 20 inner bags per sealed outer PE bag; six outer bags per lined carton (120 pieces)

{ BDOB & S-BDOB }

### BIOCLEAR-D OVERBOOTS

- PPE Category 3 Type PB[6]
- Anti-static, low-linting & durable CleanTough white material
- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drug
- Elasticated top with secure ties
- Slip-resistant soles

#### Non-sterile

- ISO Class 4 compatible

#### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL)  $10^{-6}$

#### Re-order Code

Non-sterile	Sterile	Size
BDOB	S-BDOB	Universal

#### Packing

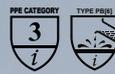
- **Non-sterile:** 30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; five outer bags per lined carton (150 pieces)
- **Sterile:** One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; five outer bags per lined carton (75 pairs)

BDOB & S-BDOB

BIOCLEAR-D OVERBOOTS



Standards



{ BDOB-L & S-BDOB-L }

### BIOCLEAR-D OVERBOOTS - LONGER LENGTH

- PPE Category 3 Type PB[6]
- Anti-static, low-linting & durable CleanTough white material
- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drug
- Elasticated top with secure ties at calf and ankle
- Slip-resistant soles

#### Non-sterile

- ISO Class 4 compatible

#### Sterile

- ISO Class 4 & EU GMP Grade A compatible
- Sterility Assurance Level (SAL)  $10^{-6}$

#### Re-order Code

Non-sterile	Sterile	Size
BDOB-L	S-BDOB-L	Universal

#### Packing

- **Non-sterile:** 30 pieces per sealed inner PE bag; one inner bag per sealed outer PE bag; five outer bags per lined carton (150 pieces)
- **Sterile:** One pair per sealed inner PE bag; 15 inner bags per sealed outer PE bag; five outer bags per lined carton (75 pairs)



BDOB-L & S-BDOB-L

BIOCLEAR-D OVERBOOTS - LONGER LENGTH

Standards



ISOLATING GLOVES OR ISOLATING GLOVES  
ACCESSORIES & GLOVES

# DOUBLE -donning

BioClean non-latex compounding gloves are designed to work as a double-gloving system, offering operators an additional layer of protection throughout the chemo preparation and administration process.

Tested against the most stringent applicable standard, ASTM D6978, BioClean compounding gloves are best in class. Our results record excellent barrier performance using  $0.01 \mu\text{g}/\text{cm}^2/\text{min}$  as the permeation limit - a level 100 times more stringent than under EN 16523-1:2015 (formally EN374-3: 2003, which is more commonly used and less stringent than the ASTM standard.)

By using a brightly colored underglove with a natural colored outer glove, any breach is immediately visible, giving the operator an early signal to change gloves.

## Our Double-donning Combinations

**BENS**  
(pg 13)

**BENS**  
(pg 13)

**BENS**  
(pg 13)

**BUPS**  
(pg 12)

**BPZS**  
(pg 12)

**BNPS**  
(pg 13)

# DOUBLE protection

## Double-Donning Procedure

- **Easy-on technology** – Allowing all non-latex chemotherapy gloves to double-glove with ease
- **Early warning** – Double-gloving with a colored underglove allows operators to identify a breach immediately
- **Safety in layers** – Double-gloving testing on a combination of our BioClean Ultimate and BioClean Emerald shows ZERO permeation detected after 4 hours against ASTM D6978
- **Flexibility in choice** – Multiple combinations of double-donnable gloves available to suit your SOP and production requirements
- **Skin friendly** – All our chemotherapy gloves are 100% latex-free, eliminating risk from protein based allergies
- **Contamination control** – All gloves are processed and packed in an NEBB certified ISO Class 4 Cleanroom and validated for sterility





{ B U P S }

**BIOCLEAN ULTIMATE  
STERILE POLYCHLOROPRENE GLOVES**  
Excellent sensitivity & tactility

- 300mm/12" length
- Sterility Assurance Level: **10<sup>-6</sup>**
- AQL: **0.65**
- Finger Tip Thickness: **5.5 mils**
- Textured
- Hand specific
- Natural
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978
- Complies with EN ISO 374, EN 420, EN 455
- Packing: One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

