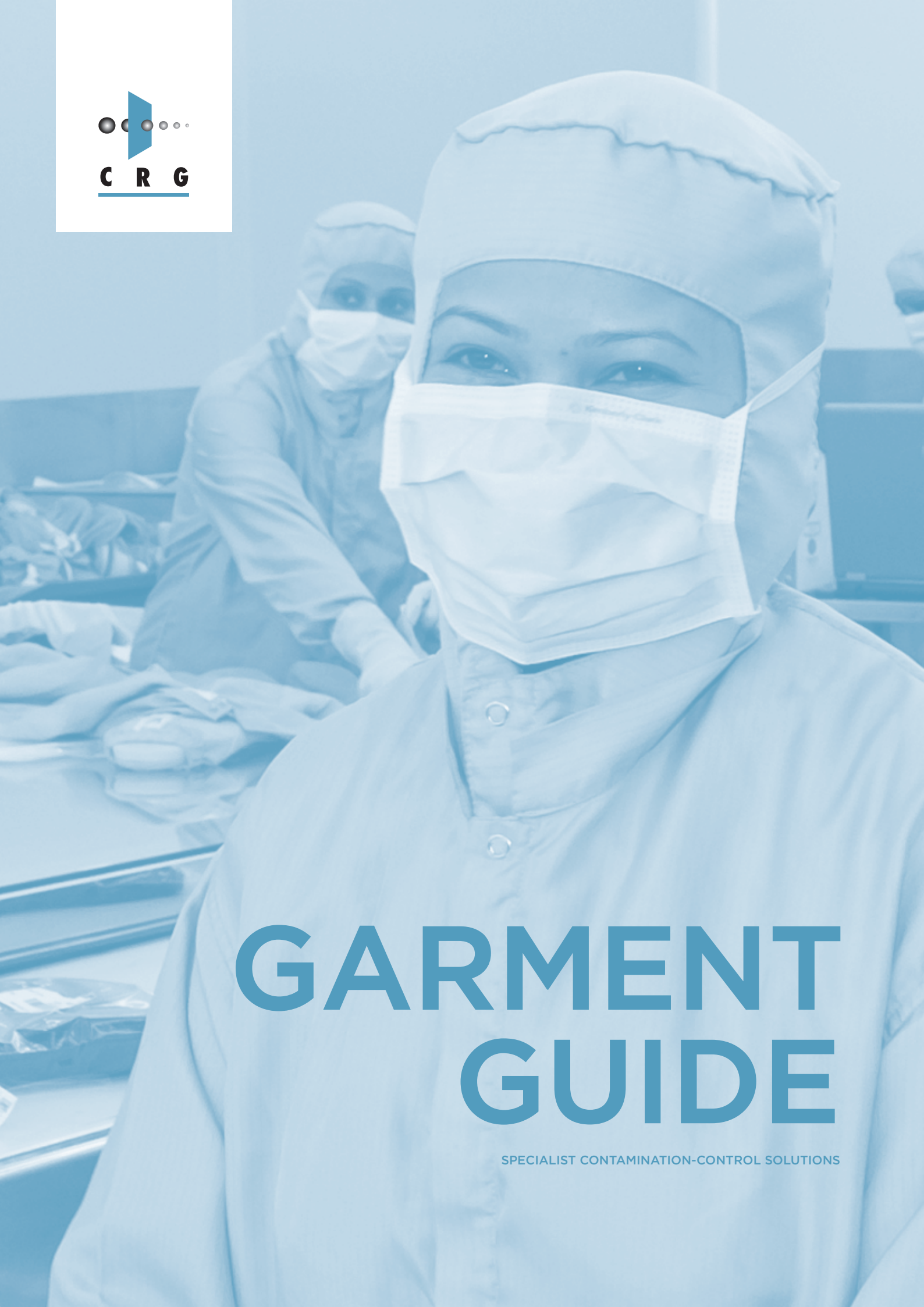


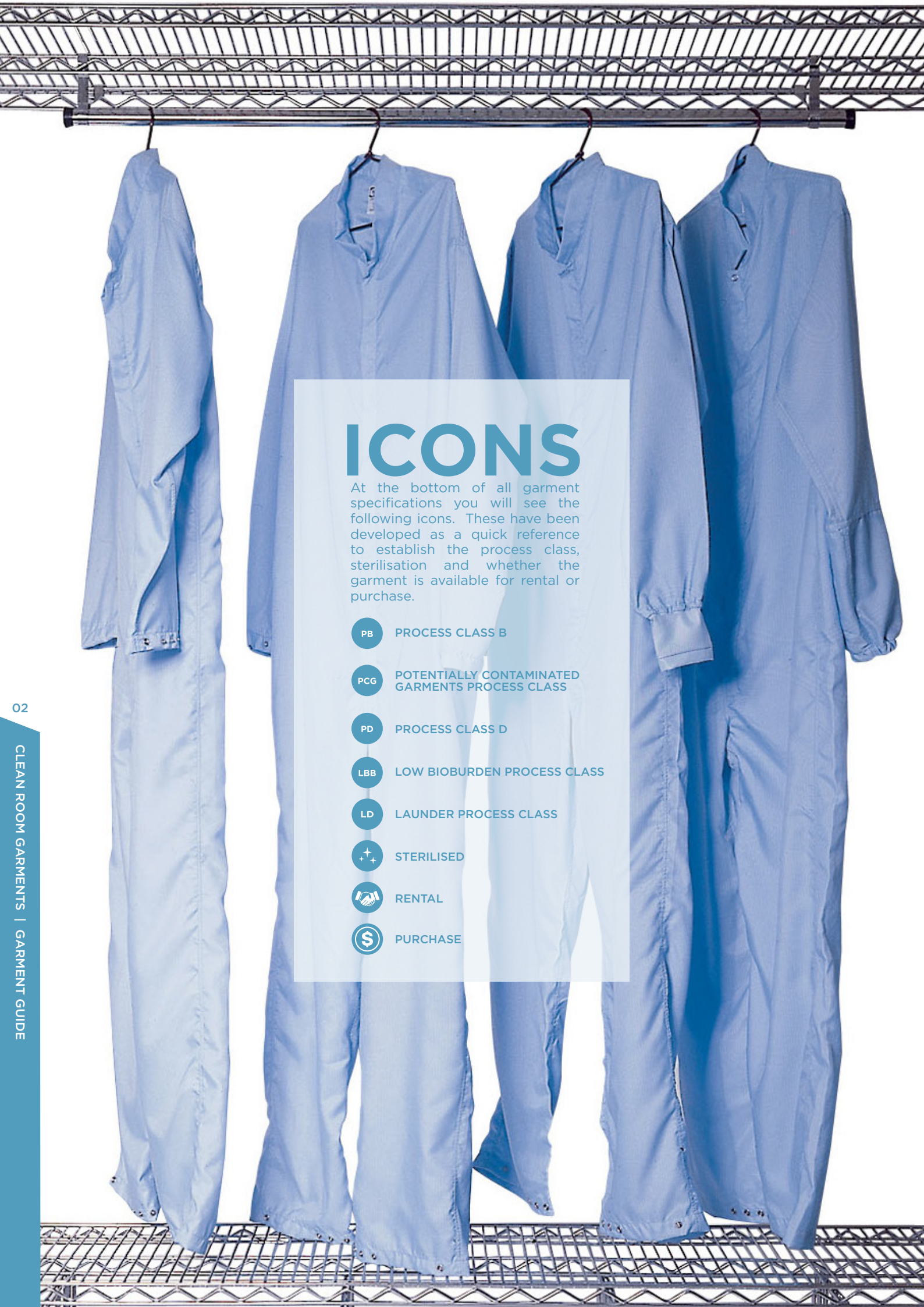
GARMENT GUIDE

SPECIALIST CONTAMINATION-CONTROL SOLUTIONS

Clean Room Garments (CRG) is a world-class provider of specialist contamination-control solutions for the pharmaceutical, medical and food processing industries – the company has been at the top of the industry's rankings for 40 years.

An Australian-based company established in 1970 and owned by the large multinational group ALSCO with an approximate net worth of A$205.5 million, putting CRG in a strong financial position. CRG provides cost-effective, innovative contamination control solutions including ultraclean garment processing, cutting-edge cleanroom garment design and specialised cleanroom products.

CONTENTS



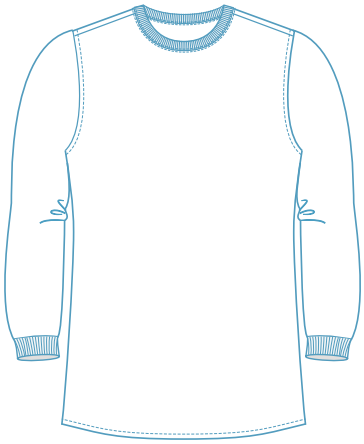
ICONS

At the bottom of all garment specifications you will see the following icons. These have been developed as a quick reference to establish the process class, sterilisation and whether the garment is available for rental or purchase.

- PB — PROCESS CLASS B
- PCG — POTENTIALLY CONTAMINATED GARMENTS PROCESS CLASS
- PD — PROCESS CLASS D
- LBB — LOW BIOBURDEN PROCESS CLASS
- LD — LAUNDER PROCESS CLASS
- STERILISED
- RENTAL
- PURCHASE

CLEAN ROOM GARMENTS | GARMENT GUIDE

GARMENTS



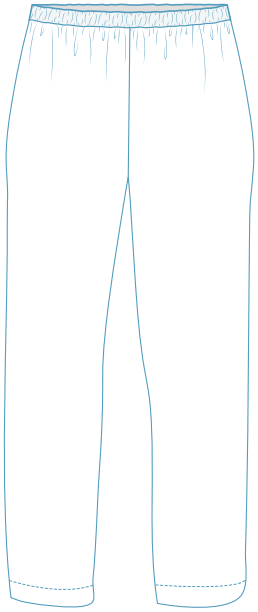
6418 UNDER GARMENT TOP

FABRIC
UNDER GARMENT (WY)..... GSWY6418
100% polyester (knit) with ECF stripe

SEAMS
Overlocked seams

SIZES
XXSM - 5XL

COLOUR
WY Navy



6422 UNDER GARMENT PANT

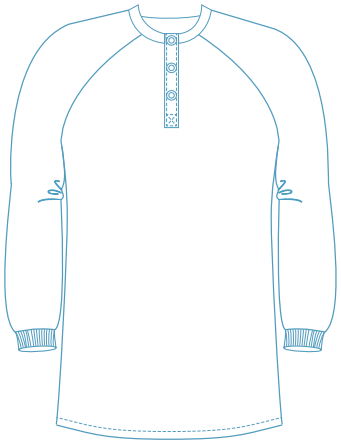
FABRIC
UNDER GARMENT (WY)..... GPWY6422
100% polyester (knit) with ECF stripe

