Ansell

GMP ANNEX 1 GUIDELINES

ARE YOU DRESSED FOR THE PART?

GMP ANNEX 1 GUIDELINES – THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN UNION VOLUME 4 EU GUIDELINES FOR GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN AND VETERINARY USE

What is Annex 1?

A legally binding part of EU GMP, Annex 1 provides guidelines and information relating to the manufacture of sterile medicinal products.

When was the new version issued?

The new version of Annex 1 was published on 25th August 2022

When is the date of implementation?

25th August 2023 (one year from the date of publication)

What is the scope of Annex 1?

Annex 1 applies to all sterile medicinal products manufactured in the European Union and the UK, as well as those manufactured elsewhere and exported into the European Union and the UK and applies to:

- Finished products
- Active substances
- Packaging materials
- Products provided in any size and combination
- Any manufacturing process
- Any manufacturing technologies
- Any manufacturing scale, where the objective is to provide a sterile product
- The design and control of facilities, equipment, systems and procedures

What is the biggest contamination risk during aseptic processing?

Sources of contamination within a cleanroom include raw materials, packaging, equipment, fluids, tools, processes and the most significant source of contamination, people. Microorganisms are shed from hair, skin, eyes and mucus membranes[1].

When people move around they shed 10 times more particles than when they are sitting or at rest, hence the reason for clear guidelines on the correct controlled behaviour of personnel.

Annex 1 Part 7.18

Activities in clean areas that are not critical to the production processes should be kept to a minimum, especially when aseptic operations are in progress.

Movement of personnel should be slow, controlled and methodical to avoid excessive shedding of particles and organisms due to over-vigorous activity. Operators performing aseptic operations should adhere to aseptic technique at all times to prevent changes in air currents that may introduce air of lower quality into the critical zone. Movement adjacent to the critical zone should be restricted and the obstruction of the path of the unidirectional (first air) airflow should be avoided.

A review of airflow visualisation studies should be considered as part of the training programme.

Sitting / at rest

We shed approx. **100,000** particles per minute

Walking

We shed approx. **1,000,000** particles per minute

Running

We shed approx. **10,000,000** particles per minute

1. *Brandes, R. Aseptic Processing: Qualification of Personnel, Mass & Peither AG-GMP Publishing, April 12, 2012*

CLEANROOM GARMENT MATERIAL & CONSTRUCTION

Part 7 of Annex 1 outlines the requirements needed regarding personnel numbers, behaviours, skills and clothing. A precise contamination control strategy needs to ensure that the PPE they're wearing is suitably assessed and monitored.

Outlined in the IEST-RP-CC003.4 standard - *Garment system consideration for cleanrooms and other controlled environments*, lists six types of non-woven fabrics for use in cleanrooms and other controlled environments, and describes each fabric as follows:

1. Spunbonded or thermal bond

A nonwoven fabric typically made from polypropylene in a relatively open structure. More commonly used in bouffant caps, shoe covers etc. This type of non-woven fabric does not demonstrate high barrier performance.

2. Flash spun

A nonwoven fabric made of high-density polyethylene continuous fibres. Flash spun non-wovens have some barrier properties and are splash-resistant to water.

3. Melt blown

Made from continuous polypropylene micro fibres and used in composite structures of many types off face masks because of its high filtration efficiency and repellence. Melt blown fabric does not have adequate strength to be used alone for garments.

4. Spunbonded/melt blown/spunbonded (SMS)

A laminate structure made from polypropylene continuous fibres, SMS offer barrier protection and comfort.

5. Film laminate

A spunbonded layer laminated to nonporous films. Demonstrates particle, blood and chemical barrier properties but lacks air and moisture permeability.

6. Microporous film laminate

A laminate made from a spunbonded layer and a microporous film for improved barrier properties. This laminate is a splash-resistant and a blood barrier. Microporous film laminate is optimal for use in surgical areas and critical environments.