Re-order Code	Size
BUPS-60	6.0
BUPS-65	6.5
BUPS-70	7.0
BUPS-75	7.5
BUPS-80	8.0
BUPS-85	8.5
BUPS-90	9.0

{ B P Z S }

**BIOCLEAN P-ZERO  
STERILE POLYCHLOROPRENE GLOVES**  
Exceptional grip & cytotoxic protection

- 300mm/12" length
- Sterility Assurance Level: **10<sup>-6</sup>**
- AQL: **0.65**
- Finger Tip Thickness: **7.0 mils**
- Textured
- Hand specific
- Natural
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978
- Complies with EN ISO 374, EN 420, EN 455
- Packing: One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

Re-order Code	Size
BPZS60	6.0
BPZS65	6.5
BPZS70	7.0
BPZS75	7.5
BPZS80	8.0
BPZS85	8.5
BPZS90	9.0



{ BENS }

**BIOCLEAR EMERALD  
STERILE NITRILE GLOVES**  
Highly tactile underglove

- 300mm/12" length
- Sterility Assurance Level: **10<sup>-6</sup>**
- AQL: **0.65**
- Finger Tip Thickness: **5.1 mils**
- Textured
- Hand specific
- Green
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978
- Complies with EN ISO 374, EN 420, EN 455
- Packing: One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

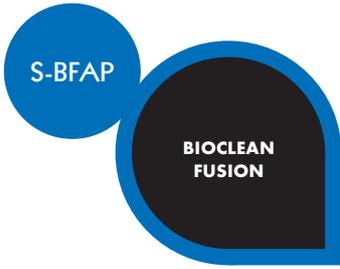
Re-order Code	Size
BENS6.0	6.0
BENS6.5	6.5
BENS7.0	7.0
BENS7.5	7.5
BENS8.0	8.0
BENS8.5	8.5
BENS9.0	9.0
BENS10.0	10.0

{ BNPS }

**BIOCLEAR N-PLUS  
STERILE NITRILE GLOVES**  
Elbow length for extra protection

- 400mm/16" length
- Sterility Assurance Level: **10<sup>-6</sup>**
- AQL: **0.65**
- Finger Tip Thickness: **7.9 mils**
- Textured
- Hand specific
- White
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978
- Complies with EN ISO 374, EN 420, EN 455
- Packing: One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

Re-order Code	Size
BNPS60	6.0
BNPS65	6.5
BNPS70	7.0
BNPS75	7.5
BNPS80	8.0
BNPS85	8.5
BNPS90	9.0
BNPS100	10.0



