



CHEMO SAFETY WEAR

The BioClean Chemo Safety Wear range includes full head-to-toe coverage combinations of aprons, gloves, coveralls, hoods, overboots, sleeve covers, goggles and facemasks and are available in both sterile and non-sterile to suit all controlled environments.

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 and provide 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.

BioClean Chemo Safety Wear gloves are non-latex, designed to work as a double-gloving system for extra protection and have been tested against ASTM D6978-05, 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.



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

• ISO Class 4 & EU GMP Grade A compatible

Re-order Code

Non-sterile	Sterile	Size
BCAS-S	S-BCAS-S	Small
BCAS-M	S-BCAS-M	Mediun
BCAS-L	S-BCAS-L	Large
BCAS-XL	S-BCAS-XL	XLarge

40 individually packed aprons per carton













{ BCDA & S-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

Non-Sterile

• ISO Class 4 compatible

Sterile

• ISO Class 4 & EU GMP Grade A compatible

Re-order Code

Sterile	Size
S-BCDA-S	Small
S-BCDA-M	Medium
S-BCDA-L	Large
	S-BCDA-S S-BCDA-M

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 cuff for tight fit at wrist
- CleanTough blue material

Non-Sterile

• ISO Class 4 compatible

• ISO Class 4 & EU GMP Grade A compatible

Re-order Code

Non-sterile Sterile Size S-BCSC **BCSC** Universal

Packing

- Non-sterile: Six bags of 30 pieces (180 pieces) per carton
- Sterile: Six bags of 15 pairs (90 individually packed pairs) per carton













{ BDCHT & S-BDCHT }

BIOCLEAN-D COVERALL WITH HOOD

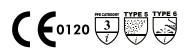
- Material tested against ASTM F739-12 using a minimum of nine cytotoxic drugs.
- PPE Category 3 Type 5 & 6
- Antistatic, low-linting & durable CleanTough white material
- Thumb loop to ensure secure hold
- · Zip with front cover
- Elasticated back, cuffs and ankles
- Elasticated face opening with reinforced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

Non-sterile

• ISO Class 4 compatible

• ISO Class 4 & EU GMP Grade A compatible

Standards



Pa-order Code

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	XX-Large
BDCHT-XXXL	S-BDCHT-XXXL	XXX-Large
BDCHT-XXXXL	S-BDCHT-XXXXL	XXXX-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 (XXXL, XXXXL, 5XL, 6XL & 7XL - 15 pieces per carton)

^{*}Size subject to minimum order quantity and lead time.



{ BDHD-L & S-BDHD-L }

BIOCLEAN-D HOOD

- PPE Category 3 Type PB[6]
- Antistatic, low-linting & durable CleanTough white material
- Elasticated face opening with reinforced edges

Non-sterile

• ISO Class 4 compatible

Sterile

• ISO Class 4 & EU GMP Grade A compatible

Re-order Code

Non-sterileSterileSizeBDHD-LS-BDHD-LUniversal

Packing

- Non-sterile: Six bags of 30 pieces (180 pieces) per carton
- Sterile: Six bags of 30 pieces (180 individually packed pieces) per carton

{ B D O B & S - B D O B }

BIOCLEAN-D OVERBOOTS

- PPE Category 3 Type PB[6]
- Antistatic, low-linting & durable CleanTough white material
- Elasticated top with secure ties
- Slip-resistant soles

Non-sterile

• ISO Class 4 compatible

Sterile

• ISO Class 4 & EU GMP Grade A compatible

Re-order Code

Non-sterileSterileSizeBDOBS-BDOBUniversal

Packing

• Non-sterile: Five bags of 30 pieces (150 pieces) per carton

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• **Sterile:** Five bags of 15 pairs (75 individually packed pairs) per carton





{ BDOB-L & S-BDOB-L }

BIOCLEAN-D OVERBOOTS

- PPE Category 3 Type PB[6]
- Antistatic, low-linting & durable CleanTough white material
- 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

Re-order Code

Non-sterileSterileSizeBDOB-LS-BDOB-LUniversal

Packing

- Non-sterile: Five bags of 30 pieces (150 pieces)per carton
- Sterile: Five bags of 15 pairs (75 individually packed pairs) per carton





{ BDCCT & S-BDCCT }

BIOCLEAN-D COVERALL WITH COLLAR

- PPE Category 3 Type 5 & 6
 Antistatic, low-linting & durable CleanTough white material
- Thumb loop to ensure secure hold
- Zip with front cover
- Elasticated back, cuffs and ankles