When selecting garments for cleanroom use, depending on the specific application, the IEST standard recommends evaluating the fabric properties including testing for (selecting those relevant to the fabric type);

- Cleanliness and cleanability
- Electrostatic properties
- Biological properties
- Durability
- Comfort
- Opacity
- Particle filtration efficiency
- Microbial penetration
- Chemical compatibility
- Fluid resistance

Construction of cleanroom garments is another important consideration, and the IEST standard outlines recommendations for thread and seam structure. Seams for cleanroom garments should be joining seams to avoid free-air/particulate passage from the inside of the garment to the outside environment. The IEST standard recommends for the construction of cleanroom garments that they are constructed using a bound joining seam, as shown in *Figure 1*.

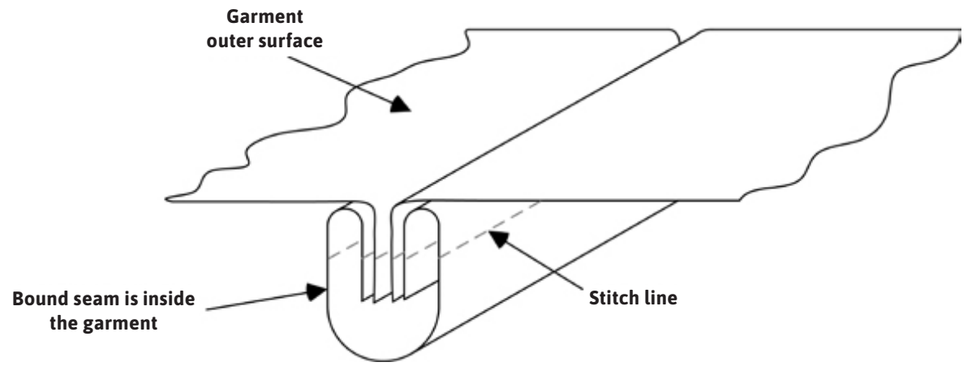


Figure 1

CLEANROOM GARMENT SELECTION & DONNING

As well as consideration for how the cleanroom garments are constructed and the type of material used, Annex 1 Parts 7.11 & 7.12 indicates what garments to wear in each cleanliness grade and how they should be worn and donned has been outlined in Part 7.13 & 7.14.

ANNEX 1 PART 7 - PERSONNEL

Part 7.11

The clothing and its quality should be appropriate for the process and the grade of the working area. It should be worn in such a way as to protect the product from contamination. When the type of clothing chosen needs to provide the operator protection from the product, it should not compromise the protection of the product from contamination. ***Garments should be visually checked for cleanliness and integrity immediately prior to and after gowning****. Gown integrity should also be checked upon exit. For sterilised garments and eye coverings, particular attention should be taken to ensure they have been subject to the sterilisation process, are within their specified hold time and that the packaging is visually inspected to ensure it is integral before use. Reusable garments (including eye coverings) should be replaced if damage is identified, or at a set frequency that is determined during qualification studies. The qualification of garments should consider any necessary garment testing requirements, including damage to garments that may not be identified by visual inspection alone.*

Part 7.12

Clothing should be chosen to limit shedding due to operators' movement.

Part 7.13 *A description of typical clothing required for each cleanliness grade is given below:*

i. Grade B (including access / interventions into grade A):
appropriate garments that are dedicated for use under a sterilised suit should be worn before gowning (see paragraph 7.14). Appropriately sterilised, non-powdered, rubber or plastic gloves should be worn while donning the sterilised garments. Sterile headgear should enclose all hair (including facial hair) and where separate from the rest of the gown, it should be tucked into the neck of the sterile suit. ***A sterile facemask and sterile eye coverings (e.g. goggles) should be worn to cover and enclose all facial skin and prevent the shedding of droplets and particles****. Appropriate sterilised footwear (e.g. over-boots) should be worn. Trouser legs should be tucked inside the footwear. Garment sleeves should be tucked into a second pair of sterile gloves worn over the pair worn while donning the gown. The protective clothing should minimize shedding of fibres or particles and retain particles shed by the body. The particle shedding and the particle retention efficiencies of the garments should be assessed during the garment qualification.* ***Garments should be packed and folded in such a way as to allow operators to don the gown without contacting the outer surface of the garment and to prevent the garment from touching the floor.***

ii. Grade C:
Hair, beards and moustaches should be covered. A single or two-piece trouser suit gathered at the wrists and with high neck and appropriately disinfected shoes or overshoes should be worn. They should minimize the shedding of fibres and particles.

iii. Grade D:
Hair, beards and moustaches should be covered. A general protective suit and appropriately disinfected shoes or overshoes should be worn. Appropriate measures should be taken to avoid any ingress of contaminants from outside the clean area.

iv. Additional gowning including gloves and facemask may be required in grade C and D areas when performing activities considered to be a contamination risk as defined by the CCS.