{ S - B F A P }

**BIOCLEAN FUSION  
STERILE POLYCHLOROPRENE GLOVES**  
Excellent grip & double-donnable

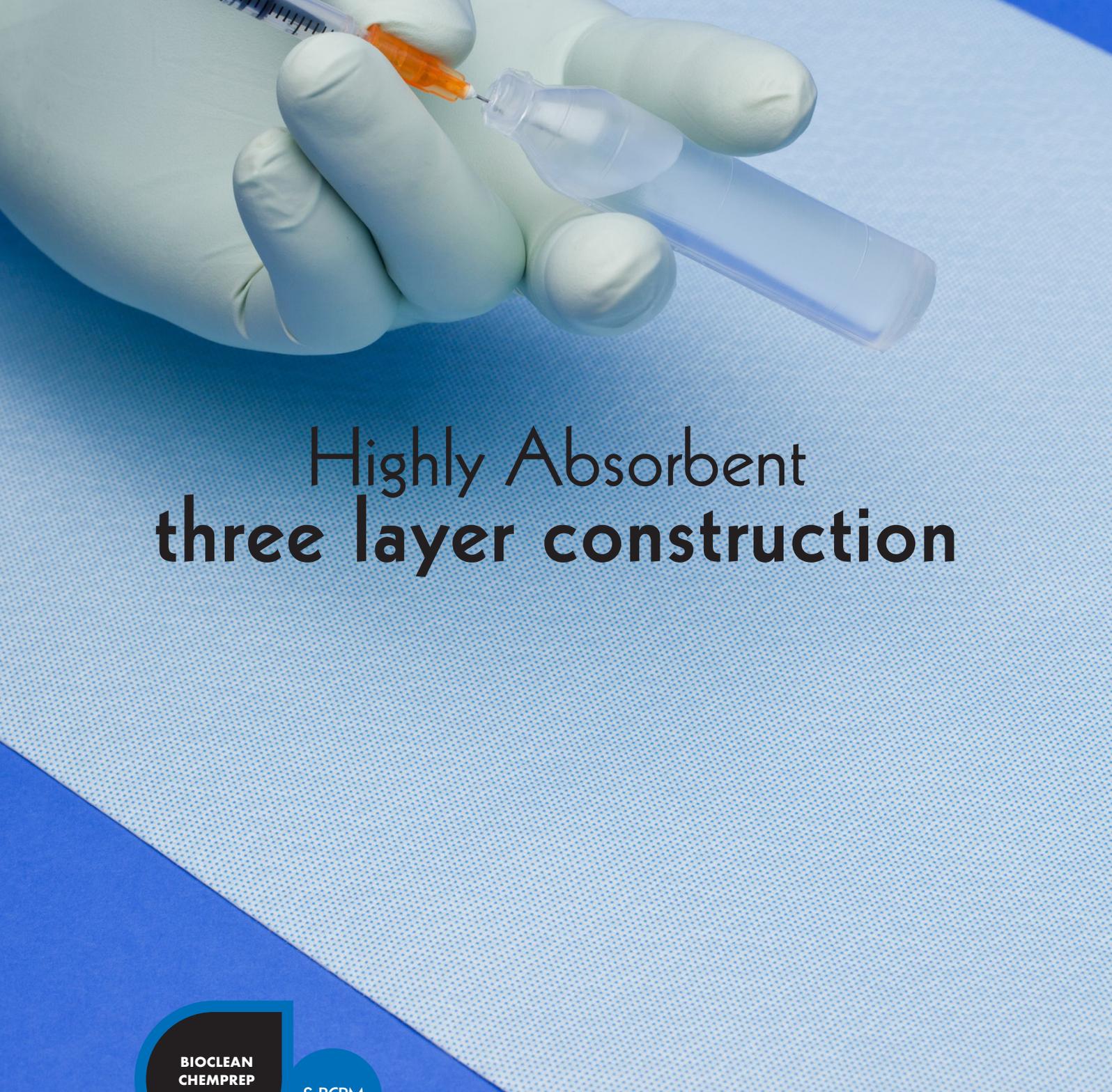
- 290mm/11.4" length
- Sterility Assurance Level: **10<sup>-6</sup>**
- AQL: **0.65**
- Finger Tip Thickness: **4.72 mils**
- Finger Textured
- Ambidextrous
- Green
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978
- Complies with EN ISO 374, EN 420, EN 455
- Packing: One pair per inner PE wallet; one wallet per sealed EasyTear PE pouch; 10 pouches per sealed outer PE bag; 20 outer bags per lined carton (200 pairs)

**Re-order Code**

S-BFAP-5055  
S-BFAP-6065  
S-BFAP-7075  
S-BFAP-8085  
S-BFAP-9090  
S-BFAP-1010

**Size**

5.0-5.5  
6.0-6.5  
7.0-7.5  
8.0-8.5  
9.0  
10.0



# Highly Absorbent three layer construction

**BIOCLEAN  
CHEMPREP  
PREP MAT**

**S-BCPM**

{ S - B C P M }

## **BIOCLEAN CHEMPREP STERILE PREP MAT**

- Mesh upper layer for even distribution
- Highly absorbent middle layer
- Impermeable bottom layer
- Low-linting, latex-free, triple laminate
- ISO Class 5 & EU GMP Grade A compatible
- Blue colour to easily identify spills
- Available in two sizes