FEATURES
Elasticised waistline

SEAMS
Overlocked seams

SIZES
XXSM - 6XL

COLOUR
WY Navy



6411 UNDER GARMENT TOP

FABRIC

UNDER GARMENT (ZC) GSZC6411
100% polyester twill hi-stretch with moisture finish

FEATURES

- 100% continuous filament polyester sewing thread and elastic
- High grade stainless steel snaps
- Knitted wrist cuffs
- Raglan sleeves

SEAMS

Overlocked seams

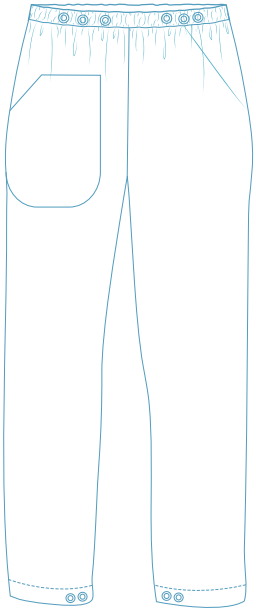
SIZES

XSM - 4XL

COLOUR

ZC Navy

PB PCG PD **LBB** LD



6412 UNDER GARMENT PANT

FABRIC

UNDER GARMENT (ZC) GPZC6412
100% polyester twill hi-stretch with moisture finish

FEATURES

- 100% continuous filament polyester sewing thread and elastic
- High grade stainless steel snaps

SEAMS

Overlocked seams

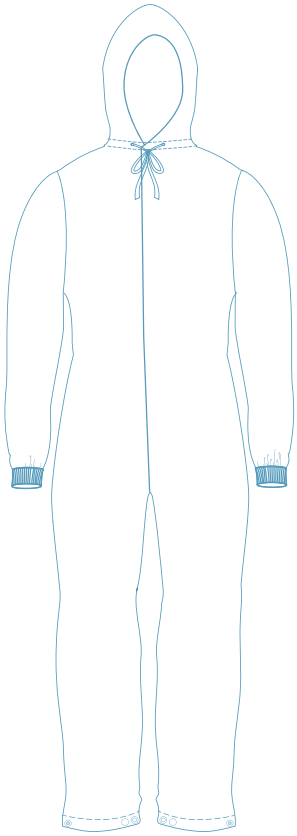
SIZES

XSM - 4XL

COLOUR

ZC Navy

PB PCG PD **LBB** LD



6731 COVERALL

FABRIC

ULTRASHIELD (US) GOUS6731
100% polyester with ECF stripe

INTEGRITY (IN) GOIN6731
100% polyester with ECF stripe

FEATURES

- Coverall with hood
- Knitted cuffs with thumb loop
- Zip front with clip closure at neck
- Adjustable stainless steel clip closure at ankle
- Neck tie
- Suitable to wear when dealing with cytotoxic drugs

SEAMS

Overlocked seams

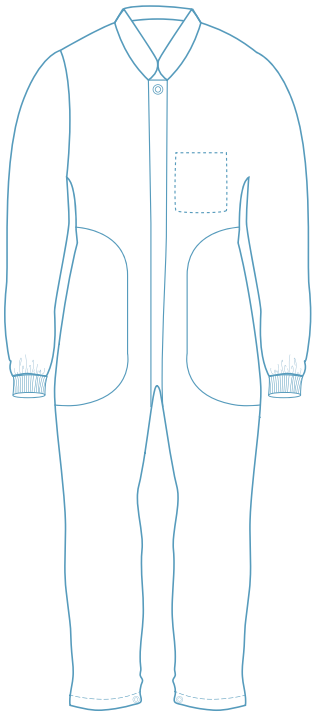
SIZES

XSM - 6XL

COLOUR

US Purple
IN Navy

PB PCG PD LBB LD



6727 POCKET COVERALL

FABRIC

LOW BIO BURDEN (SL) GOSL6727
100% breathable polyester with ECF stripe

FEATURES

- Cover front zipper
- Adjustable stainless steel clips closure at the neck line
- Mandarin collar
- Knitted wrist
- Adjustable stainless steel clip closure at ankle
- Action (elastic) back with adjustable stainless steel clips
- Set-in sleeves
- Left internal breast pocket and front hip pockets

SEAMS

Overlocked seams

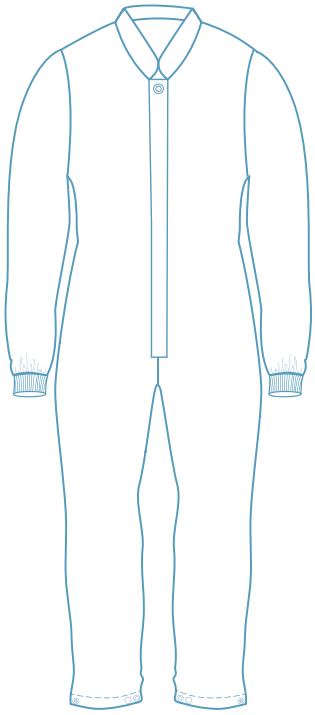
SIZES

XXSM - 6XL

COLOUR

SL Royal Blue, Aqua, Grey

PB PCG PD LBB LD



6727 COVERALL

FABRIC

ULTRASHIELD (US) GOUS6727
100% polyester with ECF stripe

ULTRACLEAN (PE) GOPE6727
100% polyester with ECF stripe

FEATURES

- Cover front zipper
- Adjustable stainless steel clips closure at the neck line and ankles
- Mandarin collar
- Knitted wrist cuffs
- Set in sleeves
- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)

SEAMS

Double needle stitched seams

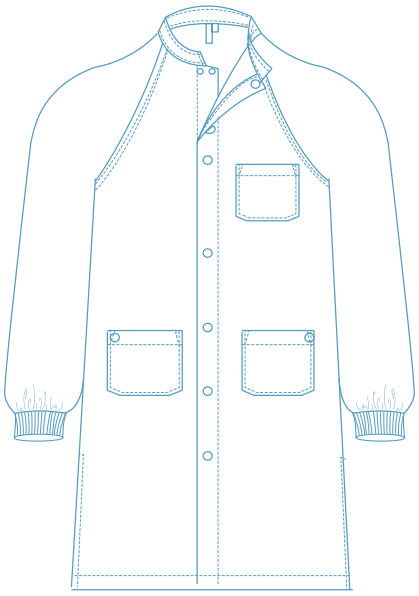
SIZES

XXSM – 6XL

COLOUR

US Lemon, Green, Purple
PE Blue, Navy, Lemon, White

PB PCG PD LBB LD



6432 STAT COAT

FABRIC

CBRI (CB)..... GCCB6432
100% polyester with ECF stripe

STAT CONTROL (SC) GCSC6432
96% polyester, 4% carbon Filament Yarn

FEATURES

- Stainless steel clip front closure
- Two piece notched lapel
- Raglan sleeves
- Left breast pocket, two lower pockets
- Knit ESD cuff

SEAMS

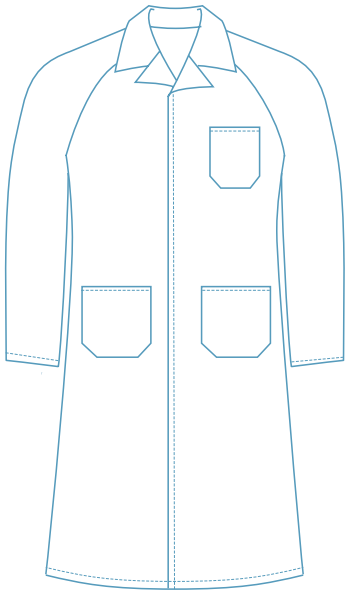
Overlocked seams

SIZES

SM - 3XL

COLOUR

CB Blue, White
SC Blue, White



6431 LAB COAT

FABRIC

ULTRASHIELD (US) GCUS6431
100% polyester with ECF stripe

POLYCOTTON (PC)..... GCPC6431
65% polyester, 35% cotton

FEATURES

- Stainless steel clip front closure
- Two piece notched lapel
- Raglan sleeves
- Left breast pocket, two lower pockets

SEAMS

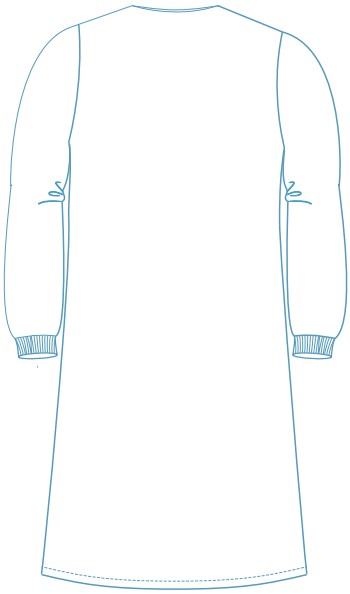
Overlocked seams

SIZES

XXXSM - 8XL

COLOUR

US Green
PC Blue, White



2189 GOWN

FABRIC

ULTRASHIELD (US) GDUS2189
100% polyester with ECF stripe

FEATURES

- Knitted cuffs
- Clip closure at neck
- Tie at waist
- Suitable to wear when administering cytotoxic drugs

SEAMS

Overlocked seams

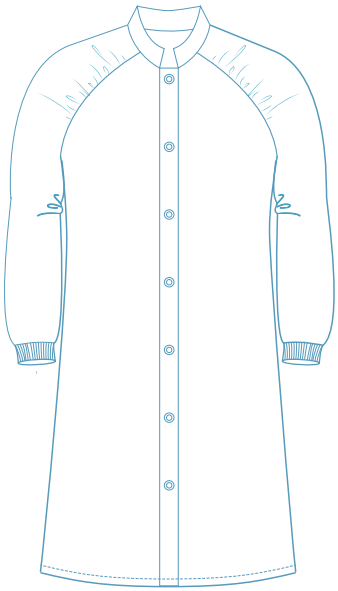
SIZES

SM - XL

COLOUR

US Purple

PB PCG PD LBB LD



6426 SMOCK

FABRIC

ULTRASHIELD (US) GDUS6426
100% polyester with ECF stripe

ULTRACLEAN (PE) GDPE6426
100% polyester with ECF stripe

LOW BIO BURDEN (SL) GDSL6426
100% breathable polyester with ECF stripe

FEATURES

- Stainless steel clip front closure
- Mandarin collar
- Knitted wrist cuffs
- Raglan sleeves
- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)