Non-sterile

• ISO Class 4 compatible

• ISO Class 4 & EU GMP Grade A compatible

Standards



Re-order Code

Non-sterile	Sterile	Size
BDCCT-XS	S-BDCCT-XS	X-Small
BDCCT-S	S-BDCCT-S	Small
BDCCT-M	S-BDCCT-M	Medium
BDCCT-L	S-BDCCT-L	Large
BDCCT-XL	S-BDCCT-XL	X-Large
BDCCT-XXL	S-BDCCT-XXL	XX-Large
BDCCT-XXXL	S-BDCCT-XXXL	XXX-Large*
BDCCT-XXXXL	S-BDCCT-XXXXL	XXXX-Large*
BDCCT-5XL	S-BDCCT-5XL	5X-Large*
BDCCT-6XL	S-BDCCT-6XL	6X-Large*
BDCCT-7XL	S-BDCCT-7XL	7X-Large*

Packing

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

^{*}Size subject to minimum order quantity and lead time.



DOUBLE-doni DOUBLE pre

BioClean non-latex chemotherapy 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 world's most stringent applicable standard, ASTM D6978-05, BioClean chemo safety gloves are best in class.

Our results record excellent barrier performance using $0.01 \mu g/cm^2/min$ 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 coloured underglove with a natural coloured outer glove, any breach is immediately visible, giving the operator an early signal to change gloves.

Our Double-donning Combinations



Double-Donning Procedure

ningotection

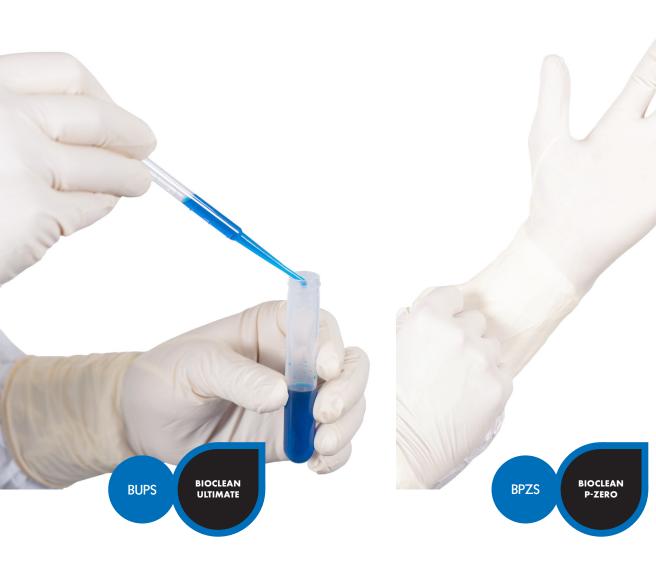




- Easy-on technology Proprietary technology allowing all non-latex chemotherapy gloves to double-glove with ease
- Early warning Double-gloving with a coloured underglove allows operators to identify a breach immediately
- Safety in layers Double-gloving testing on a combination of our BioClean Ultimate and BioClean Emerald shows ZERO permeation detected after 4 hours against ASTM D6978-05
- Flexibility in choice Multiple combinations of doubledonnable 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
- Textured
- Hand specific
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

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

Standards





{ BPZS }

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

- 300mm/12" length
- Textured
- Hand specific
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

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









{ BNPLS }

BIOCLEAN INDIGO STERILE NITRILE GLOVES Textured for enhanced grip

- 300mm/12" length
- Textured fingers
- Ambidextrous
- Purple
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

Not available in USA or Canada

Re-order Code	Size
BNPLS5055	5.0-5.5
BNPLS6065	6.0-6.5
BNPLS7075	7.0-7.5
BNPLS8085	8.0-8.5
BNPLS9090	9.0
BNPLS1010	10.0
BINFLSTUTU	10.0

Standards



{ BNPS }

BIOCLEAN N-PLUS STERILE NITRILE GLOVES Elbow length for extra protection

- 400mm/16" length
- Textured
- Hand specific
- White
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

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

Standard:





{ BENS }

BIOCLEAN EMERALD STERILE NITRILE GLOVES Highly tactile underglove

- 300mm/12" length
- Textured
- Hand specific
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

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

Standards



{ BSNS }

BIOCLEAN SUPRENE STERILE NEOPRENE GLOVES Enhanced softness & strength

- 300mm/12" length
- Textured
- Hand specific
- Double-donnable
- Mint green
- ISO Class 4 & EU GMP Grade A compatible
- Tested against ASTM D6978-05
- Packing: 20 bags of 10 pairs (200 pairs) per carton

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













{ GGL}

BIOCLEAN CLEAN VALIDATED STERILE NITRILE ISOLATOR/RABS GLOVES

- 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 D6978-05
- Packing: Each glove folded with hand inside sleeve.
 Triple bagged, 20 pieces per correx case, Two correx cases per transit correx case (40 pieces).