<b>Re-order Code</b>	<b>Size</b>	<b>Packing</b>
S-BCPM-4025B	40cm x 25cm	One piece per sealed inner PE bag; one inner bag per second PE bag; 50 double bags per sealed outer PE bag; four outer bags per lined carton (200 pieces)
S-BCPM-5640B	56cm x 40cm	One piece per sealed inner PE bag; one inner bag per second PE bag; 25 double bags per sealed outer PE bag; four outer bags per lined carton (100 pieces)



GGL

CLEAN,  
VALIDATED STERILE  
NITRILE GLOVE

{ GGL }

**BIOCLEAN CLEAN VALIDATED STERILE  
NITRILE ISOLATOR/RABS GLOVE**

- 840mm/33" length
- Smooth surface
- White
- Suitable for port sizes 150mm - 355mm (6" to 12")
- 100% inspected water & air leak tested
- Can be sanitized with VHP or IPA
- Suitable for autoclaving
- EU GMP Grade A compatible
- Complies with EN ISO 374, EN 420, EN 455 & EN 388
- Tested against permeation standard ASTM D6978
- Packing: Each glove folded with hand inside sleeve. Triple bagged, 20 pieces per correx case

Re-order Code	Port Size	Glove Size
GGL15NIT59	6"	9.75
GGL20NIT59	8"	9.75
GGL33NIT59	10"	9.75
GGL36NIT59	12"	9.75

{ CGL }

**BIOCLEAN CLEAN NON-STERILE  
NITRILE ISOLATOR/RABS GLOVE**

- 840mm/33" length
- Smooth surface
- White
- Suitable for port sizes 200mm - 355mm (8" to 12")
- 100% inspected water & air leak tested
- Can be sanitized with VHP or IPA
- Suitable for autoclaving
- EU GMP Grade A compatible
- Complies with EN ISO 374, EN 420, EN 455 & EN 388
- Tested against permeation standard ASTM D6978
- Packing: Each glove folded with hand inside sleeve. Triple bagged, 20 pieces per correx case

Re-order Code	Port Size	Glove Size
CGL20NIT59	8"	9.75
CGL33NIT59	10"	9.75
CGL36NIT59	12"	9.75

CGL

CLEAN,  
NON-STERILE  
NITRILE GLOVE



{ GGL30NITM9 }

**BIOCLEAN CLEAN VALIDATED STERILE  
NITRILE ISOLATOR/RABS MITTEN**

- 840mm/33" length
- Smooth surface
- White
- Suitable for port size 200mm (8")
- 100% inspected water & air leak tested
- Can be sanitized with VHP or IPA
- Suitable for autoclaving
- EU GMP Grade A compatible
- Complies with EN ISO 374, EN 420, EN 455 & EN 388
- Tested against permeation standard ASTM D6978
- Packing: Triple bagged, 20 pieces per correx case

Re-order Code	Port Size	Glove Size
GGL30NITM9	8"	9.75

GGL30NITM9

CLEAN,  
VALIDATED STERILE  
NITRILE MITTEN





GSG10NIT80  
&  
GSG10NIT85

CLEAN,  
VALIDATED  
STERILE SLEEVE/  
GLOVE SYSTEM



GSG10NITXLMA

CLEAN,  
VALIDATED  
STERILE SLEEVE/  
GLOVE SYSTEM

### { GSG10NIT80 & GSG10NIT85 }

#### BIOCLEAR CLEAN VALIDATED STERILE SLEEVE/GLOVE SYSTEM

- Nitrile sleeve/Polychloroprene glove
- White sleeve/white glove
- 800mm/32" system length
- Hand specific hand shape, textured surface
- Suitable for port size 200mm (8")
- EU GMP Grade A compatible
- Complies with EN ISO 374, EN 420, EN 455
- Tested against permeation standard ASTM D6978
- Packing: One sleeve per triple bag including size 8 or 8.5 PCP glove (marked L or R) and channel ring/O-ring assembly.  
Packed by pair: two triple bagged sleeve/glove/assembly per system; 10 systems per box, two boxes per outer box (20 systems)