Part 7.14

Cleanroom gowning should be performed in change rooms of an appropriate cleanliness grade to ensure gown cleanliness is maintained. ***Outdoor clothing including socks (other than personal underwear) should not be brought into changing rooms leading directly to grade B and C areas. Single or two-piece facility trouser suits, covering the full length of the arms and the legs, and facility socks covering the feet, should be worn before entry to change rooms for grades B and C****. Facility suits and socks should not present a risk of contamination to the gowning area or processes.*

BARRIER TECHNOLOGIES

Annex 1 places considerable emphasis on barrier technology to separate the operator from the product to maintain Grade A conditions. This can be accomplished using RABS and Isolators:

Annex 1 Part 4.18

Isolators or RABS, which are different technologies, and the associated processes, should be designed to provide protection through separation of the grade A environment from the environment of the surrounding room. The hazards introduced from entry or removal of items during processing should be minimized and supported by high capability transfer technologies or validated systems that robustly prevent contamination and are appropriate for the respective technology.

Annex 1 Part 4.21

The materials used for glove systems (for both isolators and RABS), should be demonstrated to have appropriate mechanical and chemical resistance. The frequency of glove replacement should be defined within the CCS.

Ansell Solution

Our clean and sterile Nitrile RABS and Isolator glove range comprises of gloves, mittens and sleeve/glove systems. 100% water leak tested for glove integrity and resistant to VHP, IPA and disinfectants for in situ sanitizing.

Other RABS and Isolator glove materials available are CSM, NRL, Neoprene, EPDM & EPDM+ the most suitable material will be dependent on the applications and can be decontaminated by autoclaving, VHP or IPA**.

BioClean™ Nitrile Sterile RABS/Isolator Gloves GGL15NIT59/GGL20NIT59/ GGL10NIT59/GGL36NIT59

- Nitrile
- Glove length 840mm/33"
- Port Sizes 6", 8", 10", 12"
- Glove Style Ambidextrous Size 9.75
- ISO Class 4 & EU GMP Grade A
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10^{-6}
- 1 piece triple bagged, 20 pieces per lined box

BioClean™ Nitrile Sterile Isolator Mitten GGL30NITM9

- Nitrile
- Glove length 840mm/33"
- Port Size 10"
- Glove Style Mitten
- ISO Class 4 & EU GMP Grade A
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10^{-6}
- 1 piece triple bagged, 20 pieces per lined box

BioClean™ Nitrile Sterile RABS/ Isolator Sleeve/ Glove System GSG10NIT80/ GSG10NIT85

- Nitrile Sleeve/Polychloprene Glove
- System length 900mm/35"
- Port Sizes 8"
- Glove Style Hand Specific Size 8.0 or Size 8.5 (BPZS)
- ISO Class 4 & EU GMP Grade A
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10^{-6}
- 1 system (L) per inner bag & 1 system (R) per inner bag, L & R systems pair packed per outer bag, 10 pairs per lined box

BioClean™ Nitrile Sterile RABS/ Isolator Sleeve/Glove System GSG10NITXLMA

- Nitrile Sleeve/ Polychloprene Glove
- System length 995mm/39"
- Port Sizes 8"
- Glove Style Ambidextrous Size 8.0 (S-BFAP)
- ISO Class 4 & EU GMP Grade A
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10-6(-6 superscript)
- 1 system per inner bag & 1 system per inner bag, two systems pair packed per outer bag, 10 pairs per lined box