SEAMS

Double needle stitched seams

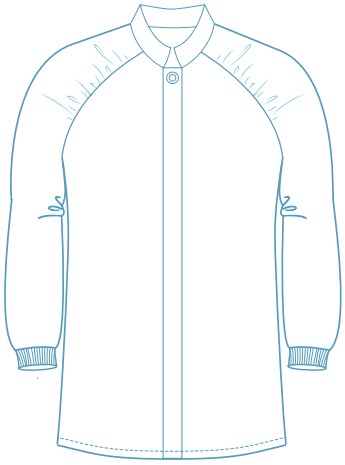
SIZES

XSM – 8XL

COLOUR

US Lemon, Green, Purple
PE Blue, White, Lemon, Navy
SL Royal Blue, Aqua, Grey

PB PCG PD LBB LD



6425 FACILITY TOP

FABRIC

LOW BIO BURDEN (SL) GSSL6425
100% breathable polyester with ECF stripe

ULTRASHIELD (US) GSUS6425
100% polyester with ECF stripe

FEATURES

- Zip front opening
- Stainless steel clips at neckline
- Mandarin collar
- Knitted wrist cuffs
- Raglan sleeves
- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)

SEAMS

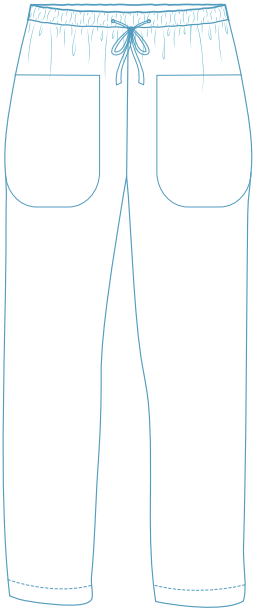
Overlocked seams

SIZES

XXSM - 6XL

COLOUR

SL Royal Blue, Aqua, Grey
US Lemon, Green, Purple



6423 FACILITY PANT

FABRIC

LOW BIO BURDEN (SL) GPSL6423
100% breathable polyester with ECF stripe

ULTRASHIELD (US) GPUS6423
100% polyester with ECF stripe

FEATURES

- Deep front pockets
- Elasticised drawstring waist

SEAMS

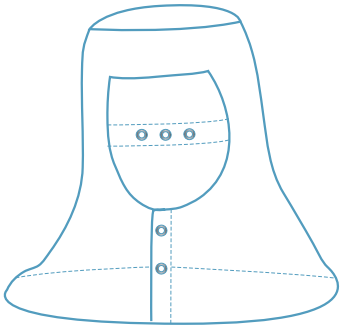
Overlocked seams

SIZES

XXSM - 6XL

COLOUR

SL Royal Blue, Aqua, Grey
US Lemon, Green, Purple



6279 OPEN FACE HOOD

FABRIC

ULTRASHIELD (US) GHUS6279
100% polyester with ECF stripe

ULTRACLEAN (PE) GHPE6279
100% polyester with ECF stripe

FEATURES

- Adjustable stainless steel clip closure under the chin
- Adjustable stainless steel closure on the back of the hood
- Open face hood, skirt extends over the shoulders
- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)

SEAMS

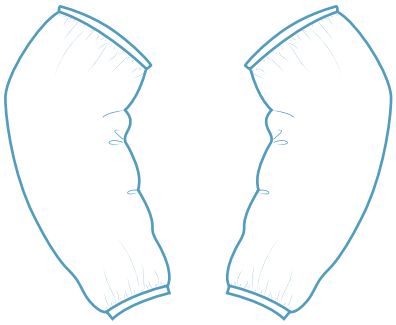
Double needle stitched seams

SIZES

XSM - 2XL

COLOUR

US Lemon, Green, Purple
PE Blue, Navy, Lemon, White



2190 SLEEVE PROTECTOR

FABRIC

ULTRASHIELD (US) GHUS2190
100% polyester with ECF stripe

ULTRACLEAN (PE) GHPE2190
100% polyester with ECF stripe

FEATURES

- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)
- Elastic cuffs

SEAMS

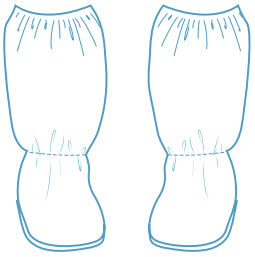
Overlocked seams

SIZES

OSFA (One Size Fits All)

COLOUR

US Purple
PE Blue, Lemon, White, Navy



6986 OVERSHOE

FABRIC

ULTRASHIELD (US) GFUS6986
100% polyester with ECF stripe

DURACLEAN (PE)..... GFPE6986
100% polyester with ECF stripe

FEATURES

- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)
- Vinyl sole

SEAMS

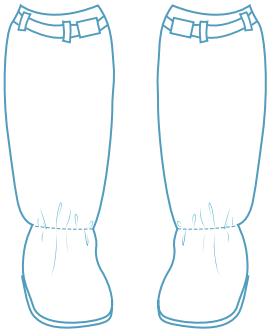
Overlocked seams

SIZES

XSM - 2XL

COLOUR

US Purple, Lemon, Green
PE Blue, Lemon, Navy, White



6987 OVERSHOE

FABRIC

ULTRASHIELD (US) GFUS6987
100% polyester with ECF stripe

INTEGRITY (IN) GFIN6987
100% polyester with ECF stripe

FEATURES

- Suitable to wear when dealing with cytotoxic drugs
- Vinyl sole

SEAMS

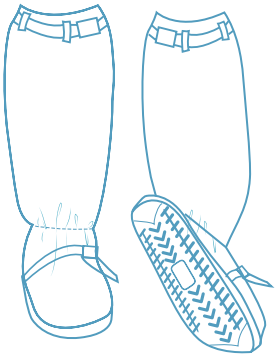
Overlocked seams

SIZES

XSM - 2XL

COLOUR

US Lemon, Purple, Green
IN Navy



6988 OVERSHOE

FABRIC

ULTRASHIELD (US) GFUS6988
100% polyester with ECF stripe

DURACLEAN (PE)..... GFPE6988
100% polyester with ECF stripe

FEATURES

- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)
- Aussie Tough sole

SEAMS

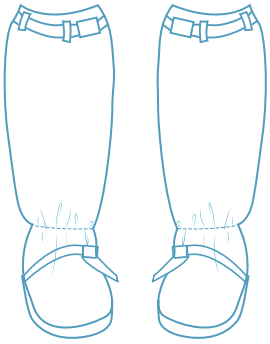
Overlocked seams

SIZES

XSM - 2XL

COLOUR

US Lemon, Green, Purple
PE Blue, Navy, Lemon, White



6989 OVERSHOE

FABRIC

ULTRASHIELD (US) GFUS6989
100% polyester with ECF stripe

DURACLEAN (PE)..... GFPE6989
100% polyester with ECF stripe

FEATURES

- Suitable to wear when dealing with cytotoxic drugs (UltraShield only)
- Aussie Lite anti static rubber moulded sole

SEAMS

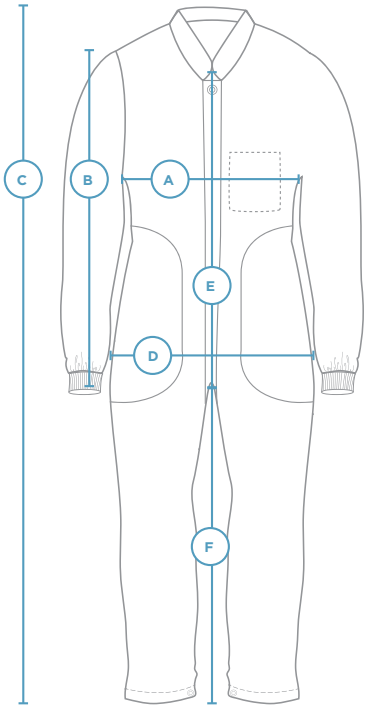
Overlocked seams

SIZES

XSM, SM, M, M/L, L, XL

COLOUR

US Lemon, Purple
PE Blue, Lemon, White

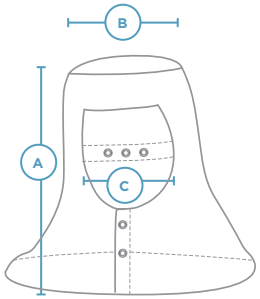


6727 POCKET COVERALL		XSM	SM	M	L	XL	2XL
A	CHEST	111.8	119.4	121.9	129.5	132.1	142.2
B	SLEEVE	66.0	67.3	67.3	67.3	67.3	67.3
C	LENGTH	156.2	160.0	161.3	162.6	167.6	170.2
D	HIP	119.4	124.5	124.5	129.5	139.7	149.9
E	TARGET	71.1	124.5	124.5	129.5	139.7	149.9
F	INSIDE LEG	73.7	73.7	76.2	77.5	82.6	83.8

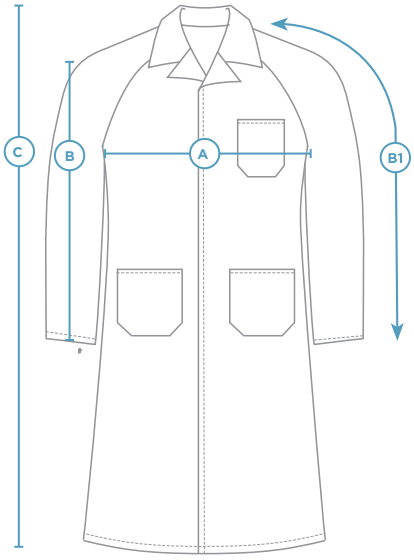
6727 COVERALL		XSM	SM	M	L	XL	2XL
A	CHEST	109.2	114.3	116.8	121.9	127.0	132.1
B	SLEEVE	62.2	62.2	63.5	63.5	66.0	66.0
C	LENGTH	152.4	157.5	160.0	162.6	163.8	170.2
D	HIP	111.8	116.8	121.9	127.0	132.1	137.2
E	TARGET	72.4	73.7	76.2	78.7	80.0	81.3
F	INSIDE LEG	48.3	50.8	53.3	53.3	55.9	61.0

6731 COVERALL		XSM	SM	M	L	XL	2XL
A	CHEST	111.8	116.8	119.4	124.5	129.5	134.6
B	SLEEVE	67.3	68.6	68.6	68.6	69.9	69.9
C	LENGTH	156.2	157.5	162.6	165.1	167.6	170.2
D	HIP	111.8	116.8	121.9	127.0	132.1	137.2
E	TARGET	77.5	77.5	78.7	81.3	83.8	86.4
F	INSIDE LEG	48.3	50.8	53.3	55.9	58.4	61.0

ALL SIZING SHOWN IN CENTIMETERS (CM) | ADDITIONAL SIZES AVAILABLE ON REQUEST



6279 HOOD OPEN FACE		XSM	SM	M	L	XL	2XL
A	BACK LENGTH	45.7	45.7	45.7	45.7	47.0	47.0
B	TOP CIRCLE	16-17	17-18	18-19	18-19	19-20	20-22
C	FACE WIDTH	12.7	12.7	13.3	14.6	15.9	16.5