Re-order Code	Port Size	Glove Size
GSG10NIT80	8"	8
GSG10NIT85	8"	8.5

**Replacement Glove**  
BPZS BioClean P-Zero

For full glove details see page 12

### { GSG10NITXLMA }

#### BIOCLEAR CLEAN VALIDATED STERILE SLEEVE/GLOVE SYSTEM

- Nitrile sleeve/Polychloroprene glove
- White sleeve/green glove
- 910mm/36" system length
- Ambidextrous hand shape, textured surface
- Suitable for port size 200mm (8")
- EU GMP Grade A compatible
- Complies with EN ISO 374, EN 420, EN 455
- Tested against permeation standard ASTM D6978
- Packing: One sleeve per triple bag including size 8 PCP glove (marked L or R) and channel ring/O-ring assembly.  
Packed by pair: two triple bagged sleeve/glove/assembly per system; 10 systems per box, two boxes per outer box (20 systems)

Re-order Code	Port Size	Glove Size
GSG10NITXLMA	8"	8

**Replacement Glove**  
S-BFAP BioClean Fusion

For full glove details see page 14

BCGS1

BIOCLEAN  
CLEARVIEW  
SINGLE-USE  
GOGGLES

anti-fog &

anti-scratch

{ BCGS1 }

**BIOCLEAN CLEARVIEW  
STERILE SINGLE-USE GOGGLES**

- Lightweight ultra-soft PVC
- Indirect ventilation system
- ISO Class 4 & EU GMP Grade A compatible
- EtO sterilized
- Non-linting head band
- Tested to ANSI/ISEA Z87.1-2010
- Toughened polycarbonate lens with anti-fog & anti-scratch coating
- Packing: Six bags of 10 individually packed goggles (60 goggles) per carton

Re-order Code

BCGS1

Standards



# Toughened, **Anti-fog** Lens

{ BCAG }

## BIOCLEAR CLEARVIEW AUTOCLAVABLE GOGGLES

- Toughened anti-scratch, anti-fog polycarbonate lens
- > 40 autoclave cycles
- Thermoplastic rubber body
- Indirect lower vents
- ISO Class 4 & EU GMP Grade A compatible when sterilized
- Non-linting head band
- Can be worn over eyeglasses

Also available with blocked upper and/or lower vents

Re-order	Code Item	Packaging
BCAG	Goggles	12 pieces
BCAG-SL	Spare lens	10 pieces
BCAG-SS	Spare straps	50 pieces

Standards



BCAG

BIOCLEAR  
CLEARVIEW  
AUTOCLAVABLE  
GOGGLES



# extra **wide lens** for **panoramic** vision

{ BCAP }

## BIOCLEAR CLEARVIEW AUTOCLAVABLE PANORAMIC GOGGLES

- Toughened anti-scratch, anti-fog polycarbonate lens
- Can be worn over large eyeglasses
- Panoramic vision
- Thermoplastic rubber body
- Indirect ventilation system
- ISO Class 4 & EU GMP Grade A compatible when sterilized
- Non-linting head band
- Lightweight & comfortable
- > 40 autoclave cycles

Re-order	Code Item	Packaging
BCAP	Goggles	12 pieces
BCAP-SL	Spare lens	10 pieces
BCAP-SS	Spare straps	50 pieces