***Please check product validation pack for full test results.*

CHOOSING THE RIGHT RABS/ISOLATOR GLOVE MATERIAL

Nitrile is a synthetic, non-solvent based, FDA approved polymer and is an ideal alternative to CSM, EPDM and latex, where the risk of latex allergies is a concern. With excellent anti-static properties, preventing the buildup of static electricity, nitrile is ideal for use with flammable liquids and powders. It can also be sanitised by Gamma Irradiation, Vapourised Hydrogen Peroxide (VHP) and Isopropyl Alcohol (IPA) and non-sterile options can also be washed, processed and packaged within a cleanroom environment, ensuring the gloves are an ultra-low contamination risk before being introduced into the isolator glove box.

ISOLATOR GLOVE MATERIAL COMPARISON

Polymer	Sterilization Gamma	Repeated sterilization		FDA Compliance	Cost	Comfort	Mechanical Properties	Chemical Resistance
		Autoclave	VHP					
Nitrile	●	◔	●	●	◑	◔	◔	◔
CSM	◔	◔	●	○	◑	◑	◔	◔
EPDM	◕	●	●	●	◔	◑	◔	◔
EPDM Plus	◕	●	●	●	◔	◑	◔	◔
Natural Rubber Latex	◔	○	◔	●	●	●	◑	◔
Neoprene	◔	○	○	●	◕	◑	◔	◕

○ Poor ◔ Fair ◑ Good ◕ Very Good ● Excellent

YOUR CONFIDENCE, OUR PRIORITY

Ansell RABS and Isolator gloves have quality built in, because our quality control procedure is one of the most rigorous in the industry, including;

Inspection & testing of raw materials

Controls & testing during manufacturing process (ensuring dipping, physical and chemical parameters are met)

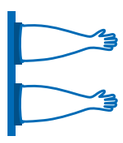
External accredited laboratory testing to comply with international standards

Final inspection controls;

Inspection for holes, visually and subsequently using a water and air pressure test

100% visual inspection

Dimension controls



Integrity test

Labelling & packing controls

WHY CHOOSE BIOCLEAN™ NITRILE ISOLATOR/RABS GLOVES?

NITRILE PRODUCT PORTFOLIO OVERVIEW

	BioClean™ GGL	BioClean™ CGL	BioClean™ GGL30NITM9	BioClean™ GSL	BioClean™ GSG10NIT80/ GSG10NIT85	BioClean™ GSG10NITXLMA
						
Material	Nitrile	Nitrile	Nitrile	Nitrile	Nitrile/ PCP	
Style	Glove	Glove	Mitten	Sleeve	Sleeve Glove System	
Sterility	Sterile & Cleanroom Laundered	Non-Sterile & Cleanroom Laundered	Sterile or Non-Sterile & Cleanroom Laundered	Sterile & Cleanroom Laundered	Sterile & Cleanroom Laundered	
Cuff Thickness	0.50mm/20mil	0.50mm/20mil	0.50mm/20mil	0.50mm/20mil	0.50mm/20mil	0.50mm/20mil
Port Size	6, 8, 10, 12"	8, 10, 12"	10"	6, 8, 10, 12"	8"	
Length	840mm/33"	840mm/33"	840mm/33"	660mm/26"	900mm/35"	995mm/39"
Hand Size	9.75/L	9.75/L	9.75/L	9.75/L	8/M, 8.5/M	

NITRILE MATERIAL BENEFITS

- FDA approved polymer
- Excellent anti-static properties
- Performs well with VHP or IPA
- Superior comfort and dexterity
- Excellent chemical resistance

CHEMICAL PERMEATION RESULTS TABLE - BIOCLEAN™ GGL & CGL

*ASTM F739 - Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.1 µg/cm² /min.
**EN 16523-1: 2015 (formerly EN374-3) - Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 1.0 µg/cm² /min.