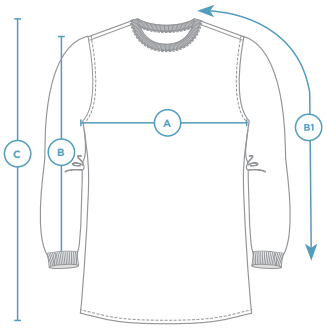
6431 LAB COAT		XSM	SM	M	L	XL	2XL
A	CHEST	-	111.8	119.4	124.5	127.0	134.6
B1	SLEEVE	-	78.7	78.7	78.7	78.7	81.3
C	LENGTH	-	96.5	99.1	100.3	101.6	102.9

2189 GOWN		XSM	SM	M	L	XL	2XL
A	CHEST	-	127.0	147.3	157.5	172.7	-
B	SLEEVE	-	62.2	64.8	69.9	74.9	-
C	LENGTH	-	108.0	110.5	110.5	111.8	-

6426 SMOCK		XSM	SM	M	L	XL	2XL
A	CHEST	111.8	116.8	121.9	124.5	129.5	-
B1	SLEEVE	78.7	82.6	82.6	82.6	85.1	-
C	LENGTH	99.1	104.1	105.4	105.4	106.7	-

6432 STAT COAT		XSM	SM	M	L	XL	2XL
A	CHEST (1/2 WIDTH)	-	116.0	122.0	132.0	142.0	152.0
B1	SLEEVE	-	78.0	79.5	81.5	83.5	85.5
C	LENGTH	-	108.0	112.5	114.5	116.0	116.5

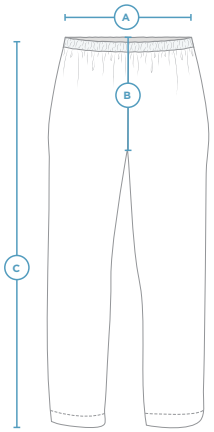
ALL SIZING SHOWN IN CENTIMETERS (CM) | ADDITIONAL SIZES AVAILABLE ON REQUEST



6418 UNDER GARMENT TOP		XSM	SM	M	L	XL	2XL
A	CHEST	104.1	104.1	116.8	121.9	124.5	134.6
B	SLEEVE	54.6	58.4	58.4	59.7	61.0	66.0
C	LENGTH	66.0	68.6	71.1	71.1	71.1	73.7

6411 UM UNDER GARMENT TOP		XSM	SM	M	L	XL	2XL
A	CHEST	106.7	116.8	127.0	137.2	147.3	157.5
B1	SLEEVE	86.4	88.9	91.4	94.0	96.5	99.1
C	LENGTH	76.2	76.2	76.2	76.2	76.2	76.2

6425 FACILITY TOP		XSM	SM	M	L	XL	2XL
A	CHEST	109.2	116.8	116.8	121.9	127.0	132.1
B1	SLEEVE	77.5	78.7	81.3	81.3	81.3	81.3
C	LENGTH	63.5	64.8	67.3	68.6	69.9	69.9

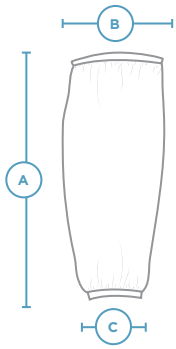


6422 UNDER GARMENT PANT		XSM	SM	M	L	XL	2XL
A	WAIST	58.4	68.6	78.7	88.9	96.5	109.2
B	TARGET	64.8	66.0	67.3	74.9	76.2	80.0
C	LENGTH	96.5	99.1	101.6	108.0	111.8	115.6

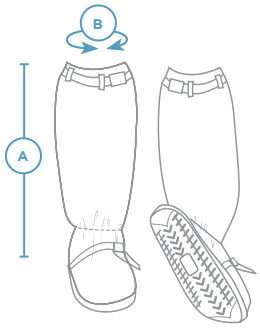
6412 UNDER GARMENT PANT		XSM	SM	M	L	XL	2XL
A	WAIST	68.6	78.7	88.9	99.1	109.2	119.4
B	TARGET	25.4	27.9	30.5	33.0	35.6	38.1
C	LENGTH	105.4	107.9	110.5	113.0	115.6	118.1

6423 FACILITY PANT		XSM	SM	M	L	XL	2XL
A	WAIST	66.0	76.2	76.2	78.7	83.8	88.9
B	TARGET	69.9	72.4	73.7	74.9	77.5	77.5
C	LENGTH	105.4	106.7	106.7	106.7	108.0	109.2

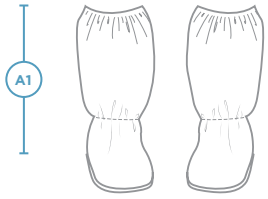
ALL SIZING SHOWN IN CENTIMETERS (CM) | ADDITIONAL SIZES AVAILABLE ON REQUEST



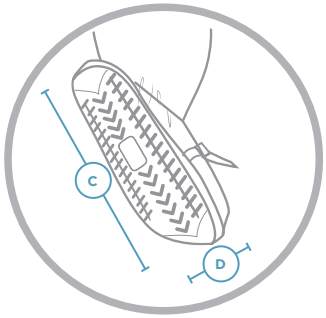
2190 SLEEVE PROTECTORS		OSFA
A	LENGTH	42
B	TOP DIAMETER	27
C	OPENING DIAMETER	20



6987, 6988, 6989



6986



6986 | 6987 | 6988 | 6989 OVERSHOE		XSM	SM	M	L	XL	2XL
A	HEIGHT - 6987, 6988, 6989	47.0	47.0	50.8	50.8	57.2	57.2
A1	HEIGHT - 6986	34.3	35.6	36.8	38.1	39.4	39.4
B	OPENING WIDTH - 6987, 6989	45.7	45.7	48.3	50.8	50.8	50.8
B	OPENING WIDTH - 6988	48.3	48.3	48.3	53.3	53.3	55.9
B	OPENING WIDTH - 6986	25.4	25.4	25.4	25.4	30.5	30.5
6989 AUSSIE LITE SOLE		**XSM**	**SM**	**M**	**L**	**XL**	**2XL**
C	LENGTH	25.7	25.7	30.3	32.5	34.0	37.0
D	WIDTH	10.0	10.7	11.5	13.0	13.3	14.0
6988 AUSSIE TOUGH SOLE		**XSM**	**SM**	**M**	**L**	**XL**	**2XL**
C	LENGTH	26.0	28.0	30.0	32.0	34.0	36.6
D	WIDTH	10.0	10.4	11.0	11.2	13.2	14.5
6986, 6987 VINYL SOLE		**XSM**	**SM**	**M**	**L**	**XL**	**2XL**
C	LENGTH	26.7	27.9	30.5	33.0	34.3	36.8
D	WIDTH	10.0	10.4	11.0	11.2	13.2	14.5

ALL SIZING SHOWN IN CENTIMETERS (CM) | ADDITIONAL SIZES AVAILABLE ON REQUEST

GARMENT ORDER DETAILS

CODE	FABRIC	DESCRIPTION	SIZES	PROCESS | CLASS					STERILISATION	RENTAL	PURCHASE	PAGE
				PB	PCG	PD	LBB	LD				
UNDER GARMENTS												
GSWY6418	WY	UNDER GARMENT TOP	XXSM-5XL	×	×	×	✓	×	×	✓	✓	04
GPWY6422	WY	UNDER GARMENT PANT	XXSM-6XL	×	×	×	✓	×	×	✓	✓	04
GSZC6411	ZC	UNDER GARMENT TOP	XSM-4XL	×	×	×	✓	×	×	✓	✓	05
GPZC6412	ZC	UNDER GARMENT PANT	XSM-4XL	×	×	×	✓	×	×	✓	✓	05
COVERALLS												
GOUS6731	US	COVERALL WITH HOOD	XSM-6XL	×	✓	×	×	×	✓	✓	✓	06
GOIN6731	IN	COVERALL WITH HOOD	XSM-6XL	×	✓	×	×	×	✓	✓	✓	06
GOSL6727	SL	POCKET COVERALL	XXSM-6XL	×	×	×	✓	×	×	✓	✓	06
GOUS6727	US	COVERALL	XSM-7XL	×	✓	×	×	×	✓	✓	✓	07
GOPE6727	PE	COVERALL	XXSM-6XL	✓	×	✓	×	×	✓	✓	✓	07
STAT COATS												
GCCB6432	CB	STAT COAT	SM - 3XL	×	×	×	×	✓	×	✓	✓	08
GCSC6432	SC	STAT COAT	SM - 3XL	×	×	×	×	✓	×	✓	✓	08
LAB COATS												
GCUS6431	US	LABCOAT	XXXSM-8XL	×	✓	×	×	✓	×	✓	✓	08
GCPC6431	PC	LABCOAT	XXXSM-8XL	×	×	×	×	✓	×	✓	✓	08
GOWNS												
GDUS2189	US	GOWN	SM-XL	×	✓	×	×	×	✓	✓	✓	09
SMOCKS												
GDUS6426	US	SMOCK	XSM-8XL	×	✓	×	×	×	✓	✓	✓	09
GDPE6426	PE	SMOCK	XSM-8XL	✓	×	✓	×	×	✓	✓	✓	09
GDSL6426	SL	SMOCK	XSM-5XL	×	×	×	✓	×	×	✓	✓	09
FACILITY GARMENTS												
GSSL6425	SL	TOP	XXSM-6XL	×	×	×	✓	×	×	✓	✓	10
GPSL6423	SL	PANT	XXSM-6XL	×	×	×	✓	×	×	✓	✓	10
GSUS6425	US	TOP	XXSM-6XL	×	✓	×	×	×	×	✓	✓	10
GPUS6423	US	PANT	XXSM-6XL	×	✓	×	×	×	×	✓	✓	10
HOODS												
GHUS6279	US	HOOD OPEN FACE	XSM-2XL	×	✓	×	×	×	✓	✓	✓	11
GHPE6279	PE	HOOD OPEN FACE	XSM-2XL	✓	×	✓	×	×	✓	✓	✓	11
SLEEVE PROTECTORS												
GHUS2190	US	SLEEVE PROTECTOR	OSFA	×	✓	×	×	×	✓	✓	✓	11
GHPE2190	PE	SLEEVE PROTECTOR	OSFA	✓	×	✓	×	×	✓	✓	✓	11
OVERSHOES												
GFUS6986	US	OVERSHOE CALF HIGH	XSM-2XL	×	✓	×	×	×	✓	✓	✓	12
GFUS6987	US	OVERSHOE TOP STRAP	XSM-2XL	×	✓	×	×	×	✓	✓	✓	12
GFIN6987	IN	OVERSHOE TOP STRAP	XSM-2XL	×	✓	×	×	×	✓	✓	✓	12
GFUS6988	US	OVERSHOE AUSSIE TOUGH SOLE	XSM-2XL	×	✓	×	×	×	✓	✓	✓	13
GFPE6988	PE	OVERSHOE AUSSIE TOUGH SOLE	XSM-2XL	✓	×	✓	×	×	✓	✓	✓	13
GFUS6989	US	OVERSHOE TOP | FOOT STRAP	XSM-XL	×	✓	×	×	×	✓	✓	✓	13
GFPE6989	PE	OVERSHOE TOP | FOOT STRAP	XSM-XL	✓	×	✓	×	×	✓	✓	✓	13