Standards



BCAP

BIOCLEAR  
CLEARVIEW  
AUTOCLAVABLE  
PANORAMIC  
GOGGLES





**BIOCLEAN  
MEA STERILE  
FACEMASK**

MEA210-1

breathe easy



{ MEA210-1 }

**BIOCLEAN MEA  
STERILE FACEMASK**

- ISO Class 4 & EU GMP Grade A compatible
- Non-latex polyurethane loops with secure fastening
- Ultrasonically sealed edges
- High bacterial, viral & particle efficiency filtration
- Packing: One piece (with blue clip) per sealed inner PE bag; 50 inner bags per sealed outer PE bag; 12 outer bags per lined carton (600 pieces)

**Re-order Code**

MEA210-1

breathe clean

# Glove Cytotoxic Testing

BioClean compounding PPE gloves are tested against the most stringent standard, the American ASTM D6978 (see results in Table 1), which employs a testing limit 100 times more stringent than its European counterpart. We do **not** promote our products using results achieved under EN 16523-1:2015 (formally known as EN374-3:2003) as, quite simply, this benchmark is not safe when assessing the suitability of a glove for protection against cytotoxic drugs.

To illustrate how misleading the EN 16523-1:2015 standard can be when used to test the permeation of cytotoxic drugs (compared to the ASTM D6978 standard - which is designed specifically for cytotoxics), we have tested our gloves using the permeation rate prescribed by EN 16523-1:2015, the results show no breakthrough after 480 minutes at the 1.00 µg/cm<sup>2</sup>/min level (see results in Table 2). We could have chosen to publish these misleading first-class results, and foregone testing using the ASTM D6978 standard, but we know that exposure to even tiny doses of cytotoxic drugs can be very harmful. This is why we insist on only using the ASTM D6978 as the benchmark for safety when it comes to glove testing.

## Comparisons between EN 16523-1:2015 and ASTM D6978

DIFFERENCE	EN 16523-1:2015 *	ASTM D6978 **	CONSEQUENCE
Thickness of the Test Specimens	Three sample has to be taken from the palm of the glove. New requirement for gloves 400mm or longer - three additional samples must be taken from the cuff area and tested for permeation.	Sample has to be taken from either the palm or the cuff of the glove, whichever is the thinner.	The ASTM D6978 requirement ensures that the area of greatest risk is assessed. The cuff is usually the thinnest part of the glove, so gloves tested under EN 16523-1:2015 are not challenged as rigorously.
Test Temperature	Testing to be conducted at a temperature of 23° ±1 °C.	Testing to be conducted at a temperature of 35° ±2 °C.	The higher temperature specified by ASTM D6978 has two consequences: <ul style="list-style-type: none"> <li>• The temperature is 2°C below body core temperature, which is similar to that of a human hand.</li> <li>• Permeation rates are greater at higher temperatures, making the test more stringent.</li> </ul>
Test Chemicals	The test chemicals list has been increased from 12 to 18. A minimum of one chemical from this predefined list must be used for the test. None of the predefined chemicals is a chemotherapy drug.	A minimum of nine chemotherapy drugs must be used for the test. Seven of them are pre-defined by the standard; the other two must be selected from a pre-defined list.	The EN 16523-1:2015 list of chemicals will not give a representation of how the gloves will perform when challenged by chemotherapy drugs. Users purchasing gloves for chemo use should be advised to have them tested for suitability.
Permeation Limit	Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 1 µg/cm <sup>2</sup> /min.	Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm <sup>2</sup> /min.	The ASTM D6978 test limit is set at 1/100th of the EN 16523-1:2015 limit. This requirement is far more stringent and reflects the potential hazards presented by chemotherapy drugs.

\* **EN 16523-1:2015**  
Protective gloves against chemicals and microorganisms

\*\* **ASTM D6978**  
Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs.