THIRD PARTY DISINFECTANT BRANDS	STANDARD	
	ASTM*	EN**
DECON-CLEAN®	240-480	240-480
DECON-SPORE 200® PLUS	240-480	240-480
KLERCIDE™ CR BIOCIDE S	240-480	240-480
KLERCIDE™ Y	240-480	240-480
LPH® SE	240-480	240-480
SPORE-KLENZ®	240-480	240-480
VESPHENE® IISE	240-480	240-480

†*Certified test result*

Please see product validation pack for full permeation results. When a number is listed in a cell, this means that an actual test has been performed. The number is showing the permeation time in minutes. When a cell is coloured, with no number, the permeation time is based on extrapolation issued from AnsellGUARDIAN®. When a cell is white, no data is available.

The chemical permeation results table is related to the barrier performance of certain personal protective equipment (PPE) against the chemicals. This information is intended to enable the Health and Safety professional at your organisation make more informed decisions about the Ansell PPE that may offer the greatest protection in the intended circumstances and assist with carrying out a risk assessment for your organisation. We wish to highlight that permeation times do not equate to safe wear time. Safe wear time may vary depending on whether the PPE is donned correctly, the surrounding temperature, the chemicals' toxicity, and other factors. Permeation information offered here is limited to the main protective material. Permeation times may vary around seams, zips, visors or any other joins or components of the PPE. It is the responsibility of your organisation's Health and Safety professional to undertake a risk assessment before choosing the appropriate PPE for the task at hand. If you want to discuss any aspect in detail, please contact us.

Estimations of the barrier properties of PPE are based on currently available data and extrapolations from laboratory test results and information regarding the chemicals' composition. Synergistic effects of mixing chemicals have not been accounted for. Estimations are subject to change if new testing is carried out or new information is available providing better grounds for extrapolations. For these reasons, any information in this report is provided for informational purposes only and Ansell fully disclaims any liability including warranties related to any statement contained herein.

ANSELL STERILE PORTFOLIO

Our extensive portfolio of sterile garments, gloves, goggles and facemasks detailed below ensure you meet all the guidelines set out in Annex 1 Part 7.

GLOVES

Neoprene (Polychloroprene)

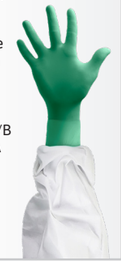
Sterile DermaShield™ 73-711

- Neoprene (Polychloroprene)
- 300mm/12"
- Hand Specific
- Double Donnable
- Beaded cuff with Surefit™ Technology
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10^{-6}

SUREFIT™ Cuff Roll-down Technology

Sterile TouchNTuff® DermaShield™ 73-701

- Neoprene (Polychloroprene)
- 295mm/11.6"
- Hand Specific
- Double Donnable
- Straight cuff with Surefit™ Technology
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type A
- ASTM D6978 Tested**
- SAL 10^{-6}



SUREFIT™ Cuff Roll-down Technology

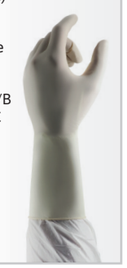
Sterile TouchNTuff® 73-500

- Neoprene (Polychloroprene)
- 300mm/12"
- Hand Specific
- Double-donnable
- Beaded cuff with Surefit™ Technology
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type B
- ASTM D6978 Tested**
- SAL 10^{-6}

SUREFIT™ Cuff Roll-down Technology

Sterile BioClean™ Ultimate BUPS

- Neoprene (Polychloroprene)
- 300mm/12"
- Hand Specific
- Double-donnable
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type C
- ASTM D6978 Tested**
- SAL 10^{-6}



Nitrile

Sterile BioClean™ N-Plus BNPS

- Nitrile
- 400mm/16"
- Hand Specific
- Beaded cuff
- ISO Class 4 & EU GMP Grade A
- PPE Cat III Type B
- ASTM D6978 Tested**
- SAL 10^{-6}

Sterile BioClean™ Excell BEXS

- Nitrile
- 300mm/12"
- Hand Specific
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type B
- SAL 10^{-6}

Sterile BioClean™ Emerald BENS

- 300mm/12"
- Hand Specific
- Double-donnable
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type B
- ASTM D6978 Tested**
- SAL 10^{-6}

Sterile TouchNTuff® 93-700

- Nitrile
- 300mm/12"
- Ambidextrous
- Double-donnable
- Beaded cuff
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type B
- ASTM D6978 Tested**
- SAL 10^{-6}