FABRIC KEY

PE	Ultraclean Polyester	PC	Poly/Cotton	SC	Stat Control
PE	Duraclean Polyester	WY	Under Garment Fabric	IN	Integrity
US	UltraShield	ZC	Under Garment Fabric		
SL	Low Bio Burden	CB	CBRI		

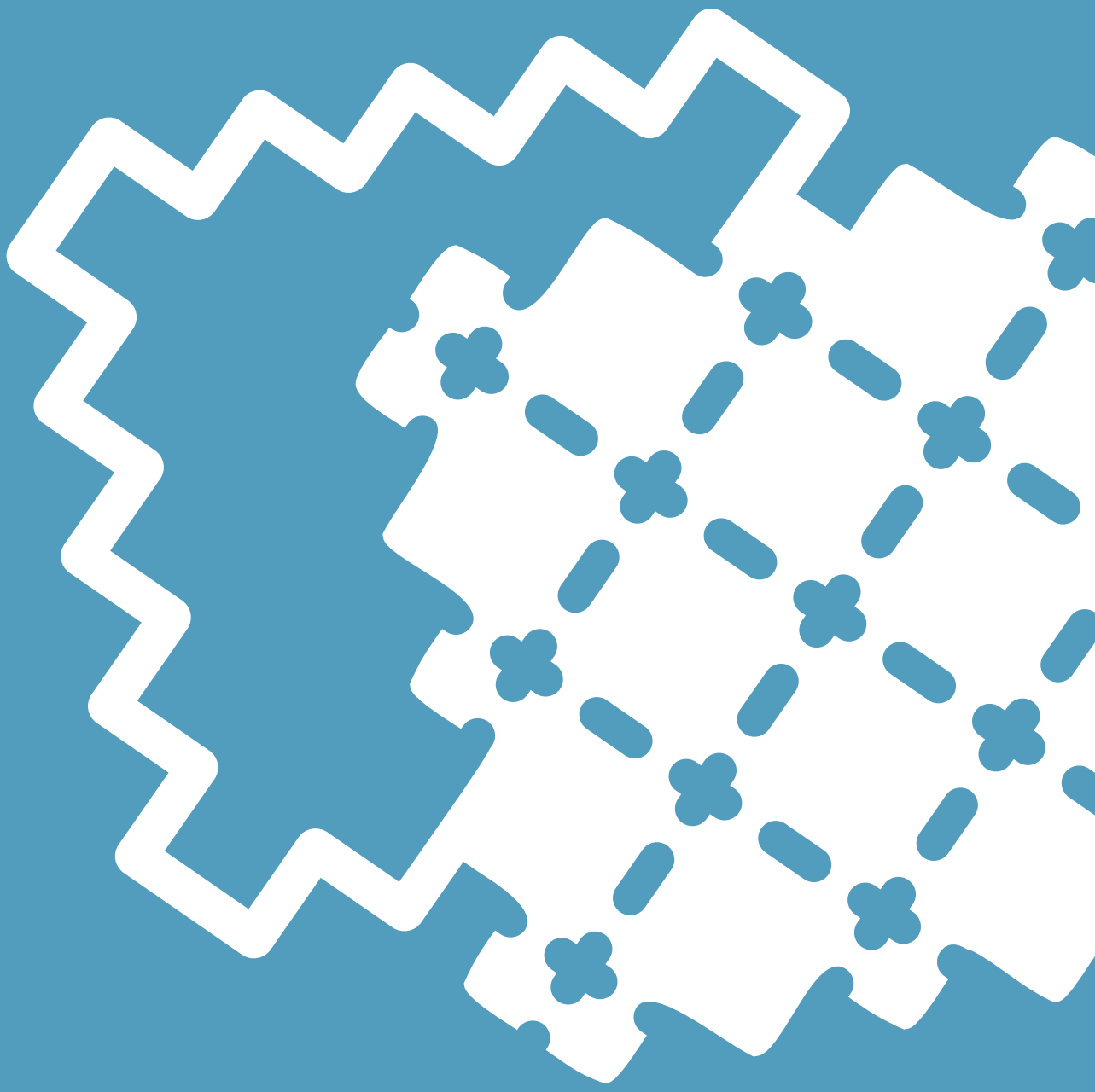
PB Process Class B

PCG Potentially Contaminated Garments Process Class

PD Process Class D

LBB Low Bioburden Process Class

LD Launder Process Class



CLEAN ROOM GARMENTS | GARMENT GUIDE

FABRIC SPEC

ULTRASHIELD FABRIC (US)			
Specifications	100% Polyester with ECF strip		
Colour range	Green (GUS), Lemon (LUS), Purple (PUS)		
Unit Weight	117 g/m^2		
Water Vapour Transmission Rate	44.72 g/hrs m^2		
Air Permeability	5.3 $cm^2/cm^2/s$ (toward airflow) 5.3 $cm^2/cm^2/s$ (away from airflow)		
Abrasion Resistance	37,000 cycles		
SURFACE RESISTIVITY (ESD)			
0 washes	$3X10^8$-$1X10^{11}$ 'Ω (Static Dissipative)		
250 washes	$3X10^8$-$1X10^{12}$ 'Ω (Static Dissipative)		
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**	
Particles/min (0 washes)	656	637	
Cleanliness Category	I	I	
Particles/min (250 washes)	325	209	
Cleanliness Category	I	I	
FILTRATION EFFICIENCY (%)	**0.3um**	**0.5um**	**5.0um**
0 washes	75.12	91.88	95.25
25 washes	95.57	96.79	97.46
50 washes	81.13	89.13	88.64
75 washes	87.27	96.23	72.01
100 washes	93.37	95.30	87.92
125 washes	86.45	96.90	100
150 washes	89.40	96.51	100
175 washes	88.32	95.12	95.87
200 washes	87.85	95.41	97.06
255 washes	86.01	97.18	100
250 washes	93.22	96.43	85.92
WATER REPELLENCY (%)			
0 washes	90.3%		
25 washes	96.6%		
50 washes	98.0%		
75 washes	96.9%		
100 washes	96.7%		
125 washes	98.4%		
150 washes	98.0%		
175 washes	95.4%		
200 washes	97.8%		
225 washes	97.6%		
250 washes	96.8%		

INDIVIDUAL DRUG INFORMATION SHOULD BE CONSULTED FOR EXPOSURE LIMITS

	CYTO PENETRATION | PURPLE US ONLY								
	0 Washes			10 Washes			50 Washes		
Drugs	20 min	30 min	60 min	20 min	30 min	60 min	20 min	30 min	60 min
Ethanol Based(μg)	<0.1	<0.1	<0.1	NA	NA	NA	<0.1	<0.1	<0.1
Powder Based(μg)	<0.1	<0.1	<0.1	NA	NA	NA	<0.1	<0.1	<0.1
% Penetration	0	0	0	NA	NA	NA	0	0	0

LOW BIO BURDEN FABRIC (SL)			
Specifications	100% Polyester knit with ECF strip		
Colour range	Grey, Aqua, Blue, White		
Unit Weight	69 g/m^2		
Water Vapour Transmission Rate	49.10 g/hrs		
Air Permeability	44.7 cm^2/cm^2/s (toward airflow) 45.7 cm^2/cm^2/s (away from airflow)		
Abrasion Resistance	45,500 cycles		
SURFACE RESISTIVITY (ESD)			
0 washes	1X10^8 - 3X10^8 ΄Ω (Static Dissipative)		
250 washes	1X10^{12} ΄Ω (Static Dissipative)		
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**	
Particles/min (0 washes)	1,084	1,058	
Cleanliness Category	I	I	
Particles/min (250 washes)	2,646	1,976	
Cleanliness Category	II	II	
FILTRATION EFFICIENCY (%)	**0.3um**	**0.5um**	**5.0um**
0 washes	59.27	88.36	94.20
25 washes	89.24	94.30	97.73
50 washes	85.18	93.37	96.05
75 washes	83.16	95.86	90.62
100 washes	79.44	95.38	80.00
125 washes	76.65	95.70	92.11
150 washes	91.39	97.65	94.34
175 washes	83.85	91.39	98.98
200 washes	78.00	89.35	100
225 washes	96.26	98.85	98.49
250 washes	77.93	89.58	100

ULTRACLEAN FABRIC (PE)

Specifications	100% Polyester with ECF strip		
Colour range	Blue (BP), White (WP), Navy (NP), Lemon (LP)		
Unit Weight	106 g/m^2		
Water Vapour Transmission Rate	62.72 g/hrs m^2		
Air Permeability	2.6 cm^2/cm^2/s (toward airflow) 2.2 cm^2/cm^2/s (away from airflow)		
Abrasion Resistance	91,250 cycles		
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**	
Particles/min (0 washes)	2,093.92	2,185.00	
Cleanliness Category	II	II	
Particles/min (250 washes)	150.59	207.60	
Cleanliness Category	I	I	
FILTRATION EFFICIENCY (%)	**0.3um**	**0.5um**	**5.0um**
0 washes	76.96	89.05	92.63
25 washes	84.63	96.90	100
50 washes	80.68	88.52	92.96
75 washes	86.71	93.26	83.33
100 washes	81.11	90.06	85.72
125 washes	90.28	94.01	100
150 washes	84.79	93.41	100
175 washes	86.21	95.62	100
200 washes	80.97	92.50	58.83
225 washes	83.57	95.45	100
250 washes	78.65	86.06	NA

DURACLEAN FABRIC (PE)

Specifications	100% Polyester with ECF strip			
Unit Weight	109 g/m^2			
Water Vapour Transmission Rate	3.24 mg/hr/cm^2			
Air Permeability	9.8 ml/m^2			
Abrasion Resistance	Good			
Flammability Index	14 (Range 0-100/least to most flammable)			
Melting Point	250 °C			
SURFACE RESISTIVITY (ESD)				
0 washes	10° Ohms per square			
FILTRATION EFFICIENCY (%)	**0.5um**	**0.7um**	**1.0um**	**5.0um**
0 washes	15%	17%	19%	60%