**Table 1: Breakthrough detection time (minutes) as per ASTM D6978**Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm<sup>2</sup>/min

CHEMO DRUG	BUPS & BENS*	BSNS	BUPS	BPZS	BENS	BNPS	BNPLS	BFAP
	<b>Double-Gloving Results</b>							
Cisplatin	>480	>240	>480	>480	>480	>480	>480	>240
Carmustine	>240	0.2	2.0	50.3	12.4	2.5	1.70	26
Cyclophosphamide	>480	>240	>480	>480	>480	>480	>480	>240
Doxorubicin Hydrochloride	>480	>240	>480	>480	>480	>480	>480	>240
5-Fluorouracil	>480	>240	>480	>480	>480	>480	>480	>240
Methotrexate	>480	>240	>480	>480	>480	>480	>480	>240
Etoposide	>480	>240	>480	>480	>480	>480	>480	>240
Paclitaxel	>480	>240	>480	>480	>480	>480	>480	>240
Thiotepa	377	15.4	47.7	107.7	30.5	111	0.52	35

\* Test was carried out using a combination of BENS as the inner glove and BUPS as the outer glove

**Table 2: Breakthrough detection time (minutes) as per EN 16523-1:2015**Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 1.00 µg/cm<sup>2</sup>/min

CHEMO DRUG	BUPS	BENS	BPZS	BNPS	BNPLS
Cisplatin	>480 (CLASS 6)				
Carmustine	>480 (CLASS 6)				
Cyclophosphamide	>480 (CLASS 6)				
Doxorubicin Hydrochloride	>480 (CLASS 6)				
5-Fluorouracil	>480 (CLASS 6)				
Methotrexate	>480 (CLASS 6)				
Etoposide	>480 (CLASS 6)				
Paclitaxel	>480 (CLASS 6)				
Thiotepa	>480 (CLASS 6)				

# Ansell TouchNTuff® Compounding Gloves

	TOUCHNTUFF 83-500	TOUCHNTUFF 93-700	TOUCHNTUFF 73-701	TOUCHNTUFF 73-500
Testing Chemotherapy Drugs	Breakthrough detection time (minutes) as per ASTM D6978 Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm <sup>2</sup> /min			
Carmustine	10.2 (10.2, 12.7, 10.2)	2.5	30.2* (30.2, 25.2, 30.4)	30.3 (30.4, 30.3, 30.3)
Cisplatin	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min
Cyclophosphamide	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Cytarabine	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	NT
Docetaxel	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Doxorubicin Hydrochloride	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Etoposide (Toposar)	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Fluorouracil	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Ganciclovir	NT	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Ifosfamide	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Irinotecan	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Methotrexate	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Mitomycin	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Oxaliplatin	No breakthrough up to 240 min	NT	No breakthrough up to 240 min	No breakthrough up to 240 min
Paclitaxel (Taxol)	No breakthrough up to 240 min	No breakthrough up to 240 min	No breakthrough up to 240 min*	No breakthrough up to 240 min
Thiotepa	11.5 (20.3, 11.5, 20.3)	No breakthrough up to 240 min	61.4* (61.4, 61.5, 76.4)	61.0 (61.0, 61.0, 75.6)
Vincristine Sulfate	No breakthrough up to 240 min	NT	No breakthrough up to 240 min*	No breakthrough up to 240 min

NT = Not Tested

\* = Permeation results as per ASTM D6978 standard for GAMMEX® PF DermaPrene®. Ansell TouchNTuff® DermaShield 73-701 glove (certified as Personal Protective Equipment) are the equivalent of the Ansell surgical glove GAMMEX® PF DermaPrene® (also called GAMMEX® Non-Latex) (certified as Medical Device). These two references have the same ingredients composition and are also manufactured on the same production line. The TouchNTuff® DermaShield 73-701 gloves receive additional after treatment.

All permeation results as per ASTM D6978 standard for GAMMEX® Non-Latex PI, equivalent to TouchNTuff® 83-500.

All permeation results as per ASTM D6978 standard for GAMMEX® DermaPrene Ultra, equivalent to TouchNTuff® 73-500.

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*Warning: No glove/garment provides complete protection against all chemicals. Users must test the gloves/garments against the particular chemicals and environment in which they will be used.*

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