Latex

Sterile BioClean™ Extra BLAS

- Latex
- 400mm/16"
- Ambidextrous
- Double-donnable
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type C
- SAL 10^{-6}

Sterile BioClean™ Alpha AL300

- Latex
- 295mm/11.6"
- Hand Specific
- Double-donnable
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type B
- SAL 10^{-6}

Sterile BioClean™ Advance BASL

- Latex
- 295mm/11.6"
- Hand Specific
- Double-donnable
- Beaded cuff
- ISO Class 4 & EU GMP Grade A/B
- PPE Cat III Type B
- SAL 10^{-6}

Sterile AccuTech® 91-225

- Latex
- 300mm/12"
- Hand Specific
- Double-donnable
- Straight cuff
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type B
- SAL 10^{-6}

Polyisoprene

Sterile TouchNTuff® 83-500

- Polyisoprene
- 300mm/12"
- Hand Specific
- Double-donnable
- Beaded cuff with Surefit™ Technology
- ISO Class 5 & EU GMP Grade A/B
- PPE Cat III Type B
- ASTM D6978 Tested**
- SAL 10^{-6}

SUREFIT™ Cuff Roll-down Technology

GLOVE LINER

BioClean™ Sterile Cut Resistant Liner S-BCRL

- Dyneema® Diamond Yarn
- ANSI A2
- EN 388 (3X4XB)
- Length 162mm/6.3"-202mm/7.9"
- Ambidextrous
- SAL 10^{-6}
- To be worn between two cleanroom gloves

WARNING: No liner provides complete protection against cuts. Use with care when handling sharp objects.

***Please check product validation pack for full test results.*

ANSELL STERILE PORTFOLIO

COVERALLS (SUITS)

BioClean-D™ Drop-down Sterile Coverall with Hood S-BDSH

- Drop-down design - aseptic donning made easy
- Quick-release press stud tabs to further facilitate aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Elasticated hood, back, wrists and ankles
- Thumb loops for a secure hold
- Three piece hood for comfort

BioClean-D™ Sterile Coverall with Hood and Integrated Boots S-BDFC

- Strategically folded to aid aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Bound seams for reduced contamination risk
- Elasticated hood, back and wrists
- Thumb loops for a secure hold
- Protective zip flap
- Three piece hood for comfort
- Integrated boots with slip-resistant soles

BioClean-D™ Sterile Coverall with Hood S-BDCHT

- Strategically folded to aid aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Bound seams for reduced contamination risk
- Elasticated hood, back, wrists and ankles
- Thumb loops for a secure hold
- Protective zip flap
- Three piece hood for comfort

BioClean-D™ Sterile Coverall with Collar S-BDCCT

- Strategically folded to aid aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Bound seams for reduced contamination risk
- Elasticated back, wrists and ankles
- Thumb loops for a secure hold
- Protective zip flap

COVERALL KITS

BioClean-D™ Sterile Kit - Coverall with collar, Overboots & Hood with Integrated Facemask S-BDKM

- Strategically folded to aid aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Bound seams for reduced contamination risk
- Elasticated back, ankles and wrists
- Thumb loops for a secure hold
- Protective zip flap
- Three piece hood for comfort with integrated flat facemask
- Optimized packaging - presented in single package to reduce packaging waste

BioClean-D™ Sterile Kit - Coverall with Hood & Separate Overboots S-BDHB

- Strategically folded to aid aseptic donning
- Lightweight, antistatic, low-linting** CleanTough™ material (polyethylene/polypropylene laminate)
- Bound seams for reduced contamination risk
- Elasticated hood, back, ankles and wrists
- Thumb loops for a secure hold
- Protective zip flap
- Three piece hood for comfort
- Separate overboots with slip-resistant soles
- Optimized packaging - presented in single package to reduce packaging waste

CHEMO PROTECTION RANGE

BioClean-D™ Sterile Apron - S-BCDA

- Strategically folded to aid aseptic donning
- Lightweight,, low-linting** CleanTough™ material (polyethylene/ polypropylene laminate)
- Tie-tapes & adjustable neck fastening
- Tested against ASTM F739-12