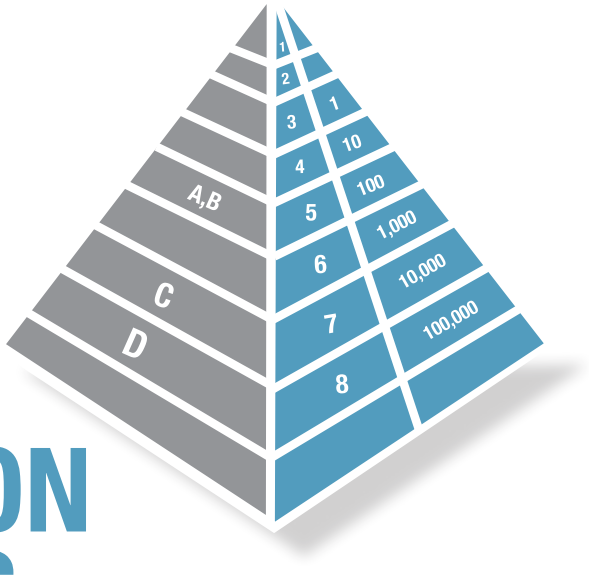
UNDER GARMENT FABRIC (WY)		
Specifications	100% Polyester with ECF strip	
Colour range	Blue, White	
Unit Weight	166 g/m^2	
Water Vapour Transmission Rate	45.31 g/hrs m^2	
Air Permeability	>68 cm^3/cm^2/s (toward airflow) >68 cm^3/cm^2/s (away from airflow)	
Abrasion Resistance	25,000 cycles	
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**
Particles/min (0 washes)	3,319.82	3,218.63
Cleanliness Category	II	II
Particles/min (50 washes)	3,496.92	3,241.62
Cleanliness Category	II	II
Particles/min (100 washes)	10,075.84	8,086.34
Cleanliness Category	II	II
Particles/min (150 washes)	7,628.18	5,425.70
Cleanliness Category	II	II
Particles/min (200 washes)	4,033.74	3,148.23
Cleanliness Category	II	II
Particles/min (250 washes)	3,862.62	2,929.74
Cleanliness Category	II	II

UNDER GARMENT FABRIC (ZC)	
Specifications	100% Polyester Twill Hi-Stretch 288T P/D + Moisture Finish
Colour range	Blue
Unit Weight	117 g/m^2
Dimension stability to washing	+/- 3%
Useable width	140 cm
Tensile strength Warp (kg)	20 kg
Tensile strength Weft (kg)	20 kg
Tear strength Warp (g/f)	1200
Tear Strength Weft (g/f)	1200
Washing fastness	3 - 4

CBRI FABRIC (CB)			
Specifications	100% Polyester with ECF strip		
Colour range	Blue, White		
Unit Weight	103 g/m^2		
Water Vapour Transmission Rate	44.57 g/hrs m^2		
Air Permeability	4.0 $cm^2/cm^2/s$ (toward airflow) 4.1 $cm^2/cm^2/s$ (away from airflow)		
Abrasion Resistance	92,500 cycles		
SURFACE RESISTIVITY (ESD)			
0 washes	$1X10^6$- $1X10^8$ 'Ω (Static Dissipative)		
250 washes	$1X10^7$- $1X10^{12}$ 'Ω (Static Dissipative)		
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**	
Particles/min (0 washes)	2462.40	2238.01	
Cleanliness Category	II	II	
Particles/min (250 washes)	720.59	505.20	
Cleanliness Category	I	I	
FILTRATION EFFICIENCY (%)	**0.3um**	**0.5um**	**5.0um**
0 washes	95.61	97.57	97.56
25 washes	82.56	90.04	76.75
50 washes	94.21	98.17	100
75 washes	82.22	94.72	100
100 washes	93.33	98.09	97.25
125 washes	94.03	97.91	98.45
150 washes	85.87	95.17	91.38
175 washes	86.10	93.18	96.70
200 washes	94.48	96.92	99.28
250 washes	86.88	97.31	90.57
250 washes	76.38	85.24	96.97

STAT CONTROL FABRIC (SC)	
Specifications	99% Polyester + Carbon Fibre 1%
Colour range	Blue, White
Unit Weight	95 g/m^2
Useable Width	153.7 cm
Air Permeability	1.0 ft^3/ft^2 per min @ 125 Pa 1.6 ft^3/ft^2 per min @ 200 Pa
Filtration Efficiency	92% @ 0.5um
Water Vapour Permeability	1100 g/hrs m^2
Hydrostatic Resistance	80cm (min)
Surface Resistivity	$1x10^8$ - $x10^9$
Static Decay	0.01 (sec)
Tensile strength Warp (kg)	86.18 kg
Tensile strength Weft (kg)	47.63 kg

INTEGRITY 2000 FABRIC (IN)			
Specifications	100% Polyester with ECF strip		
Colour range	Navy Blue		
Unit Weight	107 g/m^2		
Water Vapour Transmission Rate	76.51 g/hrs m^2		
Air Permeability	0.3 $cm^2/cm^2/s$ (toward airflow) 0.3 $cm^2/cm^2/s$ (away from airflow)		
Abrasion Resistance	71,000 cycles		
SURFACE RESISTIVITY (ESD)			
0 washes	$3X10^8$-$1X10^{10}$ ΄Ω (Static Dissipative)		
250 washes	$1X10^8$-$1X10^{12}$ ΄Ω (Static Dissipative)		
PARTICLE SHEDDING (HELMKE)	**0.3um**	**0.5um**	
Particles/min (0 washes)	162.10	173.90	
Cleanliness Category	I	I	
Particles/min (250 washes)	214.20	191.99	
Cleanliness Category	I	I	
FILTRATION EFFICIENCY (%)	**0.3um**	**0.5um**	**5.0um**
0 washes	66.80	77.87	82.38
25 washes	84.63	96.90	100
50 washes	80.68	88.52	92.96
75 washes	88.41	94.76	73.80
100 washes	84.23	96.16	100
125 washes	88.85	94.85	100
150 washes	93.32	97.42	98.85
175 washes	83.72	93.09	90.38
200 washes	70.68	84.74	91.67
250 washes	91.63	97.01	98.89
250 washes	80.11	92.47	97.62
WATER REPELLENCY (%)			
0 washes	99.8%		
25 washes	99.0%		
50 washes	99.5%		
75 washes	99.3%		
100 washes	99.7%		
125 washes	99.5%		
150 washes	99.3%		
175 washes	99.7%		
200 washes	99.3%		
225 washes	99.5%		
250 washes	99.5%		



CLEANROOM CLASSIFICATION COMPARISONS

- The pharmaceutical industry in Australia is regulated by GMP standards or the PICS code (class A to D)
- The ISO 14644-1 standard (classes 1 to 9)
- The US Federal standard 209E (classes 1 to 100 000)

ISO AIR CLEANLINESS CLASSIFICATION

Class	maximum particles/m³						FED STD 209E equivalent
	≥0.1um	≥0.2 um	≥0.3 um	≥0.5 um	≥1 um	≥5 um	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	Room Air

GARMENT RECOMMENDATIONS
FOR CLEANROOM CLASSIFICATIONS

At CRG we guarantee that the Ultraclean Garment Processing System we provide for your controlled environment will comply with the appropriate Australian Standards and Good Manufacturing Practice (GMP) requirements.

GARMENT SERVICE	YOUR FACILITY	ROOM GRADE	FABRIC	GARMENT CLEANING PROCESS	GARMENT STYLE	CHANGE RATE
Sterile Cleanroom Garments	Aseptic Filling & compounding (sterile)	Grade A in B Class 100 / ISO 5	Ultraclean Polyester	Process Class B & Sterile	Coverall, hood, overshoes, mask & gloves	Per entry
	Micro testing					
Sterile Protective Cleanroom Garments	Aseptic filling & compounding of: Hormones Antibiotics Antineoplastics	Grade A in B Class 100 / ISO 5	UltraShield Polyester	Process Class B (PCG) & Sterile	Coverall, hood, overshoes, mask & gloves	Per entry
Process Only Cleanroom Garments	Class III medical device and other industrial applications	Grade C Class 10,000 / ISO 7	Ultraclean Polyester	Process Class B	Coverall, hood, overshoes, mask & gloves	Daily / Weekly
	Class I and II medical device & other industrial applications	Grade D Class 100,000 / ISO 8		Process Class D	Smock, cap & shoecovers	
Bioclean Garments	Tableting, creams, solutions and powders	None specified Controlled environment	Breathable Polyester	Process Low Bioburden (LBB)	Coverall, shoecovers & headcover	Daily
	Primary & secondary packaging				or two piece suit, shoecovers & headcover	
Statguard Dust Coats	Static sensitive areas Assembly Test & repair Packaging	N/A	Polycotton with Electro Conductive Fibre (ECF)	Launder Only	Statcoat	Weekly
General Uniforms	Laboratories, workshops, warehouse, assembly	N/A	Polycotton or cotton	Launder Only	Coverall, Labcoat, Shirt & Pants	Daily

- Garment Cleaning Process refers to the surface cleanness level of the garment as specified in IEST-RP-CC003.4 Garment System Considerations for Cleanrooms and Other Controlled Environments
- Room Grading referenced from PIC/S GMP Guide Pg 8 item 44
- PCG - Process for Potentially Contaminated Garments
- UltraShield Polyseter - Available for wet environments

CLEAN ROOM GARMENTS | GARMENT GUIDE

PERFORMANCE & QUALITY MEASURES

Cleanroom clothing is intended to prevent substances released off the wearer's body from contaminating the environment. It is also important that the clothing does not itself release particles or fibres into the environment. Cleanroom personnel contribute about 25% of airborne particulate contamination. Skin, hair and other substances are released from the body and clothing with each person releasing about 25,000 particles per minute (p/min). Emission rates in normal clothing range from about 100,000 p/min when sitting or standing motionless, 500,000 p/min during hand, forearm and head movement and up to 5,000,000 p/min during normal walking. The particles released are generally greater than 0.3um. In addition, many particles emitted from the body can be contaminated by bacteria.

FACTORS LIMITING CLOTHING & FACE-MASK PERFORMANCE

Penetration and leakage can reduce the protective performance of cleanroom clothing. Penetration can be regarded as passage of materials through holes in the protective equipment. Such holes can occur in fabrics, filters, seams or fasteners. Leakage can occur at any point at which there is a gap between the equipment and the wearer's body or face. Face-mask performance can similarly be limited by penetration of the filter and leakage between mask and face.

Clothing penetration and leakage result from pressure differences between the inside and outside which are generated by body movement. For example, when raising and lowering arms, voids open up between the body and the clothing. Airflow into the garment can contaminate the body and airflow out of the garment can contaminate the environment. The pressure differentials generated, and thus the transfer of contaminants, depend on both the air permeability of the garment and the goodness of fit.