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 GLOVES

- 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 D6978-05
- Packing: Each glove folded with hand inside sleeve.
 Triple bagged, 20 pieces per correx case, Two correx cases per transit correx case (40 pieces).

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









{ GGL30NITM9 }

BIOCLEAN CLEAN VALIDATED STERILE NITRILE ISOLATOR/RABS MITTEN

- 800mm /31.5" length
- Smooth surface
- White
- Suitable for port sizes 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 D6978-05
- Packing: Triple bagged, 20 pieces per correx case, Two correx cases per transit correx case (40 pieces).

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









{ GSG10NIT80 }

BIOCLEAN CLEAN VALIDATED STERILE SLEEVE/GLOVE SYSTEM

- Nitrile sleeve/Polychloroprene glove
- White sleeve/white glove
- 800mm /32" Sleeve 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 D6978-05
- Packing: One sleeve per triple bag including size 8 glove and assembly (marked L or R); one pair per set; 10 pairs per white Correx box; Two Correx boxes per outer white Correx box (20 pairs)

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

{ GSG10NITXLMA }

BIOCLEAN CLEAN VALIDATED STERILE SLEEVE/GLOVE SYSTEM

- Nitrile sleeve/Polychloroprene glove
- White sleeve/green glove
- 910mm /36" Sleeve 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 D6978-05
- Packing: One sleeve per triple bag including size 8 glove and assembly; one pair per set; 10 pairs per white Correx box; Two Correx boxes per outer white Correx box (20 pairs)

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

Highly Absorbent three layer construction



{ S-BCPM }

BIOCLEAN CHEMPREP STERILE PREP MAT

- Mesh upper layer for even distribution
- Highly absorbent middle layer

S-BCPM

- 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

Re-order Code	Size	Packing
S-BCPM-4025B S-BCPM-5640B	40cm x 25cm 56cm x 40cm	Four bags of 50 double bagged mats (200 mats) per carton Four bags of 25 double bagged mats (100 mats) per carton

Glove Cytotoxic Testing

BioClean Chemo Safety Wear gloves are tested against the most stringent standard, the American ASTM D6978-05 (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 D6978-05 standard - which is designed specifically for cytotoxics), we have tested our gloves using the permeation rate prescribed by EN 16523-1:2015 (Table 2) the results show no breakthrough after 480 minutes at the 1.00 µg/cm²/min level. We could have chosen to publish these misleading first-class results, and foregone testing using ASTM D6978-05 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 D6978-05 as the benchmark for safety when it comes to glove testing.

Comparisons between EN 16523-1:2015 and ASTM D6978-05

DIFFERENCE	EN 16523-1:2015*	ASTM D6978-05 **	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 D6978-05 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 D6978-05 has two consequences: The temperature is 2°C below body core temperature, which is similar to that of a human hand. Permeation rates are greater at higher temperatures, making the test more stringent.
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/cm²/min.	Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 µg/cm²/min.	The ASTM D6978-05 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 D6978-05

Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs.

Table 1: Breakthrough detection time (minutes) as per ASTM D6978-05

Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01 $\mu g/cm^2/min$

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

 $^{^{\}star}$ 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 $\mu g/cm^2/min$

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)				

^{**} BSNS testing was terminated at 240 mins



Thermoplastic rubber body

BIOCLEAN CLEARVIEW

AUTOCLAVABLE

GOGGLES

BCAG

{ BCAG }

BIOCLEAN CLEARVIEW AUTOCLAVABLE GOGGLES

- Thermoplastic rubber body
- Indirect lower vents
- ISO Class 4 & EU GMP Grade A compatible when sterilized
- Non-linting head band
- Toughened anti-scratch polycarbonate lens
- > 40 autoclave cycles
- Can be worn over eyeglasses
- Packing: One box of 12 goggles, five boxes (60 goggles) per carton

Also available with blocked upper and/or lower vents

Re-order Code

BCAG Goggles BCAG-SL Spare lens BCAG-SS Spare strap

Standards





{ BCAP }

BIOCLEAN CLEARVIEW AUTOCLAVABLE PANORAMIC GOGGLES

- Can be worn over large eyeglasses
- Panoramic vision
- Thermoplastic rubber body
- Indirect ventilation system
- Toughened anti-scratch polycarbonate lens
- ISO Class 4 & EU GMP Grade A compatible when sterilized
- Non-linting head band
- Lightweight & comfortable
- > 40 autoclave cycles
- Packing: One box of 12 goggles, five boxes (60 goggles) per carton

Re-order Code

BIOCLEAN

CLEARVIEW

AUTOCLAVABLE PANORAMIC

GOGGLES

BCAP Goggles BCAP-SL Spare lens BCAP-SS Spare strap







Asia & Middle East

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