BioClean-D™ Sterile Apron with Sleeves - S-BCAS

- Strategically folded to aid aseptic donning
- Lightweight,, low-linting** CleanTough™ material (polyethylene/ polypropylene laminate)
- Ultrasonically bonded seams with protective tape
- Tie-tapes & adjustable neck fastening
- Tested against ASTM F739-12

BioClean-D™ Sterile Sleeve Covers - S-BCSC

- Strategically folded to aid aseptic donning
- Lightweight,, low-linting** CleanTough™ material (polyethylene/ polypropylene laminate)
- Ultrasonically bonded seam with protective tape
- Tested against ASTM F739-12
- One size fits all

***Please check product validation pack for full test results.*

ANSELL STERILE PORTFOLIO

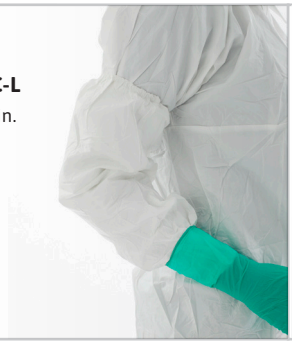
HOOD, OVERBOOTS AND SLEEVE COVERS

BioClean-D™ Sterile Hood S-BDHD-L

- Extra-long yoke for maximum coverage
- Lightweight, low-linting** CleanTough™ material
- Three piece design for excellent comfort

BioClean-D™ Sterile Sleeve Covers S-BDSC-L

- Long length min. 480mm
- Excellent ESD Properties
- Lightweight & low-linting** CleanTough™ material



BioClean-D™ Sterile Longer Length Overboots S-BDOB-L

- Longer length - 500mm
- Lightweight & low-linting** CleanTough™ material
- Tie-fastenings at top & ankle for a secure hold
- Slip-resistant sole

GOGGLES

BioClean™ Clearview Sterile Goggles BCGS1 and BVGS

- EtO or Gamma Sterilized
- EN 166 certification for assured personal eye protection
- Indirect ventilation system to reduce the risk of contamination
- Anti-scratch and anti-fog properties for clear and undistorted vision

BioClean™ Clearview Autoclavable Goggles BCAG

- Thermoplastic rubber frame for better fit and wearer comfort
- Indirect ventilation system reduced risks of contamination
- Sturdy, polycarbonate lens prevents scratches, ensures a clear view

BioClean™ Clearview Autoclavable Goggles BCAP

- Panoramic, wide-angle lens for a deeper, wider field of vision
- Indirect ventilation system reduced risks of contamination
- Autoclave-resistant design for durable clearview goggles

BioClean™ Clearview Autoclavable Goggles BCAH

- Lightweight material: Enables prolonged use and user comfort
- Indirect ventilation system: Lowers the risk of contamination
- Anti-scratch, anti-fog properties: For unobstructed vision

FACEMASKS

BioClean™ Sterile Head Loop Face Mask MEA210-1

- High particle and Bacterial Filtration Efficiency (BFE)**
- Cleanroom-compatible materials for reduced risk of contamination
- Rear clip connector for quick and secure fastening

BioClean™ Sterile Tie-on Face Mask MTA210-1

- High Bacterial Filtration Efficiency (BFE)**
- Cleanroom-compatible materials for fewer contamination risks
- Ultrasonically sealed edges and tie-tapes with a strong, reliable bond

***Please check product validation pack for full test results.*

PACKAGING & STERILISATION PROCESS

How PPE is packaged, and the packaging materials used is another critical element for consideration. All Ansell sterile PPE is double or triple bagged in durable plastic packaging to reduce contamination and includes sterilisation indicators to show the PPE has been sterilised to a sterility Assurance Level (SAL) 10^{-6}.

Certificates of Irradiation (Gamma) or Certificates of Processing (EtO) per product lot number can be downloaded via our easy to use certificate tool on www.ansell.com/life-sciences/certificates to prove the PPE has been subjected to the full sterilisation process. All packaging clearly states expiry and manufacturing dates.

For more information, visit www.ansell.com

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