FABRIC PENETRATION

Conventional clothing fabrics such as cotton, nylon, terylene or spunbond have numerous small holes through the fabric. Objective tests of such fabrics using respirable asbestos fibres or small particles indicate that over 50% of such particles penetrated through the fabrics. Fabrics giving such test results are essentially "transparent" to fine aerosols such as bacteria, skin scales or other contaminants and are therefore unsuitable unless only marginal performance is required.

WOVEN FABRICS

MADE FROM 100% CONTINUOUS FILAMENT POLYESTER FIBRE

The fibres of the garment must be fine and tightly woven, which reduces the air permeability of the garment. The air permeability is a function of the space between the woven fibres. Polyester is a synthetic fibre that is hydrophobic which means it will not absorb moisture and will not allow moisture such as perspiration to evaporate. Natural fibres such as cotton are hydrophilic, this means they absorb moisture and are more comfortable to wear but shed high levels of contaminants. Polyester garments are durable, wash well, dry quickly and are the most suitable fabric for the cleanroom environment.

GARMENT MANUFACTURE

Unsealed stitched seams and fasteners such as Velcro or conventional zips offer little resistance to either airflow or aerosol penetration. In many garments, the air permeability of seams and fasteners is much greater than that of the fabrics. Consequently, although the area of seam and fastener is typically less than 1% of the total area of a garment, the total flow of contaminated air through seams and fasteners can be much greater than that through the fabric, particularly if the fabric is relatively impermeable to air.

Clean Room Garments manufactures its garment seams to exacting standards to help prevent this happening. Seams are "French Seam" stitched; the seams are overlocked, stitched again to encase the overlock, then stitched down onto the garment.

LEAKAGE

Many garments have gaps between the clothing and the body, most commonly at the neck. Contamination can readily pass through such gaps. Penetration through seal gaps can permit unhindered passage of large particles that would otherwise be unable to pass through the fabrics of construction, so contamination of the body can occur even when the clothing worn is effectively impervious to the contaminant. A garment that permits inward leakage will just as easily permit outward leakage. Cleanroom garments using the same fabrics and construction techniques as protective clothing will be equally poor at keeping contamination inside the clothing as they are at keeping environmental contamination outside the clothing. A garment constructed from an efficient fabric with well sealed seams and fasteners may therefore fail to provide effective protection for either the body or the environment unless it is well sealed to the wearer's body.

Studies of cleanrooms have shown this to be a common occurrence. For example, when a cleanroom is occupied by personnel, microbial contamination increases greatly even when personnel wear surgical masks in addition to cleanroom clothing. Coveralls, hoods and boots worn as a set only reduce by half the airborne contamination produced when just smocks and boots are worn, and gowns worn with head covers reduce the contamination level by only 19%.

From the above it will be appreciated that it is not adequate to specify cleanroom clothing in terms of fabric performance only, it is necessary to specify fabric, seam and fastener penetration and suit-seal leakage. While it might appear that protective performance could be increased by providing better seals, sealing can cause thermal discomfort or heat strain by preventing or reducing air exchange.

MEASUREMENT OF FABRIC PERFORMANCE

FILTRATION EFFICIENCY

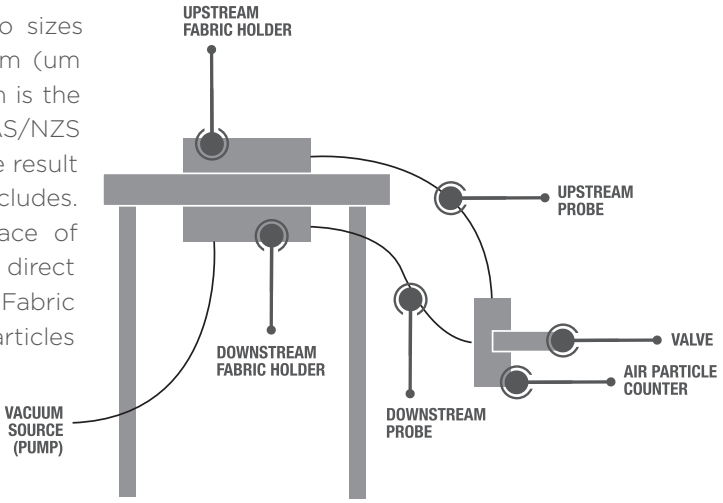
Filtration efficiency of fabrics is the main method by which the particle exclusion performance of fabrics can be measured. Fabric is placed on a fabric holder with the inside surface up, pulled flat and clamped into place with an o-ring and the top of the holder. A pump draws air through the fabric and particle count samples of air are taken from the air outside and inside the fabric holder. The filtration efficiency is the amount of particles filtered from the air by the fabric when compared to unfiltered "control" air, expressed as a percentage. A brief explanation of these results follows the table below:

SAMPLE FILTRATION EFFICIENCY TABLE

FABRIC FILTRATION EFFICIENCY %	0.3um	0.5um	1.0um	5.0um
Fabric A	70	79	88	95
Fabric B	69	74	87	99

The four columns indicate each of the particle sizes the APC is capable of monitoring. The two sizes that are most important are 5um and 0.5um (um is a micrometre (micron), or .001mm). 0.5um is the size that most cleanroom classifications AS/NZS ISO 14644 are based around. The percentage result shows how many particles the fabric excludes. Particle penetration is often quoted in place of filtration efficiency in documentation. It is the direct opposite of filtration efficiency; for example Fabric A above allows 21% (100%-79%) of 0.5um particles through.

PREPARATION OF TEST EQUIPMENT



AIR PERMEABILITY

Air permeability is an indicator of the "breathability" of a fabric, or how much air will pass through it under pressure. Fabrics with low air permeability will allow less contamination to pass through them (either from operator to environment or vice versa), but with the resultant trade off in comfort. The lower the air permeability of the fabric, the more attention must be paid to the fit and seal of the garments, as air pressure will always escape via the easiest path.

The air permeability test is carried out by clamping fabric into a sealed holder, then creating a constant pressure gradient across it. Once the desired pressure is reached and has become stable, the volume of air required to be pumped into the "upstream" side of the fabric to maintain this pressure gradient is measured, in ml of air per second. Then, with the area of fabric clamped into the holder taken into account, the mean air permeability is calculated, expressed as ml of air per square cm of fabric per second (ml/cm2.s)

WATER VAPOUR TRANSMISSION

This test is one of the best indicators of the likely "comfort factor" of a fabric as it measures how quickly water vapour – for example, in the form of sweat – passes through fabric. It is a more important factor to consider in garments such as hoods, or for those worn by workers who do not move around much as airflow is not generated in the garment to help heat loss. In some of the highest performance fabrics, there is also a "wicking" effect – the fabric actively draws moisture away from the body.

The water vapour transmission test is done by weighing an amount of water into a container, sealing the fabric to be tested over the mouth of the container (normally using hot melt glue), then placing the container and fabric into an environment with controlled temperature and humidity for a length of time. The amount of water, in the form of evaporating water vapour, that passes through the fabric barrier can be measured by the amount of weight that is lost over time from the container. The result is expressed as grams water lost per hour per square metre of fabric (g/hr.m2).

WATER REPELLENCY (SPRAY RESISTANCE)

Testing for water repellency forms part of CRG's routine testing on barrier fabrics, to ensure that it retains this property for its entire lifespan. The procedure involves weighing a piece of blotting paper, clamping it behind a surface of the test garment at a 450 angle and running 500ml of water over the fabric through a shower head from a constant height (61cm). Any water that penetrates the fabric will be absorbed by the blotting paper, which is removed from behind the fabric and reweighed after the test has finished. The weight of the blotting paper after testing is compared to the pre-test weight, and the result is expressed as a percentage.

Although the testing procedure is extremely simple, it must be done very carefully as small variations in the weight of the blotting paper after testing can cause a failure. For example, touching the paper with wet fingers will cause a large discrepancy in the results.

THERMAL EFFECTS OF CLOTHING

The human body converts energy derived from food into work with typical conversion efficiencies ranging from about 25% for a fit person carrying out exercise with the major muscle groups down to almost zero when carrying out static work such as holding weights above the head. All energy which is not converted into useful work will be lost as heat. The higher the work load, the greater the amount of heat to be lost. Heat can be lost by convection, radiation, conduction, sweat evaporation and by heating and humidifying air that is breathed in. It should be appreciated that only a few joules per gram is lost by sweat dripping off the body whereas the evaporation of 1 gram of sweat in contact with the body can lose about 2,400 joules. Heat is more easily lost in light, open clothing than in well sealed clothing and more easily lost in cold environments than in hot environments. Well sealed garments exhibiting poor air and water vapour permeation can substantially reduce sweat evaporation as sweat evaporation is much reduced in the high humidities present within the garments. Such well sealed garments can cause significant heat storage for moderate or harder work in other than cold environments. Garments which cause thermal discomfort or heat strain are often misworn in an attempt to reduce discomfort, i.e. the fastener may be opened to permit easier flow of air. Any such miswear substantially reduces the protection provided by the clothing.

If sufficient heat cannot be lost, heat is stored in the body and the body's core temperature rises. Moderate heat storage can cause thermal discomfort, which although not directly health threatening, can cause loss of attention which could result in reduced quality of product. Severe heat storage can progressively result in cramps, coma and death.

Cleanroom workers often have to wear coveralls, hoods, gloves and face masks which substantially reduce the area of skin off which heat can be lost by convection, radiation or sweat evaporation. In 15°C environments, wearing gloves and headcovers reduces the body's ability to lose heat by 10 to 50%. In addition, face masks absorb heat and moisture from the exhaled air which is transferred to the inspired air, thus reducing heat loss by breathing.

Well fitted, high performance garments, particularly when worn in conjunction with face masks, can therefore so reduce heat loss from the body that heat strain may be much more common than is presently reported.

PHYSICAL CHARACTERISTICS OF FABRICS

ELECTRICAL RESISTIVITY

100% polyester is almost entirely insulative, that is, it does not conduct electricity – static or otherwise. However, it generates a great deal of static electricity through friction with clothing and other surfaces. This can result in anything from a mild shock as the charge is dissipated on contact with a metal or other conductive surface that is earthed, to complete destruction of a sensitive electronic component or an explosion or fire hazard in an area containing flammable vapours.

The common solution to this problem is to run conductive fibres, usually carbon-based, through the fabric to pick up these static charges and direct them to where they can be discharged in a controlled fashion. These conductive fibres produce the distinctive check or stripe appearance of cleanroom fabric. The quantity, type, weave pattern and thickness of these conductive threads will all have an effect on the static properties of fabric. For example, fabric with conductive fibres woven in a tight check pattern will have much better static properties than one with wide stripes between the fibres. Fibre thickness is important as thicker conductive fibres offer less electrical resistance and therefore allow better conductivity, but also create larger holes in a tightly woven fabric through which particles can penetrate.

To measure the static dissipative performance of a fabric, its resistance to the flow of an electrical current is measured. The results are expressed as ohms (the unit of resistivity) per square. In the measurement of surface resistivity, the same numerical result is obtained regardless of the size of the square.

There are three general zones of performance for materials measured for electrical resistivity. Less than 105Ω (ohms) is regarded as conductive, 105Ω to 1012Ω as static dissipative, and greater than 1012Ω as insulative. Clean Room Garments' Aussie sole has a resistivity of 108Ω to 109Ω, making it a good static dissipater in environments where this property is important.

A related test is static decay, where a static charge is applied to a fabric held in an insulative clamp and the time taken for it to decay by a set amount is measured. This test is quite common in countries where a significant proportion of the cleanroom market is involved in integrated circuit manufacture and is static sensitive.

ABRASION RESISTANCE

Two types of test are usually specified when measuring abrasion resistance. These are the Taber test and the Wyzenbeck test, although the Wyzenbeck test is rarely used for anything but upholstery. Both of these tests measure either the appearance of fabric (fibre breakage, hole formation, etc) after a given amount of cycles (rubs), or at what point destruction of the fabric (broken threads) occurs. The Taber test also measures the mass of material lost (in grams) after the specified amount of cycles. A number of different test loads and abradants can be specified for these tests, usually agreed upon with the customer before the testing commences.

High abrasion resistance in fabric indicates better durability, but this is often at the cost of a heavier weight fabric that is not as comfortable to wear and more difficult (and therefore costly) to manufacture into a complex garment.

FABRIC SELECTION

Selection of fabric type must be a careful balance between the customer's contamination control needs and those of their production staff. The cleaner the environment that must be achieved, the higher the performance of the fabric that must be used. But with very clean environments comes greatly increased running costs, as a much cooler and less humid environment needs to be maintained in order to allow production staff to operate in relative comfort.

How rigorous is the environment? Do the operators continually come into contact with sharp or abrasive surfaces? Do staff need to be protected from liquid spills? Is static sensitive equipment involved?

BIOBURDEN TESTING

There are no national or international standards that specify levels of micro-organisms on cleanroom garments. On the other hand, almost all standards and guidelines concerning the pharmaceutical, medical and food industries state that “micro-biological tests have to be done” on garments. They just do not explain how these tests have to be performed or what the acceptance criteria are.

CRG tests for bioburdens on garments twice a week. 2 sample customer garments of each of the following fabrics are chosen at random: Blue Polyester, Purple UltraShield, and Integrity. Once laundered and dried, the front of the garment (hip area) and back of the garment (seat area) are selected for sampling and coding. A sample is taken by briefly placing the agar surface of a contact plate in contact with the chosen area of the garment. Once samples are collected, garments are sent for rewash. Test plates are incubated at 32°C for 5 days. Plates are inspected after this period for any bacterial growth and the total CFU counted. We try to achieve an action limit of 5cfu (colony forming units).

The types of organisms found can tell us a lot about the source of the contamination on the fabrics, as most of them are found almost exclusively in water, people or just general dust. High counts of the water types may indicate that the garments were not dried properly, or that the water is not particularly clean, while high counts of organisms associated with people may indicate that the garments were not washed particularly well, or that our operators were not isolated well enough from the environment.

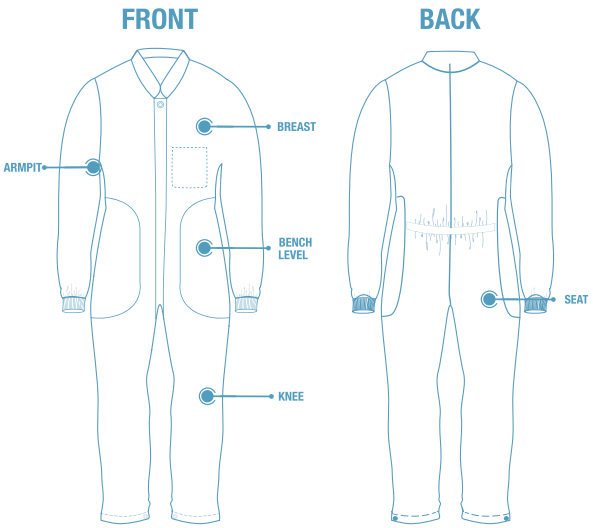
WATER TESTING

The water system consists of the following:

1. storage tank pre filtration
2. carbon filters - coarse and fine to remove gross contamination and chlorine
3. bag filters 10um
4. pump to compensate for lost pressure
5. a three stage unit consisting of a 3um, 1um and a 0.35-0.5um absolute filter

We have a limit of 100cfu per ml, which is based on the USP guidelines for process water at point of use.

SAMPLING OF PERMEABLE GARMENTS



PARTICLE COUNTING

FABRICS

AS1807.19 is based on a method developed by the ASTM (American Society for Testing and Materials) in 1968, and has remained basically unchanged over the last 30 years. In simple terms, the method involves sucking or vacuuming particles from a set portion of the garment surface onto a filter membrane clamped into a holder. The membrane is then placed under a microscope and the particles on it are counted according to a statistical formula to arrive at a result per 0.1m2. The process is laborious, but provides a very accurate indication of the level of particle contamination on the garment in question.

An alternative method for determining particle contamination on materials is the Helmke Drum method, which is also called the tumbling or rotating method. Garments are placed in a rotating drum that is open at one end and tumbled to release particles from the fabric. An automatic particle counter samples the air within the drum to determine the particle density of the air.

There are arguments for and against each method. The Helmke Drum test is much simpler to perform than the AS1807.10-2000 method, but is only useful in tracking the performance of the laundering process, or to compare similar materials. It is no indication of the quality of the garment itself. Garments, especially larger ones like smocks and coveralls, also have a tendency to “ball” in the drum, which results in less particles being released by the tumbling process and a lower than expected count.

The AS method is more subjective, as the operator must determine what is or isn’t a particle on a membrane surface that is often covered with various creases, shadows and other imperfections. There is also a limit to the size of the particles that are visible at the magnification used. Even at 100x, particles smaller than 5um are effectively invisible, hence the standard’s reliance on this size level for specifications. As the Helmke Drum classifications are based on 0.5um particles, the results of the two tests have no correlation at all.

CLEANROOM MONITORING

To assess the cleanliness of clean cabinets, isolators, and rooms, particle concentration larger than a given size is determined by either microscopy (for larger sizes) or an optical particle counter. For speed, cost and statistical validity, assessments are usually carried out with an optical particle counter.

Modern optical particle counters provide data on a number of different sizes simultaneously which are displayed on an internal screen and may be saved using a printer, or downloaded to a PC and manipulated by a spreadsheet program into tables to be interpreted at a later date.

CRG's cleanroom is a vertical flow room and classed as a Grade B PIC's guide to good manufacturing for medicinal products (GMP) (ISO Class 5).

The facility is certified annually by a third party NATA certified testing service to Australian Standards. The testing service verifies that the airflow velocity changes the air in the room often enough (air change rate), that there are no pinholes in the filters (filter integrity), and that the pressures being maintained in the room is enough to prevent particles from entering (room integrity).

We also monitor all rooms with continuous particle counters (FMS). Results are compared to AS/NZS14644.

FACILITY MONITORING

Although it is necessary for a clean area to be regularly tested, such testing only indicates the level of cleanliness at a point in time, often when normal (particle producing) operations are not taking place.

Many of CRG's customer's clean manufacturing environments often need to be more rigorously monitored to ensure that there is a constant awareness of conditions, including logging particle "spike" events which could be catastrophic if missed. This need is being driven by the desire to reduce operational costs, improve production yields and quality, to increase confidence in good manufacturing practices or to fulfill regulatory requirements.

One way of achieving more regular monitoring is to install a Facility Monitoring System. A Facility Monitoring System is an arrangement of instruments linked to a central monitoring computer. The computer controls the intake of data from the various devices and logs and displays the information, reporting to the operator any changes in conditions or trends.

The inputs to the Facility Monitoring System may be from numerous sources. In clean areas the optical particle counter data may be transferred to the computer. Alternatively, particle counters linked to scanning manifolds (an array of tubes connected to a single APC) may be installed. Environmental conditions such as differential pressure, airflow velocity, temperature and relative humidity often play an important part in ensuring quality. These may also be monitored using appropriate sensors and the data collected via the PC/software.

Such automated, computer controlled Facility Monitoring Systems provide increased vigilance whilst decreasing the labour requirements on these activities. If the system is well planned, then a fast detection of potential problems in operating conditions should occur, enabling counter measures to be taken rapidly. Over the longer term any significant trends in operating conditions can be monitored and statistical analysis of data allows for closer control and identification of normal and abnormal conditions.

STERILISATION

We find that ETO is the best method for sterilising polyester. Autoclaving causes these materials to shrink or become badly creased, and gamma causes cross-linking in the polymers, leading to brittleness and reduced lifespan.

We sterilise in-house, and our method is revalidated annually using an 'overkill' method. This involves loading a steriliser chamber with garments, placing biological indicators (BI's) in multiple locations and running a half length cycle. The method is in accordance with the AS ISO 11135 Medical devices - Validation and routine control of ethylene oxide sterilisation.

The cycle is validated to a SAL of 10^ -6. Copies of the validation packs are available if required. We conventionally release using BIs.

Sterile garments are packed in gas permeable bags. Each bag is individually marked with the batch number and expiry date, so every garment is traceable to an individual cycle. The gas permeable bags have an ETO chemical indicator printed on them so we have a visual indication that the bag has been through the steriliser.

Proof of sterilisation for us is having all of the cycle parameters met (temperatures, pressures, gas weights, times, clear BI's, etc.). This is documented on an approved cycle record by a QA Representative.

Certificates of Sterilisation are available for all cycles on the CRG website www.cleanroom.com.au. Written procedures exist for non-conforming lots, where the cycle is re-processed or recalled in the unlikely event it has already left.

CHIPPING & BARCODING

CRG aims to identity chip all garments and mops going through our cleanroom processing facility. This provides CRG and clients with the ability to track where their garments are and how many times they have been returned to CRG for washing and/or sterilisation. This information is then stored on CRG's database and can be accessed by a customer's Key Account Manager.

This removes the risk of barcodes being damaged or unreadable. The chips are sewn into the garment / mop so there will be no change in comfort or quality standards of the item.

Where chips can not be offered, a barcode is used.

C R G

For more information phone 02 9851 4600 or visit our website www.cleanroom.com.au

TRUSTED LEADERS IN CONTAMINATION AND INFECTION CONTROL